ADAPTIVE REGULATION IN INDIA-GROUNDWATER, ELECTRIC VEHICLES, AND HEALTH DATA

A Dissertation

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To Karthik, my life partner. For your love, inspiration, and unconditional support.

EXECUTIVE SUMMARY

- I. Traditional regulatory approaches rely on one-time decision-making processes, with limited ex-ante assessments and ex-post reviews. However, in the real world, changes are inevitable and the policy's actual performance could be very different from the expected. Thus, to be meaningful and effective, the regulations should have built-in mechanisms to learn and keep pace with the changing conditions. Adaptive regulation offers an array of such mechanisms where decision-making is not a one-time process, instead, it is iterative and planned, and policy adjustments are based on new information and changing circumstances.
- II. Adaptive regulation is researched more in western countries than in other parts of the world including India. Most of the existing literature on India relates to climate adaptation and adaptive governance with limited research on adaptive regulation. India has a federal structure and its Constitution has provisions drawn from the constitutions of more than 60 countries including the UK and the US. Therefore, regulatory learnings from India could resonate with countries having similar governance structures. Further, India is the fifth largest economy and the world's largest democracy. In a globalized world, regulatory choices of major economies like India could have lessons for other emerging economies. This research study attempted to explore whether adaptive regulations are prevalent or not in India's regulatory settings by analyzing the law/policy documents and interviewing key stakeholders in three sectors Groundwater, Electric Vehicles, and Health Data.
- III. The three selected sectors are salient from India's perspective. Groundwater is considered the backbone of India's water and food security as it fulfills 85 % of drinking water needs and more than 60% of the irrigation needs of the country. However, this resource is fast depleting. Annually, India extracts the highest percentage of groundwater in the world, followed by the US and China (whose combined groundwater extraction is less than India's). Air pollution is another major area of concern. Each year in India, ambient air pollution causes a staggering 670,000 deaths. Also, India is the fourth largest automobile market

in the world adding more than 21 million vehicles to Indian roads per year. Transportation sources account for one-third of particulate matter pollution and a higher percentage of nitrogen oxides. To address ambient air pollution, the Indian government aims to reach 30 % electric vehicle penetration by 2030. And lastly, India is committed to achieving Universal Health Coverage for all by 2030. To achieve this goal, the country's National Digital Health Mission (aka Ayushman Bharat Digital Mission) is building a digital ecosystem for providing digital healthcare services across the country and intends to create more than 1.3 billion digital health IDs.

- IV. This dissertation attempted to answer two research questions: (1) How adaptive are India's regulations on Groundwater, Electric Vehicles, and Health Data? And (2) How adaptive should India's regulations be on Groundwater, Electric Vehicles, and Health Data? To investigate and find answers to these research questions, three qualitative methods are used-systematic literature review, document analysis, and interview analysis.
- V. Based on the review of literature, 6 broad features of adaptive regulation are synthesized from the perspective of a learning-oriented decision-making process. These are: (i) assessing risk and uncertainties, (ii) broader and fuller impact assessment, (iii) monitoring and evaluation, (iv) iterative decision-making and policy adjustment, (v) public participation, and (vi) adaptive governance structures. These six features are embedded in the form of an adaptive regulatory cycle with three stages of pre-implementation, implementation, and post-implementation. Sector-wise analysis is anchored on the application of the adaptive regulatory cycle with six adaptive features. Further, directed content analysis approach is used for analyzing sector-specific official law/policy documents of the federal government of India (and two state governments in the groundwater sector) and interview transcripts of 33 key stakeholders.
- VI. In Groundwater sector, India's regulatory cycle in the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments) indicates moderate to high adaptiveness on the books while moderate

adaptiveness in practice. In the implementation stage (monitoring and evaluation), it indicates high adaptiveness on the books and low adaptiveness in practice. And in the post-implementation stage (iterative decision-making), it indicates medium adaptiveness on the books but high adaptiveness in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the former shows high presence both on the books and in practice while the latter shows moderate presence both on the books and in practice.

- VII. In EV sector, India's regulatory cycle in the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments) indicates low to moderate adaptiveness on the books whereas moderate to high adaptiveness in practice. In the implementation stage (monitoring and evaluation), it indicates high adaptiveness on the books and moderate adaptiveness in practice. And in the post-implementation stage (iterative decision-making), it indicates high adaptiveness both on the books as well as in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the inference is mixed. Public participation shows moderate presence on the books but high prevalence in practice. And inter-agency coordination shows low presence on the books but moderate prevalence in practice.
- VIII. In Health data sector, India's regulatory cycle in the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments) indicates low adaptiveness on the books and moderate adaptiveness in practice. In the implementation stage (monitoring and evaluation), it indicates high adaptiveness on the books and moderate adaptiveness in practice. And in the post-implementation stage (iterative decision-making), it indicates high adaptiveness both on the books as well as in practice. Regarding the two overarching adaptive features of public participation and inter-agency coordination, the former shows high presence both on the books and in practice while the latter shows low presence both on the books and in practice.

- IX. The three sectors vary immensely in their law/policies and the agency practices; therefore, it is difficult to draw generalizations across the sectors. However, based on the combined document and interview analysis, it is evident that monitoring and evaluation (M&E) is one feature where all three sectors show a gap in practice. Further, iterative decision-making shows high prevalence in practice in all three sectors. However, the interview analysis suggests that across the sectors these iterations and policy revisions are not informed by formal policy evaluations. Therefore, this finding also connects with the limited effectiveness of M&E in practice.
- X. To address the identified gaps, sector-specific recommendations and recommendations to strengthen India's regulatory cycle are given. These recommendations are informed by the US -India comparative analysis and the best practices on adaptive regulation recommended by international bodies and academic researchers. To successfully implement the recommendations and the adaptive regulatory practices in general, behavioral insight strategies are identified.
- XI. Overall, this research makes three contributions to the advancement of knowledge. First is the development of an adaptive regulatory cycle with six broad features of adaptive regulation. The six features are informed by the literature review and are embedded in different stages of the regulatory cycle. This regulatory cycle could be used as an analytic tool to study the presence of adaptive decision-making processes in law/policy making at the country, state, or agency level.

The second contribution of this research is the investigation of the prevalence of adaptive regulation in India, which is an under-studied area in law/policy research. The directed content analysis approach is used to analyze the law/policy documents of three sectors in India and to analyze the interview transcripts of 33 key stakeholders across three sectors. No previous study to the best of the author's knowledge has explored the prevalence of adaptive regulation in India using the combined methodology of document and interview analysis based on the directed content analysis approach.

The third contribution of this research is the development of an adaptive regulatory cycle for India. It has key recommendations informed by the best practices recommended by international bodies and academic researchers. The recommendations are embedded in different stages of the adaptive regulatory cycle, are specific to India's context, and address the gaps identified by the findings of the document and interview analysis. A key recommendation is that India should strengthen its systems of monitoring and evaluation, to support better iterative decision making. Further, these recommendations could be relevant for other emerging economies to improve their regulatory processes and overall advance regulatory learning.

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Chapter-1

Theoretical Analysis of Adaptive Regulation

Summary: This chapter provides an overview of literature on adaptive regulation and explains the process of developing 'Adaptive Regulatory Cycle' which forms the basis of documentary and interview analysis for the entire dissertation study. Section I introduces adaptive regulation and related concepts such as adaptive policy, adaptive law, dynamic law, adaptive management, and adaptive governance. Section II describes the types of adaptive regulation, followed by Section III which briefly discusses the adaptive strategies (from adaptation literature) and their similarities with adaptive regulation. Section IV mentions the pros and cons of adaptive regulation followed by Section V which briefly analyses the static versus adaptive regulation. Section VI analyses the need of adaptive regulations followed by Section VII which explains the six broad features of adaptive regulation based on the review of literature. Section VIII describes the 'Adaptive Regulatory Cycle' informed by the six features and defines the meaning attributed to each of the six features for this study's purpose. Lastly, Section IX outlines the purpose of the dissertation study and specifies the research questions.

I. Theory and Concepts

Adaptive regulation is defined as "a structured regulatory process that enables learning and modification of policy over time via adjustments informed by data collection and analysis" Or: "laws built to learn". In literature, many terms are used interchangeably with adaptive regulation, such as adaptive management, adaptive policy, adaptive law, dynamic law, and adaptive governance, to name a few. In the preliminary analysis, it is found that many of these terms have overlapping features. Therefore, without drawing rigid boundaries, these terms are briefly explained with an objective to comprehensively understand the concept of adaptive regulation.

The genesis of 'adaptive policies' dates back to the early twentieth century. John Dewey's idea of treating policies as experiments² resonates with the present-day meaning of adaptive policies. K. N. Lee's scholarship described these experiments as the means to understand the complex environmental systems. Lee defined adaptive policies as the ones that are "designed from the outset to test clearly formulated hypotheses about the behavior of an ecosystem being changed by human use.' During the same time, Dennis Rondinelli advocated for adopting an 'adaptive approach' to reorient international development. According to him, an adaptive approach, "relies on strategic planning, on administrative procedures that facilitate innovation, responsiveness, and experimentation, and on decision-making processes that join learning with action."

Similarly, Lempert et al., advocated that 'adaptive strategies' could improve the robustness of policy decisions, particularly while dealing with situations of deep uncertainty. In such situations, the traditional tools of decision analysis are considered inadequate as the decision-makers do not know or may not know all the variables influencing policy choices.⁵ They developed a method (computer-assisted reasoning) to identify key uncertainties

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¹ Bennear, Lori S. and Wiener, Jonathan B. (2019) Adaptive Regulation: Instrument Choice for Policy Learning over Time, Draft working paper. 8.

² Policy experiments to promote learning and adapting to changes. For details, *see*, Busenberg, G. J. (2001) Learning in Organizations and Public Policy. Journal of Public Policy, 21 (2), 173-189.

³ Lee, K. (1993). Compass and Gyroscope: Integrating Science and Politics for the Environment. Washington, Island Press. Also *see*, Kwakkel, J.H. et al., (2010). Adaptive Airport Strategic Planning. European Journal of Transport and Infrastructure Research. 10(3), 249, 253.

⁴ D.A. Rondinelli, D.A. (1993). Development Projects as Policy Experiments: An Adaptive Approach to Development Administration, 2nd ed. Routledge, New York. Also, *see*, Swanson, Darren and Bhadwal, Suruchi. (2009). Creating Adaptive Policies- A Guide for Policymaking in an Uncertain World.

⁵ Lempert, R.J. (2002). A New Decision Sciences for Complex Systems. Proceedings of the National Academy of Sciences of the United States of America, 99 (3), 7309-7313.

influencing policy performance, generate "an ensemble of plausible future scenarios," and create key strategies of policy performance in comparison to the alternatives.⁶

Walker et., al elaborated on the 'process' of adaptive policymaking. They developed a stepwise approach called "planned adaptation," with pre-specified policy alternatives for specific trigger values and a monitoring mechanism. They explain adaptive policy-making as a two-phase process: a thinking phase and an implementation phase. In the thinking phase, a basic policy is designed and analyzed for vulnerabilities. The basic policy considers relatively certain as well as uncertain vulnerabilities. In the implementation phase, mitigating actions and hedging actions are taken for these vulnerabilities respectively. Additionally, for the uncertain vulnerabilities, the policy creates monitoring mechanisms to reveal their manifestation. The decision-makers monitor the signposts and take necessary action. As long as the signposts indicate that the policy is on its track to achieving the intended outcomes, the policy remains active, else, it is reassessed.

Another related concept of 'adaptive management' gained prominence in environmental governance due to the seminal works of C.S. Holling and Carl Walters. Holling focused on applying the principles of adaptive policies in environmental management and Walters described "adaptive management as a way to deal with scientific uncertainty when managing renewable resources." Craig and Ruhl elaborated and emphasized that in adaptive management, "the timing of decisions is spread out into a continuous process. Instead of making 'one grand decision,' agencies engage in a series of iterative decision-

⁶ *Id.* at 7310.

⁷ Walker, Warren E. et al., (2001). Adaptive Policies, Policy Analysis, and Policy-making. European Journal of Operational Research, vol. 128, no. 2, 282-289.

⁸ Vulnerabilities are the plausible events or developments that could negatively impact the performance of the plan.

⁹ Mitigating actions are the actions taken in advance to reduce the certain adverse effects of a policy; Hedging actions are the actions taken in advance to spread or reduce the risk of possible adverse effects of a policy. For details *see* Walker et al., *supra* note 7, at 285, Kwakkel et al., *supra* note 3, at 259.

¹⁰ Signposts- The information that requires to be tracked for determining if the policy is achieving its conditions for success or not.

¹¹ Defensive actions are taken "after the fact" to clarify the policy, preserve its benefits, or meet outside challenges in response to specific triggers that leave the basic policy remains unchanged; Corrective actions are the adjustments to the basic policy in response to specific triggers. For details see Walker et al., *supra* note 7, at 285, Kwakkel et al., *supra* note 3, at 260.

¹² See Kwakkel et al., supra note 3, at 255.

¹³ Angelo, Mary J. (2009). Resilience and Environmental Law Reform Symposium: Stumbling Toward Success: A Story of Adaptive Law and Ecological Resilience, 87 Nebraska Law Review, 950, 953.

 $^{^{14}}$ Id. Also see generally, C. S. HOLLING ET AL., (C.S. Holling ed., 1978) ADAPTIVE ENVIRONMENTAL ASSESSMENT AND MANAGEMENT.

¹⁵ *Id.* at 953.

making following a structured, multistep protocol."¹⁶ Adaptive management has been described as a choice of strategies that make regulatory responses agile to new information and experience. As a policy tool, adaptive management requires: (a) freedom of movement-the availability of policy options to choose from; (b) tailored agility- decision-making that is time and space-specific, and (c) and informed alertness- an open-minded attitude to change along with a mechanism for monitoring and evaluation.¹⁷

'Adaptive governance' is a broader concept than adaptive management. It is described as a governance process that responds to feedback from an agency undertaking adaptive management through collaboration and cooperation across different levels of governmental, non-governmental, and individual action.¹⁸ Thus, adaptive governance refers to the larger governance ecosystem and the social context that facilitate adaptive management by overcoming barriers in identifying and implementing the needed policy adjustments.¹⁹ Walker et al. aptly point out that "adaptive management... has frequently failed because the existing governance structures have not allowed it to function effectively."²⁰

Similar to adaptive governance, 'adaptive law' is a broader concept and is described by Craig and Gunderson to include four features: (1) multiplicity of articulated goals; (2) polycentric, multimodal, and integrationist structure; (3) adaptive methods based on standards, flexibility, discretion, and regard for context; and (4) iterative legal-pluralist processes with feedback loops, learning, and accountability.²¹ Professor Robert Gordon's writings in law mention 'adaptation theory.' This theory of legal change recognizes that

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¹⁶ Craig, Robin K. and Ruhl, J. B. (2014). Designing Administrative Law for Adaptive Management, Vanderbilt Law Review, 67 (1), 26. (The multi-step protocol involves: (1) definition of the problem, (2) determination of goals and objectives for management, (3) determination of the baseline, (4) development of conceptual models, (5) selection of future actions, (6) implementation and management actions, (7) monitoring, and (8) evaluation and return to step (1))

¹⁷ International Risk Governance Center (IRGC). (2016). Planning Adaptive Risk Regulation, Conference Report, 10-11. Lausanne: EPFL International Risk Governance Center.

⁽Adaptive Delta Management, works as an adaptive management policy tool for flood safety and freshwater supply in the Netherlands).

¹⁸ Cosens, Barbara A. and Williams, Mark K. (2012). Resilience and water governance: Adaptive governance in the Columbia River Basin, Ecology & Society, 17(4), 3.

¹⁹ Chaffin, Brian C. et al., (2014). A Decade of Adaptive Governance Scholarship: Synthesis and Future Directions, 19 Ecology and Society, 56.

²⁰ Walker, Brian et al., (2004). Resilience, Adaptability and Transformability in Social-Ecological System, 9 Ecology and Society, 5.

²¹ Craig A. (Tony) Arnold, and Gunderson, Lance H. (2013). Adaptive Law and Resilience, 43 Environmental Law Reporter, 10426, 10429, 10432.

both constancy and dynamism support the purpose of law.²² According to the adaptation theorists, the function of law is "learning to recognize, or imitate, regimes of spontaneous order already present in social life" and expressing a more active role of law, "it is a kind of problem-solving technology that responds, or adapts, to 'needs' emerging from society."²³ Gordon states that legal science is "related to something more fundamental than mere politics: to principles of fundamental right as realized teleologically through historical experience and, even more important, to needs spontaneously emerging from social life and to the long-term logic of historical development."²⁴ This theory resonates with the core idea behind adaptive regulation where in the laws are designed to keep pace with changing times.

Dynamic law' is another concept closely related to adaptive regulation. J. Pidot describes dynamic law to include three types of regulations (adaptive regulation being one of them): (a) durational regulation- legal rules with periodic opportunities for reconsideration, revision, or repeal; (2) adaptive regulation- legal rules with defined procedures requiring reconsideration as and when new information emerges; and (3) contingent regulation- legal rules with mechanisms adjusting the substantive content of rules when new information emerges or when foreseeable future scenarios occur.²⁵

Evidently, the scholars have defined and used these terms differently but these terms share several overlapping attributes. For example, adaptive regulation shares common features with adaptive management such as iterative decision-making and evidence-based changes through structured and systematic processes. Similarly, adaptive policy and dynamic law share common attributes with adaptive regulation such as substantive and procedural mechanisms for policy adjustments, mechanisms for collecting information, mechanisms for monitoring and evaluation, to name a few. On the other hand, the terms adaptive law and adaptive governance convey broader concepts, referring to the larger regulatory ecosystem that plays a facilitatory role in implementing adaptive regulation. Thus, all these terms seem inter-related in significant ways and researching their relevant literature could be helpful in understanding adaptive regulation.

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²² Gordon, Robert W. (1981). Historicism in Legal Scholarship, 90 Yale Law Journal, 1017, 1036.

²³ *Id.* at 1029.

²⁴ Id. at 1040.

²⁵ Pidot, Justin R. (2015). Governance and Uncertainty, 37 Cardozo Law Review, 112, 117.

In this dissertation research, the term adaptive regulation is the primary focus of study. However, the use of other terms is made and suitably acknowledged to incorporate learning from their relevant attributes.

II. Adaptive Regulation and types

Scholars have distinguished the adaptive regulations in two broad categories: planned and unplanned; and discretionary and automated.²⁶ Their distinction is briefly noted below:

1. Planned and Unplanned adaptive regulation

Planned adaptive regulation- Regulations are called planned adaptive when the adaptive features are built-in a regulatory framework by design from the outset.²⁷ These involve a series of occasions for policy makers to review their analyses and consider revisiting the regulations.²⁸ For example, a statute mandating periodic reviews or having sunset provisions.²⁹ Planned adaptive regulations (PAR) add dynamism to otherwise static regulations, imply a flexible working environment, and entail policymaking as an openended phenomenon.³⁰ PAR has two basic features: (a) a prior commitment and inclusion of periodic revision or revaluation while designing the regulation and (b) a mechanism to monitor and synthesize new knowledge and information that could be used for revisions and re-evaluations.³¹ These regulations include a planned research effort to deal with information and knowledge gaps, that may sometimes increase the uncertainties. However, they improve the overall understanding of the policy area and the learnings benefit future policymaking.³²

Unplanned adaptive regulation- In unplanned adaptive regulations, the changes in law and regulations take place over time, however, there is no prior planning or envisioning.³³ For

²⁶ See, Bennear and Wiener, supra note 1, at 7.

²⁷ McCray et al., (2010). Planned Adaptation in Risk Regulation: An Initial Survey of US Environmental, Health, and Safety Regulation, 77 Technological Forecasting & Social Change, 951–959. https://dspace.mit.edu/bitstream/handle/1721.1/96045/McCray-2010Planned%20adaptation%20i.pdf?sequence=1&isAllowed=y.

²⁸ Wiener, Jonathan B. and Ribeiro, Daniel L. (2016). Environmental Regulation Going Retro: Learning Foresight from Hindsight. Journal of Land Use and Environmental Law 32: 1–72. Also *see* International Risk Governance Center (IRGC). (2017). Transatlantic patterns of risk regulation: Implications for international trade and cooperation. Report. Lausanne: EPFL International Risk Governance Center, 58. ²⁹ Sunset provisions require an agency to reconsider the rules or standards after a designated time period. After the specified period, the program or the rules would automatically terminate and would need reauthorization to continue. For details *see* Bennear & Wiener, *supra* note 1.

³⁰ See Mc Cray et al., supra note 27, at 958.

³¹ *Id*

³² See, IRGC, supra note, 17 at 5.

³³ See Bennear & Wiener, supra note 1, at 16.

example, legislative amendments and rule revisions. These are called unplanned adaptive because though they are adapting with time but the change is not planned, such as there are no monitoring mechanisms to collect data and inform revisions or reviews.

This type of adaptive regulation is similar to the concept of 'static law' as defined by Pidot. He defines static law as a legal rule "intended at the outset to regulate in perpetuity." 34 Such law also undergoes a change or amendment, however, at the designing stage, there is no explicit provision for the same and the change or amendment is more a response to new situations and realities.³⁵

2. Discretionary and Automated adaptive regulation

Discretionary adaptive regulation. After the promulgation of initial regulation, such regulations require an action by the regulator to introduce a change. This action is based on a structured analysis of the regulatory performance. However, the regulator has the discretion of introducing or not introducing the change vis-à-vis the regulation. Federal Reserve Board's Open Markets Committee regularly considers the interest rates, however, the OMC sometimes adjusts these rates.

Automated adaptive regulation- In this type of regulations, the terms of adaptation are built-in and whenever the set outcomes are realized, the regulation changes automatically. For example, an adaptive cap and trade system with predetermined price floors and ceilings. When the price floor or ceiling threshold is reached, the cap changes automatically.³⁶ These regulations closely relate to the scholarship on adaptive policies where signposts and triggers are defined in advance and on reaching the triggers, pre-defined defensive or corrective actions are swung into action.³⁷

Further, there could be hybrid regulations with features of both discretionary and automated regulation, i.e. some components requiring discretionary intervention of a regulator and some that could be automated.³⁸

³⁴ See Pidot supra note 25, at 117.

³⁵ *Id.* at 118.

³⁶ See Bennear & Wiener, supra note 1, at 24, 25.

³⁷ Triggers are the critical values of the signpost variables that lead to implementation of defensive or corrective actions or to a policy reassessment. For details see supra notes, 7 to 12.

³⁸ See Bennear & Wiener, supra note 1, at 29.

III. Adaptive strategies and Adaptive Regulation

A related scholarship on the types of adaptive strategies and adaptive measures is mentioned here.³⁹ Though this scholarship relates to government adaptation strategies in the context of climate change, there are a few overlapping attributes that relate to the scholarship on adaptive regulation. Two types of adaptive strategies are relevant here:

1. Reactive and Proactive Strategies

Reactive adaptation refers to a system's ability "to experience a disturbance or impact and return to its prior state." Reactive adaptation strategies look backward and seek to recover from observed effects. These responses face lesser uncertainty when compared to proactive responses, however, they are cost-intensive and deal with situations when damage has been done.

Proactive adaptation strategies are forward looking. They incorporate the uncertainty of future changes into the overall strategy by anticipating the impacts to the existing system and making alterations in the system to enable a more effective response capacity.⁴² These responses are flexible and designed to be effective under a variety of future conditions.⁴³

Adaptive regulation is both forward looking and backward looking in its approach but in a planned way. It can neither be classified as an ex-ante nor an ex-post regulatory approach. It could be best described as a hybrid of both where "hindsight adds to the foresight." Adaptive regulations are designed in such a way that they respond to learning and experience (hindsight) as well as planning ahead and creating mechanisms for data collection and monitoring (foresight) in a structured way.

³⁹ Camacho, Alejandro E. (2009). Adapting Governance to Climate Change: Managing Uncertainty Through a Learning Infrastructure 59 Emory Law Journal. 1,16. Also *see*, Olson, D (2016). Declining Water Supply: How Utah Can Become Adept at Adapting to the Impacts of Climate Change. Utah Law Review On Law, 120-166.

⁴⁰ See Camacho, supra note 39. Also see, Easterling III, William, E. et al., (2004). Coping with Global Climate Change: The Role of Adaptation in the United States, at 5. Pew Center on Global Climate Change. ⁴¹ See Camacho, supra note 39, at 18-19.

⁴² *Id.* at 18.

⁴³ *Id*.

⁴⁴ For details *see*, Bennear, Lori S. and Wiener, Jonathan B. (2021). Institutional Roles and Goals for Retrospective Regulatory Analysis. Journal of Benefit-Cost Analysis, 12: 466-493.

2. Substantive and Procedural Strategies

This classification is based on the choice of mechanisms for adaptation efforts that could be substantive or procedural.⁴⁵ In substantive strategies, the entities choose from an array of substantive actions to manage the effects of change. Whereas the procedural strategies attempt at managing the process of adaptation, like altering the decision-making processes, that enable developing more effective substantive strategies.⁴⁶ Procedural strategies do not choose the adaptation actions per se but choose the processes that lead to effective adaptation actions. Procedural adaptation strategies are considered to bridge the gap between uncertainty and substantive adaptation measures.⁴⁷

On similar lines, the scholarship on dynamic law differentiates between adaptive regulation and contingent regulation based on procedural and substantive processes.⁴⁸ Adaptive regulations are described as the legal rules with defined procedures that require reconsideration as and when new information emerges. On the other hand, contingent regulations are described as the legal rules with mechanisms that adjust the substantive content of rules when new information emerges or when foreseeable future scenarios occur.⁴⁹

IV. Pros and Cons of Adaptive regulation

Pros - There are many strengths of adopting adaptive regulations such as reducing policy errors, reducing social welfare losses, improving regulatory learning, better handling of the risks and uncertainties, and incentivizing of knowledge creation.

1. Reduces policy errors and fosters innovation

Adaptive regulation is an iterative process of decision-making, spread over a continuum and informed by data and evidence over time. Therefore, such regulations reduce the

⁴⁵ Camacho, *supra* note 39, at 20-25.

⁴⁶ Id

⁴⁷ See Olson, supra note 39, at 148-49. Also see generally California Natural Resources Agency. (2009). California Climate Adaptation Strategy, 23. Available at

https://resources.ca.gov/CNRALegacyFiles/docs/climate/Statewide Adaptation Strategy.pdf.

California's Climate Adaptation Advisory Panel ("CAAP") established a procedural mechanism to assesses priorities, identify climate adaptation strategies, and develop a framework to promote collaboration within and among agencies

⁴⁸ See Pidot supra note 25.

⁴⁹ *Id*.

potential of policy errors by avoiding under-regulation and over-regulation. In the context of rapidly evolving sectors such as technology, this approach could calibrate the policy decisions based on evidence and new information, thus, prevent both over-regulation of net beneficial technologies and under-regulation of net harmful technologies, as well as foster innovation.⁵⁰

2. Reduces the social welfare losses

Regulation based on outdated or incomplete science can lead to tremendous social welfare losses. However, if a regulation waits for the science to develop and become certain, that would also amount to social welfare loss. In such scenarios, adaptive regulation functions to reduce the social welfare losses. For example, in drug approval if the drug is to be declared safe and effective, the regulator requires enormous amount of data before approval. This could mean a large number as well as longer clinical trials to evaluate the effect of drug in the whole population. ⁵¹ Such a process could hurt the interests of stakeholders including patients, firms, and physicians. However, adaptive licensing, which is one form of adaptive regulation, allows a process wherein the drug is approved for a small population and based on the results as more safety and efficacy data becomes available, its use is expanded to a larger population. ⁵²

3. Better structured to handle the uncertainties

Compared to traditional policymaking, the adaptive approach is better structured to handle a range of uncertainties related to policy choices. Further, it does not require to delay implementation until the resolution of all uncertainties. Implementing a basic policy (low risk) that is designed to adapt can be started right away and the developments of uncertain factors and events can be monitored, and policy can be changed according to the new developments. Adaptive regulations are designed to respond to scenarios where the original policy objectives undergo a change or when unexpected events occur. In such scenarios, the experiences add to the knowledge base and benefit the new policy choices.⁵³

⁵⁰ See Bennear & Wiener, supra note 1, at 3,4.

⁵¹ See Price (II) W. Nicholson and Rai. K. Arti. (2016). Manufacturing Barriers to Biologics Competition and Innovation. 101 Iowa law Review, at 1060, 1061.
⁵² Id.

⁵³ Marchau, V.A.W.J. et al., (2010). Dynamic adaptive transport policies for handling deep uncertainty, Technology Forecasting and Social Change. 77, 940, 949.

4. Promotes regulatory learning

Adaptive regulation could be a mechanism for regulatory learning in myriad ways. Jurisdictions could coordinate experimentation in two or more settings and then compare the results of different policy measures. Similarly, regulatory designs and outcomes could be improved by learning from regulatory variation across countries⁵⁴ and from experimentation and knowledge aggregation over time.⁵⁵ In planned adaptations, there is emphasis on deliberate organizational separation in which the 'learning' function is isolated systematically from the 'changing' function such as through independent regulatory oversight bodies⁵⁶ or multi-agency working groups.⁵⁷

5. Incentivizes creating new knowledge

Another advantage of adaptive regulation, particularly, planned adaptation is that it incentivizes creating new policy-relevant knowledge. If a decision is deemed to be permanent, there will be no incentive to revisit it based on new knowledge. However, when future learning and revision is a part of policy design, revisiting the adopted policy and revalidating the initial policy assumptions is followed as a part of regulatory process.⁵⁸

Cons- Adaptive regulations have their limitations as well, such as the cost-intensiveness, tendency to defer decisions, issues of agency discretion and public accountability, impact on policy stability, and political maneuvering.

1. An excuse to defer policy decisions

Agencies could use adaptive regulation as a tool to "dodge difficult, controversial decisions," and defer challenging decisions for future action.⁵⁹ Also, adaptive regulation may not always provide the information required for iterative decision-making and might end up as an empty formality. These regulations are useful when experimentation with policy options can be reasonably expected to fill the information gaps faced by regulators. However, when the variables are too many and diverse or the timescale of policy

⁵⁴ Wiener, Jonathan B. and Alemanno, Alberto. (2015). The Future of International Regulatory Cooperation: TTIP as a Learning Process toward a Global Policy Laboratory. Law & Contemporary Problems 78: 103–136.

⁵⁵ See IRGC, supra note 28, at 61.

⁵⁶ See Mc Cray et al., supra note 27, at 958.

⁵⁷ See Bennear & Wiener, supra note 44.

⁵⁸ See Mc Cray et al., supra note 27, at 958, 959.

⁵⁹ Ruhl, J.B. and Fishman, Robert L. (2010). Adaptive Management in the Courts, 95 Minnesota Law Review. 424, 459-60.

implementation too big (e.g., decades to centuries), experimentation is unlikely to produce useful information.⁶⁰ Sometimes, producing knowledge and enhancing learning opportunities as a part of adaptive process, become end goals in themselves, thus posing normative concerns.⁶¹ Considering most reviews are expected to be done by the agency itself (the one that created the rules), there could be resistance in critiquing one's decisions, thus, deferring the reviews altogether.

2. Increases agency discretion and reduces public accountability

Adaptive regulation could be seen as a mechanism of increasing agency discretion, thus, contrary to democratic values. These could be construed as mechanisms of truncating public participation and ignoring public inputs. ⁶² Adaptive processes could be viewed as opaque to outside observers, thus, challenging public accountability of these processes. Also, agencies could collaborate in loose networks to hide accountability issues. ⁶³

3. Cost intensive

Revisiting and updating agency actions involve costs because data collection and monitoring are required over extended time periods. Though these processes are not elaborate and do not go through the formal procedures of notice -and-comment rulemaking (e.g. in the US), yet they place burden on staff's time and resources, e.g. for gathering information.⁶⁴ Adaptive regulation could be challenging for organizations that regulate huge sectors of economy but have limited budgetary allocations.⁶⁵

4. Undermines the notion of policy stability and compliance

Acknowledging uncertainty in policymaking and considering it an open-ended process has not yet been accepted as the regular regulatory process.⁶⁶ Public expectations are still imbued with stable and predictable policies, making adaptive choices difficult to be implemented. Changing rules and policies could be seen as an indicator of policy instability,

⁶⁰ Doremus, Holly. (2011). Adaptive Management as an Information Problem, 89 North Caroilna Law Review, 1455- 1498.

⁶¹ See Pidot, supra note 25, at 163.

⁶² Ruhl, J.B. (2009). It's Time to Learn to Live With Adaptive Management (Because We Don't Have a Choice), 39, Environmental Law Reporter, 10920, 10921.

⁶⁴ See Bennear & Wiener, supra note 1, at 4. Also see Price & Rai, supra note 51, at 1060.

⁶⁵ See Price & Rai, supra note 51, at 1060. Also see, e.g. Peter Barton Hutt, Recent Developments, The State of Science at the Food and Drug Administration, 60 ADMIN. L. REV. 431, 447-50 (2008) (discusses resource constraints at the FDA).

⁶⁶ See Mc Cray et al., supra note 27, at 958.

impacting interests of different stakeholders.⁶⁷ From industry perspective, business investments are long term and it prefers the stable laws and policies even if they fit poorly than the uncertain standards. ⁶⁸ Revising standards could negatively impact the industry stakes.⁶⁹ The compliance population generally expects the regulations to be enforceable and credible. Anticipating policy revision may undermine the credibility and the perceived fairness of the initial policy, thus weakening industry compliance.⁷⁰

5. Political maneuvering

Political maneuvering is another limitation attributed to adaptive regulations.⁷¹ In policy and politics, 'flip-flopping' is not considered an appealing trait, thus, it could undermine an agency's public reputation implying weakness or, even "unprincipled malleability" due to political pressure.⁷² Political leaders may use the adaptive provisions to fulfil their political agendas.⁷³

V. Static Regulation vs. Adaptive Regulation

Static laws are defined as the legal rules "intended at the outset to regulate in perpetuity." ⁷⁴ Such rules are created without specific provisions for future revisions and modifications. The static laws also undergo a change or amendment, however, at the design stage, there is no explicit provision for the same. The change or amendment is more a response to new situations, realities, and uncertainties but the laws did not account for such uncertainties when they were being drafted.⁷⁵ Static laws are considered unsuitable for complex and chaotic situations that demand a flexible and nimble approach. With new information and technological advancements, such laws are rendered obsolete because these are designed

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⁶⁷ See Bennear & Wiener, supra note 1, at 5.

⁶⁸ See Price & Rai, supra note 51, at 1060.

⁶⁹ The tension between the automobile industry and the US administration regarding the revision of fuel economy standards is an apt example. For details, *see*, Davenport, Coral. 2019. "Automakers Plan for Their Worst Nightmare: Regulatory Chaos After Trump's Emissions Rollback." New York Times, April 2019. https://www.nytimes.com/2019/04/10/climate/auto-emissions-cafe-rollback-trump.html. Also, *see*, Davenport, Coral, and Tabuchi, Hiroko. 2019. "Automakers, Rejecting Trump Pollution Rule, Strike a Deal With California." New York Times, July 25, 2019.

https://www.nytimes.com/2019/07/25/climate/automakers-rejecting-trump-pollution-rulestrike- a-deal-with-california.html.

⁷⁰ See IRGC, supra note 28, at 60.

⁷¹ Bowling, Terra. (2010). Symposium on Adaptive Management. Sea Grant Law and Policy Journal, Vol. 3, No. 1, 1-8.

⁷² Gubler, Zachary J. (2014). Experimental Rules. Boston College Law Review 55: 129-179.

⁷³ See, for example, the mid-term review of the fuel economy standards in the US. Also, see, supra note 69.

⁷⁴ See, Pidot, supra note 25, at 117 and 131.

⁷⁵ *Id.* at 118.

for circumstances that stand changed. Many times, it is seen that the static laws remain on books for a longer time than warranted because the procedures for their amendment and review are cumbersome and time-intensive. Thus, static laws add to the regulatory inefficiency, undermine people's faith in the government, and are ill-equipped to solve complex problem scenarios. Scholars suggest that static laws could help in solving simpler and easier problems but as complexity increases and the problems become "thornier," dynamic approaches and solutions are required.

On the other hand, adaptive regulation provides an evolutionary approach of decision-making informed by inputs from monitoring mechanisms. It is not deterministic about the most appropriate regulatory choice. It is an open-ended approach that allows lawmakers to adjust their decisions based on new conditions without committing to policy responses in advance. Thus, it reduces the up-front costs associated with 'front-end loaded' decision making and spreads it over time. This approach is unique in producing new information as a part of the adaptive process. However, this approach is criticized for many reasons including the high costs of implementation, being in conflict with established statutory provisions and judicial expectations, and increasing agency discretion, to name a few. Despite these limitations, there is a consensus among scholars that when compared to a static law which is prescriptive, adaptive regulation is much more suited to address the needs of future regulatory challenges.

VI. Why Adaptive Regulation?

In general, regulatory policies around the world are one-time decision-making processes, based on ex-ante assessments with limited, or ad-hoc ex-post reviews. However, in the real-world, changes continue to happen across time and space. Thus, to be meaningful, the regulations need to keep pace with these changes. Adaptive regulations offer an array of

⁷⁶ *Id.* at 139.

⁷⁷ *Id.* at 140.

⁷⁸ See Doremus, supra note 60, at 1465–66. See, e.g., Biber, Eric. (2013). Adaptive Management and the Future of Environmental Law. 46 Akron Law Review, 933, 938; Also, see, Craig and Ruhl, supra note 16.

⁷⁹ See, Pidot, supra note 25, at 159. See, Biber, supra note 78, at 945–48.

⁸⁰ See Doremus, supra note 60.

⁸¹ See Ruhl and Fischman, supra note 53. Also, see, Craig and Ruhl, supra note 16. Also, see Thrower, Julie. (2006). Adaptive Management and NEPA: How a Nonequilibrium View of Ecosystems Mandates Flexible Regulation, 33 Ecology Law Quarterly, 871, 879.

⁸² For details, see, supra section-IV on Pros and Cons of Adaptive Regulation.

mechanisms where the regulations are designed to learn and the iterative decisions are based on evidence and new information.

In regulatory decision-making, many times the policy-makers resort to working assumptions due to scientific and other substantive uncertainties. Over time, the reasonableness of these assumptions could be questioned due to new research in science, evolution in technology, or experience of actual policy implementation. Thus, it is important to have regulatory mechanisms that "keep policy yoked to an evolving knowledge base, once decisions are put on the books." Many areas of governance like technology, environment, involve significant uncertainty and change. If this uncertainty is acknowledged at the design stage, it could help to better accomplish the overall objectives of law/policy. Instead of waiting for the uncertainties to resolve, adaptive regulations create provisions for updating the regulations over time. New information and experiences become the basis of further iterations, revisions, or necessary repeal of the regulation. 85

In environmental context, disruptive events like the climate change have questioned some of the basic assumptions of environmental science. Therefore, the decision-making models relying on the past to predict the future are increasingly becoming inadequate, and require adaptive and resilient approaches to environmental management. ⁸⁶ Craig advocates that the existing laws need to be revised because the "presumed stationary baseline" no longer reflects the ecological realities and the regulators should have the flexibility to adapt to these shifting baselines. ⁸⁷ Despite scientific recognition that ecosystems are complex and dynamic systems, ⁸⁸ the environmental laws on the books remain outdated. ⁸⁹ The changing

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⁸³ See, McCray et al., supra note 27.

⁸⁴ See Pidot, supra note 25, at 116.

⁸⁵ *Id.* at 151.

⁸⁶ Adler, Jonathan H. (2016). Dynamic Environmentalism and Adaptive Management: Legal Obstacles and Opportunities. Faculty Publications. 1661. Environmental Policy in the Anthropocene, Property and Environment Research Center, 65-91.

⁸⁷ Craig, Robin K. (2010). Stationarity is Dead-Long Live Transformation: Five Principles for Climate Change Adaptation Law. 34 Harvard Environmental Law Review, 9, 18. Also see, Ruhl, J.B. (2010). Climate Change Adaptation and the Structural Transformation of Environmental Law, 40 Environmental Law 363, 364, 366.

⁸⁸ See Adler, supra note, 86, at 68.

⁸⁹ *Id.* at 69,70 (Botkin observes, "whether or not environmental scientists know about geological time and evolutionary biology, their policies ignore them").

ecological conditions are fast outpacing the capacity of many legal frameworks⁹⁰ and the absence of long-term objectives is resulting in reactive policies than proactive ones.⁹¹

Anticipating how the policy measures would influence the ecological systems and human activities, and how such activities, in turn, feed back into the system and create additional and sometimes unanticipated or even unintended environmental implications is a tremendously difficult process. Scholars suggest that incorporating adaptive management at all levels of governance could be the right way forward to address regulatory challenges posed by the complex ecological systems. The adaptive approach recognizes that much relevant information is known only after making the management decisions, thus, necessitating re-evaluation and adjustment to account for the new learnings and developments. Thus, the law needs a fundamental shift in its goals and objectives, from preserving and restoring to improving resilience and adaptive capacity.

Another scholarship emphasizing the need for change in regulatory approaches builds around the *sources of policy unsustainability*. It identifies some of the sources leading to policy unsustainability, like improper policy design, post-implementation changes in the policy-making system, and failure of policy-making system to adapt to changing circumstances. Addressing these sources requires a shift in policy-makers' expectations and the creation of regulatory structures that are more adaptive to the complexity and the pace of socio-economic and technological changes. Policy-makers require to shift their emphasis "from static optimization under constraints to adaptability," to experiment and monitor the

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⁹⁰ Schramm, Daniel and Fishman, Akiva. (2010). Legal Frameworks for Adaptive Natural Resource Management in a Changing Climate. Georgetown International Environmental Law Review, 22 (3), 491, 497-498.

⁹¹ Trouwborst, Arie. (2009). International Nature Conservation Law and the Adaptation of Biodiversity to Climate Change: A Mismatch? Journal of Environmental Law, 21 (3), 419, 424. (noting the need for "international nature conservation law to shift from reactive and ad hoc approaches to proactive and holistic ones")

⁹² See Adler, supra note 86, at 72.

⁹³ See Schramm and Fishman, supra note 90, at 497-498.

⁹⁴ Doremus, Holly. (2001). Adaptive Management, the Endangered Species Act, and the Institutional Challenges of 'New Age' Environmental Protection. Washburn Law Journal, 41:50-89.

⁹⁵ See Craig, supra note 87, at 68. Also see, Trisolini, Katherine. (2014). Holistic Climate Change Governance: Towards Mitigation and Adaptation Synthesis. Summer Reporter University of Colorado Law Review, 85: 615.

⁹⁶ See Cherry, Barbara A. (2007). The Telecommunications Economy and Regulation as Co- evolving Complex Adaptive Systems: Implications for Federalism, Federal Communications Law Journal, 59: 369, 384. Also see Cherry, Barbara A. and Bauer, Johannes M. (2004). Adaptive Regulation: Contours of a policy model for the Internet Economy 26, 1-37.

⁹⁷ See Cherry, Implications for Federalism, supra note 96, at 384.

policy effects, willingness to use new research tools, and willingness to evaluate and modify the overall policy-making ecosystem.⁹⁸

Another view supporting a need for change in the design of regulatory institutions and approaches is built around the prevailing *modes of economic production*. It argues that the present-day institutions were created to respond to the problems of an era when industrialism was the mode of economic production. However, there has been a shift from industrial mode to an informational mode of production, warranting a change in the substance of regulatory institutions and mandates.⁹⁹ Regulatory mandates of industrial-era presumed well-defined industries and ascertainable markets. Whereas, in the information-era, these definitions and boundaries are blurred making it difficult to precisely articulate the nature and substance of compliance, enforcement, and other forms of regulatory oversight.¹⁰⁰ Thus, a change in the basis of the political economy requires a shift in the design of regulatory institutions as well as the formulation of regulatory mandates.¹⁰¹

A shift from static to adaptive regulation is also pitched for regulating the *areas characterized* by rapid developments, e.g. emerging technologies. In such areas, the government agencies are considered to lack the required information for decision-making due to limited or no knowledge-base to predict the outcome of regulatory choices. ¹⁰² Scholars have referred to such situations as 'non-routine' problems and have suggested that the traditional government structures are good at managing the 'routine problems' not the 'non-routine' ones. ¹⁰³ This is because the non-routine problems demand nimble and flexible organizations that could adapt and create spaces for 'non-routine solutions' based on communication, information, and developed by innovative problem solvers who are driven by information. Further, solving non-routine problems requires heterarchy instead of hierarchy. Heterarchy implies "pluralistic structures that rely heavily on the initiative of their members, who seek to learn quickly and effectively about how to best handle

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⁹⁸ Id. at 384-85.

⁹⁹ Cohen, J. E. (2016). The regulatory state in the information age. Theoretical Inquiries in Law, 17(2), 369, 370-371.

¹⁰⁰ *Id.* at 374.

¹⁰¹ *Id.* at 414.

¹⁰² Paddock, L. (2010). An integrated approach to nanotechnology governance. UCLA Journal of Environmental Law and Policy, 28(1), 251, 270-271.

¹⁰³ Kettl, Donald F. (2005). The Next Generation of the United States: Challenges for Performance in the 21st Century. IBM Center for the Business of Government. Available at http://www.businessofgovernment.org/sites/default/files/Peformanceinthe21stCent.pdf

uncertain futures."¹⁰⁴ Thus, in the case of non-routine problems, adaptive regulation would require heterarchy that would include regulators as well as members of industry, researchers, non-profit organizations and many others. Early and regular engagements of all these organizations and stakeholders would be required for a successful solution and such adaptive changes, in turn, would have to be monitored, again through some form of stakeholder process, assessing its effectiveness and adjusting the process in the light of new information and experience. ¹⁰⁵

Similarly, regulating risk in rapidly evolving sectors is premised on projected risks, costs, benefits, safety, and other issues. However, due to rapidly evolving context and new knowledge, revisions and continuous re-evaluation of risks are needed. In such scenarios, static regulation would result in a one-time decision that could lead to gaps in risk management, discourage healthy risk-taking, and stifle creativity and innovation due to 'technological lock-ins'. Thus, adaptive approaches to risk assessment and management are needed for flexibility and learning throughout the regulatory process.¹⁰⁶

Some authors have questioned the basic *notion of "settlement"* associated with law particularly when the context and the circumstances change or continue changing. 107 "Recognizing and replacing our default push for settlement in law" is important for adaptation. Scholars recognize that human society resists the idea of 'impermanence and change' and that such social constructs undergird the existing legal system. They do not advocate completely doing away with 'settlement' as it serves important functions in a legal system. However, they advocate that this notion could be increasingly becoming dysfunctional in a rapidly changing world. It is imperative to find a way for legislative, executive, and judicial bodies recognizing that changed circumstances require a re-examination of decisions and that the goals of the legal system would be better served by having mechanisms to incorporate new realities and alter 'final' decisions based on changing realities without necessarily unsettling

¹⁰⁴ *Id.* at 20-21.

¹⁰⁵ Id

¹⁰⁶ See, IRGC, supra note 17, at 4,5.

¹⁰⁷ Flatt, Victor B. (2016). Unsettled: How Climate Change Challenges a Foundation of Our Legal System, and Adapting the Legal State. Brigham Young University Law Review, at 1425.

¹⁰⁸ *Id.* Also *see* Craig, A. Arnold (2014). Adaptive Water Law, 62 University of Kansas Law Review, 1043, 1054. *See* generally Siemens, Herman W. (2008). Nietzsche and the Temporality of (Self-)Legislation, in Nietzsche on Time and History, 191 (Manuel Dries ed., 2008). (Nietzsche believed change was the key to understanding the nature of the human condition.)

the policy.¹⁰⁹ And where this notion is causing harm and inefficiency, there should be a concerted effort not to settle.¹¹⁰

Thus, there are many scholarships justifying the need of adaptive regulation over the static one. To delve deeper into the adaptive approach, the following section analyzes and reviews the literature on frameworks related to adaptive regulation.

VII. Broad features of Adaptive Regulation

In general, the frameworks are considered useful tools to understand the basic constituents of a concept. This study began with a systematic review of literature to identify the frameworks related to adaptive regulation. Based on the literature review, six broad features of adaptive regulation are identified that have been repeatedly propounded by scholars. These features are not considered as the sine qua non of adaptive regulations, nevertheless, their presence is likely to indicate the adaptability of regulations. The features are summarized in Table-1.

Table 1. Broad features of Adaptive Regulations based on literature review

| Dimension | Components | Source |
|---|---|---|
| Acknowledging risk, uncertainty, and change | (1) Explicit acknowledgement and characterization of risks and uncertainties (2) Forward Planning - Policies are devised to be robust across a range | (1) Jonathan B. Wiener (2020); Holly Doremus et al., (2011); Huang et al., (2011); Mc Cray et al., (2010); Cooney and Lang (2007) |
| Broader and Fuller impact assessment | Acknowledging the inter- connections across systems and considering the broader (fuller) impacts of policy choices (e.g., ancillary impacts, distributional impacts) | (2) J. Pidot (2015); Huang et al., (2011); Swanson et al. (2010); Warren Walker and Vincent Marchau (2003); US Fish and Wildlife Service (2000) Bennear and Wiener (2021); Jonathan B. Wiener (2020); Bennear and Wiener (2019); Craig, Arnold (2014); Craig, Arnold and Gunderson (2013) |

¹⁰⁹ See Flatt, supra note 107, at 1432.

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¹¹⁰ Id. at 1435.

¹¹¹ The search strategy used the terms that are closely related to the concept of adaptive regulation including adaptive policy, adaptive management, adaptive law, adaptive governance, and dynamic law, to name a few. To understand the rationale behind including these terms in literature review, *see*, *supra* section-I on 'Theories and Concepts' page 1 to 3. For details on the method of systematic literature review, *see*, sub-section III, 'Systematic review of literature' Chapter-2 (Introduction to the topic and Methodology).

| Monitoring, Evaluation, and feedback | Policy adjustments are informed by: (1) Data collection and analysis (2) Inputs from various actors (including members of the public) and agencies | (1) Bennear and Wiener (2021); Bennear and Wiener (2019); Aldy, Joseph E. (2014); James E Parker- Flynn (2014); Holly Doremus et al., (2011); Swanson et al. (2010); Daniel Schramm and Akiva Fishman (2010); Cooney and Lang (2007); National Research Council (2004) (2) Craig, Arnold and Gunderson (2013); Huang et al., (2011); Ruhl, J.B. (2011); Marchau et al., (2010); Cooney and Lang (2007) |
|--|---|---|
| Iterative decision- making and Policy Adjustment | Iterative approach to making decisions and the opportunity to adjust policy over time (e.g. Periodic reviews, regulatory experimentation, policy variation) | Bennear and Wiener (2019); J. Pidot (2015); Ruhl and Craig (2014); Holly Doremus et al., (2011); Huang et al., (2011); Daniel Schramm and Akiva Fishman (2010); Cooney and Lang (2007); Walker and Marchau (2003); Dennis Rondinelli (1993) |
| Public participation | Participatory role of the affected people in the decision-making process. | Cosens et al., (2017); Aldy, Joseph E. (2014); Huang et al., (2011); Swanson et al (2010); Cooney and Lang (2007) |
| Adaptive governance structures | Multiple decision-making institutions and scales (vertical/horizontal), coordination and integration | Cosens et al (2017); James E Parker-Flynn (2014); Craig, Arnold and Gunderson (2013); Jonathan Verschuuren and Jan McDonald (2012); Huang et al., (2011); Ruhl, J. B. (2011); Daniel Schramm and Akiva Fishman (2010) |

1. Acknowledging risk, uncertainty, and change

Uncertainty is considered ubiquitous in policy-making.¹¹² In general, the policy failures are considered to result from the failure to account for the uncertainties while designing policies.¹¹³ However, adaptive management and adaptive regulations recognize the risk and uncertainty and respond to them directly.¹¹⁴ For example, planned adaptive regulation acknowledges uncertainty and risk by keeping provisions for future review and revision,

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¹¹² Cooney, Rosie and Lang, Andrew T.F. (2007). Taking Uncertainty Seriously: Adaptive Governance and International Trade, 18 European Journal of International Law, 18: 523, 531-534.

¹¹³ Walker, Warren E. et al., (2010). Addressing deep uncertainty using adaptive policies: Introduction to section 2. Technology Forecasting and Social Change, 77 (6), 917–92.

¹¹⁴ Doremus, Holly et al., (2011). Making Good Use of Adaptive Management, CPR White Paper Pub. No. 1104: 2. Also *see* Huang, et al., (2011). Climate change and the puget sound: Building the legal framework for adaptation. Climate Law, 2(1), 299-344.

and adjusting policy decisions.¹¹⁵ This results in neither under-regulation of the net harmful technologies nor over-regulation of the net beneficial technologies.¹¹⁶ It incorporates a planned targeted research effort to reassess the knowledge base and bridge knowledge gaps. This process may increase the uncertainties as new information becomes available, however, it enables an improved understanding of the dynamic problem context and informs appropriate regulatory choices.¹¹⁷

The challenge could be the perceptual differences of risk and uncertainties by different stakeholders, e.g. scientists, political leaders, members of the public, industry, etc. However, clarifying uncertainty at the policy-design phase, providing a credible assessment of scientific and technical information, along with good framing and communication, could engender the confidence of industry and other stakeholders.

To address risk and uncertainties, the adaptive regulations emphasize the need for forward planning in a structured way.¹²² The forward planning processes could be subject to procedural or substantive requirements, or both.¹²³

On similar lines, the literature on adaptive policies emphasizes the need to acknowledge and assess the vulnerabilities at the design stage. Adaptive policies plan for a range of future conditions using integrated and forward-looking analysis.¹²⁴ They create mechanisms to identify potential vulnerabilities and opportunities associated with the proposed policy.¹²⁵ The vulnerabilities are screened to ascertain their level of uncertainty. For relatively certain

¹¹⁵ See Mc Cray et al., supra note 27, at 951.

¹¹⁶ See Bennear & Wiener, supra note 1, at 3.

¹¹⁷ See IRGC, supra note 17, at 5.

¹¹⁸ See IRGC, supra note 17, at 7.

¹¹⁹ *Id.* at 8-9. (Kenneth Oye listing the limiting factors for adaptive policies and the way forward.)

¹²⁰ Id.

¹²¹ *Id.* at 7.

¹²² See Huang et al., supra note 114, at 308. Also see United States Fish and Wildlife Service (USFWS). (2000). Notice of Availability of a Final Addendum to the Handbook for Habitat Conservation Planning and Incidental Take Permitting Process, Federal Register / Vol. 65, No. 106 / Thursday, June 1, 2000 / Notices at 35252. (The USFWS describes elements of adaptive management strategy to "develop alternative strategies and determine which experimental strategies to implement").

¹²³ Procedural regulations create defined procedures that require a reconsideration of policy as and when new information emerges. Regulations governing substantive process create mechanisms that adjust the substantive content of the rules/ policies when new information emerges or when foreseeable future scenarios occur. For details, *see* Pidot, *supra* note 25.

¹²⁴ Swanson, Darren et al., (2010). Seven tools for creating adaptive policies. Technology Forecasting and Social Change, 77: 924-939.

¹²⁵ Vulnerabilities are the possible developments that could negatively impact the policy and could lead to policy failure. Whereas, opportunities are the possible developments that could positively impact the policy and increase the policy success. For details *see* Kwakkel et al., *supra* note 3, at 259-60.

vulnerabilities, the policy outlines mitigating actions i.e. the actions taken in advance for reducing the 'certain adverse effects.' For uncertain vulnerabilities, the policy identifies hedging actions i.e. the actions to be taken in advance for reducing the risk of the potential 'uncertain adverse effects.' There is constant monitoring of the vulnerabilities and actions are taken when these vulnerabilities manifest. 128

2. Broader and fuller impact assessment

This feature highlights the importance of interconnections across systems in the real world and the need to assess broader and fuller impacts of the policy choices. The objective is to avoid the perils of narrow decision-making. Fuller impact assessment helps in reducing the unintended consequences of the policy as the regulators assess the full portfolio of impacts at the design stage, including ancillary benefits and the countervailing risks.¹²⁹

Related literature on adaptive laws acknowledges that adaptive laws have broadly defined goals and promote poly-resilience. Such laws acknowledge the interconnections between social, economic, ecological, and political systems, and endeavor to facilitate co-benefits. For example, if a law narrowly focuses on conserving biodiversity and fails to consider the interconnections between nature, law, and society, it may lead to an array of unintended consequences, including political backlash, social conflict, economic hardship, or even under or non-implementation altogether. However, the scholars acknowledge that it may not always be possible to add to the net benefits of all the systems, therefore, the lawmakers have to make choices and trade-offs such as by focusing on the approach that maximizes the co-benefits. ¹³¹

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¹²⁶ See, Marchau et al., supra note, 53.

¹²⁷ *Id.* (Additionally, shaping actions are identified i.e. the actions taken in advance for controlling the future to the extent possible such as by reducing the chance that an external event occurs that could fail the policy).

¹²⁸ *Id.* (During the implementation phase, as events unfold, the signposts are monitored, and the necessary actions are taken. As long as the signposts indicate that the policy is on its track to achieving the intended outcomes, the policy remains active, else, it is reassessed).

¹²⁹ Wiener, Jonathan B. (2020). Learning to Manage the Multirisk World. Risk Analysis, 40: 2139. *See* IRGC, *supra* note 17, at 22. Also, *see*, Bennear and Wiener, *supra* note 1, at 3.

¹³⁰ See Craig and Gunderson, supra note 21 at 10426, 10429, 10432. Also see Craig, Arnold. (2014). Resilient cities and adaptive law. Idaho Law Review 50(2), 245-264. ("Adaptive law aims to achieve multiple coexistent forms of resilience, a concept known as poly-resilience. In particular, a legal system that is adaptive to change serves to strengthen the adaptive capacity of both social systems, including institutions and communities, and ecological systems (or ecosystems)").

¹³¹ See Craig and Gunderson, supra note 21, at 10431. Also see Long, Andrew. (2010). Tropical Forest Mitigation Projects and Sustainable Development: Designing U.S. Law for a Supporting Role. William Mitchell Law Review, 36: 968; Hirokawa, Keith. (2012). Driving Local Governments to Watershed Governance. Environmental Law, 42: 157.

3. Monitoring, evaluation, and feedback

Adaptive regulations have built-in mechanisms of monitoring and feedback to enable policy adjustments. ¹³² Monitoring mechanisms take into account specific policy outcomes across space and time. 133 Regular data collection and analysis form the basis of policy review and updating. 134 It is important to plan for prospective data collection, 135 so that the collected data is relevant and it adds value to the process of review. ¹³⁶ In this way, adaptive regulations could be designed to respond to new information as well as to generate that information.¹³⁷

Adaptive regulations recognize the importance of inputs and feedback from various stakeholders as well as agencies. This feedback enables policy-makers to detect the emerging issues¹³⁸ as well as any unintended consequences of the policy implementation. The outcomes of the monitoring process are fed back into the regulatory process to reassess the basic assumptions, redefine goals, recalibrate policy objectives, and highlight the overall knowledge gaps. 139

The literature also mentions about the importance of 'feedback loops' which connect the implementation and monitoring and aid the decision-makers to assess if a particular policy

¹³² See Bennear & Wiener, supra note 1. Also see National Research Council. (2004). ADAPTIVE MANAGEMENT FOR WATER RESOURCES PLANNING. The National Academies Press, Washington, DC. ("Careful monitoring of adaptive management outcomes both advances scientific understanding and helps adjust policies or operations as part of an iterative learning process'); Schramm and Fishman, supra note 90 (The authors call for "transforming discretionary management authorities that may be currently perceived as 'extras' into legal mandates", thus proposing "clear mandates for scientific baseline setting, monitoring, and reporting," in their legal framework for adaptive management), and Doremus, Holly et al., supra note 114, at 2.

¹³³ See Cooney and Lang, supra note 112, at 537-38. Also see, Swanson et al., supra note 124, (The authors emphasize that adaptive policies monitor key performance indicators that trigger built-in policy adjustments.)

¹³⁴ Flynn, James E. Parker. (2014). The Intersection of Mitigation and Adaptation in Climate Law and Policy. Environmental Law and Policy Journal, 38: 1, 46. (The author proposed a framework for implementing the mitigation-adaptation lens. The framework has four parts, one being 'monitoring and follow up' to ensure that policy responses 'accurately incorporate and respond to uncertainties.' Also see also Craig, Robin supra note 87 (noting the need to 'Monitor and Study Everything All the Time'). ¹³⁵ See Bennear and Wiener, supra note 44, at 23. Also see Cropper et al., (2017). Looking Backward to Move Regulations Forward. Science, 355 (6332): 1375–1376, and Dudley et al., (2019). Crossing the Aisle to Streamline Regulation. Wall Street Journal, May 13, 2019. https://www.wsi.com/articles/crossing-theaisle-tostreamline- regulation-11557788679.

¹³⁶ Aldy, Joseph E. (2014). Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy. Report prepared for the Administrative Conference of the United States, November 18, 2014.

¹³⁷ See Pidot, supra note 25, at 153.

¹³⁸ See Marchau et al., supra note 53.

¹³⁹ See Cooney and Lang, supra note 112, at 537-38.

decision is received well by the public or not. Based on the feedback, the policy and its tools are adapted.¹⁴⁰ In the feedback function, the 'trans-governmental networks' are considered to play an instrumental role in exchanging information, conferring about trends, identifying potential roadblocks to adaptive strategies, and facilitating well-informed decision-making.¹⁴¹

4. Iterative decision-making and Policy adjustment

In adaptive regulations, the decision-making is a continuous process of learning where new information and post-implementation experience informs future revisions.¹⁴² New information could be about any development in the regulatory sector whereas, post-implementation experience is specifically regarding the impact of the policy choices undertaken. Adaptive regulations have built-in provisions for learning and iterative decision-making¹⁴³ such as periodic review,¹⁴⁴ retrospective review, or sunset clause.¹⁴⁵

While reviewing the laws/policies and evaluating if they meet the intended goals, several outcome criteria could be considered such as cost, benefits, effectiveness, cost-effectiveness, ancillary impacts, economic efficiency, and distributional equity. Further, an effective system of triage could be adopted to identify the most important criterion to assess and analyze the performance of rules and regulations. ¹⁴⁷

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¹⁴⁰ See Craig and Gunderson, supra note 21, at 10426, 10440 (2013). Also see United States Fish and Wildlife Service (USFWS) (2000). Notice of Availability of a Final Addendum to the Handbook for Habitat Conservation Planning and Incidental Take Permitting Process, Federal Register / Vol. 65, No. 106 / Thursday, June 1, 2000 / Notices at 35252.

¹⁴¹ Ruhl, J. B. (2011). General Design Principles for Resilience and Adaptive Capacity in Legal Systems – With Applications to Climate Change Adaptation. The North Carolina Law Review, 89, 1373, 1398. (The trans-governmental networks are the networks of similarly placed technocrats in different agencies having the needed expertise to understand practical exigencies of their particular field). Also, *see* Huang et al., *supra* note 67.

¹⁴² See Bennear and Wiener, supra note 1, at 1,2.

¹⁴³ See Craig and Ruhl, supra note 16 (Authors define adaptive management as an iterative decision-making process). Also see Walker, W. and Marchau, V. (2003). Dealing with uncertainty in policy analysis and policy-making. Integrated Assessment 4 (1),1–4; Marchau et. al., supra note 53, (According to the authors, adaptive policies include policies that respond to changes over time and that make explicit provision for learning); Huang et al, supra note 114 mentions 'principled flexibility' an important component of the adaptation legal framework; Doremus, Holly et al., supra note 114, at 2; and Pidot supra note 25.

¹⁴⁴ See Mc Cray et al., supra note 27. Also see, Schramm and Fishman, supra note 90, at 491, 501 (The authors emphasize the need of "legal mandates for periodic review and adjustment" in their legal framework).

¹⁴⁵ See Bennear and Wiener, supra note 1, at 13, 32. Also, see, generally Gubler, supra note 72, at 3.

¹⁴⁶ See Bennear and Wiener, supra note 44.

¹⁴⁷ See, Aldy, supra note, 136.

The agencies could employ different methods for regulatory learning including randomized methods¹⁴⁸ or observational methods,¹⁴⁹ though each have their strengths and limitations. In the observational methods, learning could be through policy variation¹⁵⁰ such as comparing the policies across jurisdictions (dynamic adaptive federalism)¹⁵¹ or comparing the policy (before and after) over two or more time periods¹⁵² or there could be learnings from the implementation of pilot programs.¹⁵³

There could be regulatory sandboxes that allow the industry (stakeholders) to test new ideas and products in a live environment without incurring the regulatory consequences. These sandboxes foster innovation by lowering the barriers and costs while ensuring the safety.¹⁵⁴

Related literature on adaptive governance and adaptive management recognizes the importance of learning as a central task of a policy/institution rather than a supplementary function. This learning could be both simple and complex. Simple learning involves acquiring new information and resolving the problems more effectively over time. And complex learning involves redefining the problem and revisiting/ reconstituting the

¹⁴⁸ Administrative Conference of the United States (ACUS). Adoption of Recommendations. Federal Register / Vol. 82, No. 249 / Friday, December 29, 2017 / Notices at 61738, 39. (Randomized approaches randomly assign the individuals or entities subject to a regulatory intervention (as experimental group and control group). Therefore, the results have a high level of internal validity because any other factors that might lead to changes in the relevant outcomes should be distributed randomly between the group subject to the regulatory intervention (experimental group) and the comparison group (control group). However, there could be legal, policy and ethical concerns for subjecting similar parties to different rules.)

¹⁴⁹ *Id.* (Observational studies are also called "natural experiments," as they seek to draw inferences based on variation arising naturally over time or across settings in the absence of randomization. The results do not have a high internal validity because other factors may confound a study's results. Unlike randomization, this method does not raise the legal, policy, and ethical concerns. Because the agency is exploiting the natural variation that would have arisen from the rule anyway or is learning from the existing variation, e.g. variation between different jurisdictions.)

¹⁵⁰ *Id.*

¹⁵¹ Engel, Kirsten H. (2017). Democratic Environmental Experimentalism. UCLA Journal of Environmental Law and Policy, 35: 57. (The author proposes a hybrid of Dynamic, Adaptive federalism and Democratic experimentalism. Applying the "primary features of each framework to the challenges of adaptation demonstrate the need for some aspects of both-for the regulatory experimentation and flexibility offered by democratic experimentalism and the safety net offered by dynamic federalism").

¹⁵² See ACUS, supra note 148.

¹⁵³ Id. Also, see IRGC, supra note 17, at 5.

¹⁵⁴ Fenwick, Mark et al., (2017). Regulation tomorrow: What Happens When Technology Is Faster Than the Law? American University Business Law Review, 6(3), 591-93. Also *see* World Bank Group. (2017). G-20 Global Partnership For Financial Inclusion, Digital Financial Inclusion: Emerging Policy Approaches, at 12-14.

¹⁵⁵ See Cooney and Lang, supra note 112, at 534-35.

relevant knowledge base about the policy problem.¹⁵⁶ The scholars emphasize on 'learning by doing' and treating policy interventions as quasi-experiments.¹⁵⁷

5. Public participation

Often the terms community participation, public participation, stakeholder participation, stakeholder engagement, community involvement, community engagement, citizen participation, etc., are used interchangeably.¹⁵⁸ Adaptive laws provide for avenues of community participation and capacity building.¹⁵⁹ Participatory capacity implies that those affected by a law/policy, should have the right and resources to participate in the decision-making processes that affect their lives and interests.¹⁶⁰ The law could promote participatory capacity by providing the requirement for public participation, judicial forums to recognize and enforce the rights, and capacity building through resource allocation and authority to facilitate local response.¹⁶¹

Broader participation in policy-making adds to the production of knowledge by marshalling varied perspectives and diverse viewpoints.¹⁶² Further, engaging stakeholders and the public in the review process could help in building a culture of retrospective review. This includes engaging public through review petitions, soliciting data, replicating agency analyses, etc.¹⁶³

6. Adaptive governance structures

Adaptive law supports adaptive structures. ¹⁶⁴ These structures of governance are essentially polycentric in nature, implying there are multiple centers of decision-making

¹⁵⁷ See Cooney & Lang, supra note 112, at 535-36. Also see Rondinelli, supra note 4 (According to him, adaptive approaches rely on administrative procedures that facilitate "innovation, responsiveness, and experimentation.")

¹⁵⁶ *Id*.

¹⁵⁸ National Environmental Justice Advisory Council (NEJAC). (2013). Model Guidelines for Public Participation- An Update to the 1996 NEJAC Model Plan for Public Participation, at 1.

¹⁵⁹ Amsler, Lisa Blomgren. (2013). Local Government: The Legal Framework and Context for Voice. Making Public Participation Legal. Also *see* Ruhl, *supra* note 141 at 1397 (The author advocates that, "Governance institutions will need a broader array of instruments ranging from "hard" prescriptive mandates to "soft" incentive- and information-based tools").

¹⁶⁰ Cosens, B. A., et al., (2017). The role of law in adaptive governance, Ecology and Society 22 (1):30, 5-6. Also, *see*, Huang et al., *supra* note, 114, at 311, 312, and 338.

¹⁶¹ *Id.* Also, *see*, Working Group, supra note, 159.

¹⁶² See Cooney & Lang, supra note 112, at 538-39. (The authors mention that "Adaptive governance prioritizes recognition and accommodation of the diverse values and knowledges of different stakeholders.")

¹⁶³ See, Aldy, supra note, 136, at 70.

¹⁶⁴ See Craig, Arnold, supra note 108 at 245, 252.

that could include overlap in their authority to respond (referred to as redundancy) or the lower levels of government have representation at the higher levels (referred to as complementarity) ¹⁶⁵ or the authority for decision-making is kept closest possible to the scale of impact (e.g. local, community) (referred to as subsidiarity). ¹⁶⁶

Polycentric structures could be at the federal, state, or local government level and could include various types of public-private partnerships, industry groups, think-tanks, non-governmental organizations, etc. A decentralized and polycentric approach facilitates adaptive approaches and allow for risk diversification, policy experimentation, and innovation across jurisdictions.¹⁶⁷ Decentralizing decision-making to the lowest and the most effective jurisdictional level enables adaptive policies to be successful.¹⁶⁸

A related attribute is 'coordination' among these structures. Adaptive structures do not work in siloes or in fragmented ways but are coordinated, integrated, and strengthened by robust communication channels. These are intricately connected with vertical and horizontal decision-making processes, both within and between agencies.¹⁶⁹

Evidently, the scope of the above six features is quite comprehensive with multiple dimensions. Therefore, for this study purpose, the six features are considered from a limited perspective of policy/regulatory cycle. In the following section, meanings are attributed to each of the six features for clarity. Based on the six features, an adaptive regulatory cycle is developed which forms the basis of documentary and interview analysis of the entire dissertation study.

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¹⁶⁵ See Cosens et al., supra note 160, at 4. Also see Ruhl, supra note 141, at 1373, 1398, (The author supports dynamic federalism and the call for "overlapping federal and state (and, through states, local) jurisdictions"). ¹⁶⁶ See Cosens et al., supra note 160. Also see Verschuuren, J.M, and McDonald, J. (2012). Towards a Legal Framework for Coastal Adaptation: Assessing the First Steps in Europe and Australia. Transnational Environmental Law, 1 (2), 355, 377, 379. (The authors advocate allocating "regulatory responsibility in a way that promotes subsidiarity and consistency." They mention that there are advantages of having a central institution or process that sets overarching standards and coordinates efforts requiring multi-level or multi-sectoral engagement).

¹⁶⁷ See Adler, supra note 86, at 77. Also see Flynn, supra note 134, at 40, 41 (The author proposes a framework where "cooperative federalism" is an important component. He advocates creation of a "dedicated federal mitigation and adaptation agency" that would "oversee and coordinate the research of policies, laws, and measures," impacting climate change mitigation and adaptation.)

¹⁶⁸ See Swanson et al., supra note 124.

¹⁶⁹ See Huang et al., supra note 114. Also see Schramm & Fishman, supra note 90, at 500, 503, 504 (The authors advocate for, 'Interagency and inter-jurisdictional cooperation and coordination').

VIII. Adaptive Regulatory Cycle

Typically, a policy or regulatory cycle has three basic stages i.e. pre-implementation, implementation, and post-implementation though there could be several steps in these broad stages. For example, the Government of United Kingdom's regulatory policy methodology framework has seven steps of regulatory policymaking: (1) identify the issue; (2) research and analysis; (3) develop policy options; (4) consultation (formal and informal); (5) recommendation and decision; (6) implementation; and (7) evaluation. Whereas, the European Union's policy cycle has four steps: (1) policy development; (2) policy setting; (3) implementation and monitoring; (4) evaluation.

The Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM) recommended a framework for environmental health risk management. It is a six-phase process for making risk management decisions and include the following steps: (1) define the problem; (2) analyze the associated risks; (3) examine options for addressing the risks; (4) decide the options to be implemented; (5) take action to implement the decision; and (6) evaluate the actions. All six steps require active collaboration with the stakeholders. Another example is of the US Centers for Disease Control and Prevention's policy process which has five domains: (1) problem identification, (2) policy analysis, (3) strategy and policy development, (4) policy enactment, (5) policy implementation. Additionally, it has two overarching domains - stakeholder engagement and evaluation, which are to be considered throughout the policy cycle. 173

On similar lines, a three-stage 'Adaptive Regulatory Cycle' is developed based on the six broad features of adaptive regulation. Each stage of this regulatory cycle has adaptive features that enable regulatory learning and improvement over the lifecycle of a policy or regulation. The adaptive features are shown in different stages of the regulatory cycle. (Fig.1)

¹⁷⁰ Information Commissioner's Office. (2021). Government of United Kingdom, 'Regulatory Policy Methodology Framework.' Available at https://ico.org.uk/media/about-the-ico/policies-and-procedures/2619767/regulatory-policy-methodology-framework-version-1-20210505.pdf

¹⁷¹ Council of European Union. (2018). "The EU Policy Cycle to Tackle Organised and Serious International Crime."

¹⁷² Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM).
(1997). Framework for environmental health risk management. Vol. I and II. Washington, DC: National Academy Press.

¹⁷³ Centers for Disease Control and Prevention, Office of the Associate Director for Policy and Strategy, CDC Policy Process. Available at https://www.cdc.gov/policy/analysis/process/index.html.

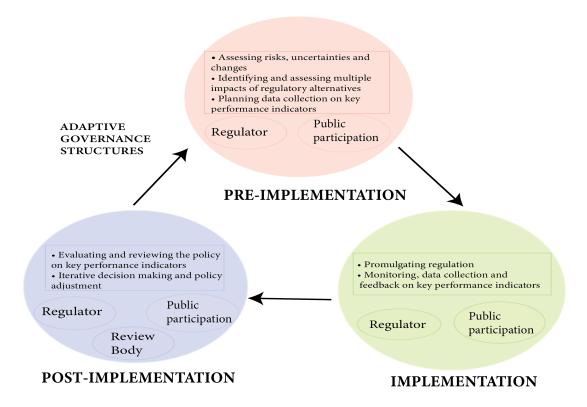


Figure. 1 Adaptive Regulatory Cycle

1. Pre-Implementation

Adaptive regulations acknowledge the importance of assessing the risks and uncertainties and responding to them directly. In adaptive regulatory cycle, this implies that while formulating the regulations/policies, the agencies undertake risk assessment. Another feature is the fuller impact assessment of the policy/ regulatory alternatives. The objective is to avoid the perils of narrow decision-making. This implies that the decision-makers assess the full portfolio of impacts such as the costs, benefits, and distributional effects, including co-benefits and the countervailing risks. Lastly, adaptive regulations acknowledge the importance of planning relevant data collection. This implies there is adequate planning to identify the relevant information to be collected so that it could result in meaningful monitoring and reviews.

2. Implementation

In this stage, the regulation/ policy is implemented. Adaptive regulations have built-in mechanisms of monitoring and feedback that enable policy adjustments. This implies relevant data collection and analysis take place; policy outcomes and key performance

indicators are monitored, and the outcomes of monitoring and feedback are fed back into the regulatory process i.e. inform future policies and regulations.

3. Post-Implementation

In adaptive regulations, the decision-making is not a one-time binary yes/no but a continuous process where new information and post-implementation experience inform the future decisions. This implies there are built-in provisions of policy learning and iterative decision-making, such as periodic review, retrospective review, and sunset clause. In this stage, the regulations are evaluated such as by comparing the ex-post assessments with the ex-ante assessments. This implies policy changes or improvements are based on evaluation of policies.

4. Overarching features

Public participation and adaptive governance structures are the overarching features which play an important role in all stages of the regulatory cycle.

Public Participation- Public participation has a very broad meaning. Often the terms community participation, public participation, community involvement, community engagement, stakeholder engagement, stakeholder involvement, citizen participation, etc., are used interchangeably.¹⁷⁴ In adaptive regulatory cycle, the term public participation implies the right of the affected public to participate in the decision-making processes (regulatory/ policy-making).¹⁷⁵ The word public includes both general public and the stakeholders/ right holders.

Adaptive Governance Structures- Adaptive governance structures represent the larger ecosystem that enables the implementation of adaptive regulations. A decentralized and polycentric approach facilitates adaptive approaches and allows for risk diversification, policy experimentation, and innovation across jurisdictions. In the adaptive regulatory cycle, these include the presence of polycentric structures and the inter-agency coordination both vertical (across different levels of government) and horizontal (at the same level of government).

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¹⁷⁴ See, NEJAC, supra note 158.

¹⁷⁵ *Id.* ("any and all persons and groups who are potentially interested, concerned, or affected by an action should be included (or given equal opportunity to participate) in the decision-making process").

IX. Research Questions

The dissertation attempts to answer two research questions: (1) How adaptive <u>are</u> India's regulations on Electric Vehicles, Groundwater, and Health Data? And (2) How adaptive <u>should</u> India's regulations be on Electric Vehicles, Groundwater, and Health Data?

To investigate and find answers to these research questions, area specific law/policy documents of the federal government of India (and two state governments in groundwater sector) are analyzed and 32 key stakeholders interviewed.

Additionally, the law/policy documents of the federal government of the US (and two state governments in groundwater sector) are analyzed along with secondary literature review. Considering the concept of adaptive regulation is more applied and studied in the US than India, analyzing the US regulations helped in drawing a comparative analysis of the regulatory processes with potential lessons for both countries.

The next chapter describes the rationale of selecting India and the US and the three areas of study, and details the methodological approaches adopted in the research study.

Chapter-2

Introducing the Topic and Methodology

Summary: This chapter introduces the dissertation topic, 'Adaptive Regulation in India: Electric Vehicles, Groundwater, and Health data' and describes why India and the three case study sectors are the focus of research. Similarly, it describes why regulations in these three sectors are studied summarily in the US context. Then, it delves into the methodology and describes the process of systematic literature review which informed the six broad features of adaptive regulation. Further, it describes the two qualitative research methods used in the study i.e. document analysis and semistructured interviews. It notes that for India, both methods are used while for the US only document analysis is used. All the analyzed documents are the law/policy documents which are available in public domain. And for the interviews, it describes the sampling strategies used for selecting the participants and other details, such as developing the semi-structured interview guide and the approval of the Institutional Review Board (IRB). It further explains the directed content analysis approach used for analyzing the documents and the interview transcripts. It elaborates on the process of coding i.e. creating labels under broad categories and placing the information under the relevant label and category while analyzing the documents/transcripts. This study used NVivo software for the coding process. The methodology described in this chapter is applied in analyzing the data in each of the following three chapters.

I. Adaptive Regulation in India: Groundwater, Electric Vehicles, and Health data

Many regulatory policies around the world are typically developed using one-time decision-making processes, largely built on ex-ante assessments with limited, and often ad-hoc expost reviews or revisions. However, the world is continuously changing across domains - social, economic, technological, political, and cultural. Therefore, to be meaningful and effective, the regulations need to keep pace with the changing realities. Adaptive regulations offer an array of mechanisms where the regulations could be designed to learn. In such regulations, the decision-making is not a one-time process, instead planned iterative decision-making informs policy updates based on new information and changing circumstances.²

A. Why India?

Adaptive regulation as a concept has developed and debated more in the United States and Europe, with limited research in other parts of the world including India. There is limited literature on the prevalence and practice of adaptive regulation in India. Most of the existing literature relates to climate adaptation and adaptive governance. This dissertation fills this gap by exploring the adaptiveness of laws/policies in three case study sectors in India.

India has a federal structure with clear division of powers between the centre and the states.³ Therefore, regulatory learnings from India could resonate with other countries having similar governance structures. Further, India's Constitution is the lengthiest written constitution in the world, with features informed by the constitutions of more than 60 countries, including the UK and the US.⁴ In particular, the concepts of fundamental rights and judicial review are adopted from the American Constitution.⁵ Thus, understanding

¹ Bennear, Lori S. and Wiener, Jonathan B. (2019) Adaptive Regulation: Instrument Choice for Policy Learning over Time, Draft working paper. Also, *see* Wagner, Wendy E. et al., (2017). Dynamic Rulemaking 92 New York University Law Review 183.

² See, Bennear and Wiener, supra note 1.

³ Batra, Suman. (undated) Constitution of India- Of the people, for the people and by the people. Ministry of External Affairs, Govt. of India, available at

https://mea.gov.in/Images/attach/Article_on_Constitution_of_India.pdf

⁴ Indian Constitution- A Bag of Borrowings (2021). International Journal of Advanced Legal Research. Blog post. Jan 10, 2021.

⁵ *Id*.

adaptive regulation in India could be significant and could offer interesting insights regarding regulatory learning practices from which scholars and other countries may learn.

Further, India is a fast-growing economy⁶ with the second largest population in the world.⁷ In a globalized world, regulatory choices of major economies like India could have implications, not only for its people and resources nationally but also globally. Thus, this dissertation attempts to examine whether adaptive regulation is prevalent or not in India's regulatory settings (perhaps with different terminology) and to explore this, three sectors are analyzed — Groundwater, Electric Vehicles, and Health Data. The analysis is based on the review of law/policy documents (document analysis) and semi-structured interviews of key stakeholders (interview analysis).

B. Why the three sectors: Groundwater, Electric Vehicles, and Health data?

The three selected sectors are salient and offer an opportunity to study laws of different jurisdictions in India. These are salient from India's perspective and also globally. For instance, India extracts the maximum percentage of groundwater annually (28.9 %) in the world, followed by the US and China (whose combined groundwater extraction is less than India's). Groundwater is considered the backbone of India's water and food security as it fulfils 85 % of drinking water needs and more than 60% of irrigation needs of the country. However, this resource is fast depleting in India. Similarly, ambient air pollution causes a staggering 670,000 deaths in India each year and transportation sources account for one-third of Particulate Matter (PM) pollution and a higher percentage of nitrogen oxides (NOX). Further, India is the fourth largest automobile market in the world adding more than 21 million vehicles on Indian roads per year. To address the ambient air pollution,

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⁶ Banga, Rashmi. (2021). Building a resilient Economy. UNCTAD. "UNCTAD in its Trade and Development Report 2021 has estimated that in 2021, the global growth will hit 5.3% and India to hit 7.2%." For details, *see*, https://unctad.org/news/building-resilient-economy.

⁷ US Census Bureau. (July 1, 2021). World Population. Top 10 most populous countries. For details, *see* https://www.census.gov/popclock/print.php?component=counter.

⁸ Giordano, Mark. (2009). Global Groundwater? Issues and Solutions. 34 Annual Review of Environment and Resources, 34:153, 158.

⁹ The World Bank. (2012). India Groundwater: a Valuable but Diminishing Resource. Retrieved from https://www.worldbank.org/en/news/feature/2012/03/06/india-groundwater-critical-diminishing

¹⁰ Balakrishnan, K. et al., (2018). The impact of air pollution on deaths, disease burden, and life expectancy across the states of India: The Global Burden of Disease Study 2017. The Lancet Planetary Health.

¹¹ International Council on Clean Transportation. (2011). India Air Pollution & Health. Publications on India, available at https://theicct.org/india#publications

¹² India Brand Equity Foundation. (November 2020). Indian Automobile Industry Report. Ministry of Commerce & Industry, Government of India.

the Indian government aims to reach 30 % electric vehicle (EV) penetration by 2030.¹³ And lastly, India is committed to achieving universal health care for all by 2030.¹⁴ To achieve this goal, the country's National Digital Health Mission aims to build a digital ecosystem for providing digital healthcare services across the country.¹⁵

The three sectors also offer an opportunity to study laws of different jurisdictions in India. According to India's Constitution, law-making can happen in three ways- at the federal level, at the state level, and both at the federal and the state level. The 7th schedule of the Indian Constitution distributes the legislative subjects into three lists- the Union list has subjects of national importance on which the Parliament can legislate, the State list has subjects of local importance on which the state legislatures can legislate, and the Concurrent list has subjects on which both the federal and the state governments can legislate.¹⁶

1. Groundwater

Water is listed in List II (State list). Therefore, the state legislatures can legislate on matters related to water including groundwater. Among the states in India, two states: Punjab and Rajasthan are chosen for this research study. In terms of groundwater depletion, these states are amongst the worst affected states in the country and offer an opportunity to study regulations of two different jurisdictions. Punjab is a hotspot sector with the highest non-renewable groundwater extraction of 34.66 km³ in the country, whereas its renewable groundwater volume is only 20.35 km.³ Of the non-renewable groundwater extraction (34.66 km³), a staggering 92 % (33.97 km³) is used for irrigation only, which is twice that of the High Plain aquifer of the U.S.¹¹ Out of 138 assessment units in Punjab, only 22 units (16 per cent) are safe and five units (four per cent) are semi-critical. The remaining 111

¹³ Sahay, Richa. (2019). How can India transition to electric vehicles? Here's a roadmap. World Economic Forum. (Oct. 3, 2019).

¹⁴ Sarwal and Kumar, NITI Aayog, Government of India, 'The long road to Universal Health Coverage.' Available at https://www.niti.gov.in/long-road-universal-health-coverage.

Also see, World Health Organization (WHO) Sustainable Development Goals, SDG 3 Targets. Available at https://www.who.int/health-topics/sustainable-development-goals#tab=tab-2

¹⁵ National Health Authority. (July 2020). National Digital Health Mission-Strategy Overview.

¹⁶ Schedule VII, Constitution of India

¹⁷ For details *see*, Dangar, Swarup, et al., (2021). Causes and implications of groundwater depletion in India: A review, Journal of Hydrology, 596. Also *see*, Panda, D.K and Wahr, J. (2016). Spatiotemporal evolution of water storage changes in India from the updated GRACE-derived gravity records. Water Resource. Research, 52, 135-149, *and* Central Ground Water Board (CGWB). (2014). Ministry of Water Resources Govt. of India. Faridabad Groundwater Year Book- India 2013-14.

units (80 per cent) are critical and over-exploited.¹⁸ The scenario has worsened since 2011 with more than 40 units exceeding groundwater development greater than 200 % and a few exceeding 400 %.¹⁹ Till recently, groundwater was largely unregulated in Punjab as the state legislature passed a statute on water resources (including groundwater) in 2020. Thus, there is an opportunity to analyze a recent legislation of a state which is considered a national outlier in groundwater depletion.

Similarly, Rajasthan has the second highest percentage of the stage of groundwater development²⁰ of 140 % (after Punjab's 166 %), whereas the national average is 63%.²¹ Out of 292 assessment units in Rajasthan, only 45 units (15 percent) are safe, 29 are semicritical (10 percent), and 218 are critical and over-exploited (75 percent).²² Rajasthan is located in semi-arid western part of India and geographically is the largest state of the country. Despite an alarming situation, it does not have a state groundwater legislation. The state is relying on the federal government's groundwater regulations published from time to time. Therefore, analyzing groundwater regulations of Rajasthan enables analysis of the regulations of federal government of India. The federal regulations are applicable to all those states who have not legislated on groundwater till date.²³

¹⁸ Report of the Comptroller and Auditor General (CAG) of India on Groundwater Management and Regulation. (2021). Union Government. Ministry of Jal Shakti. Department of Water Resources, River Development, and Ganga Rejuvenation. Report no. 9 (Performance Audit). Available at, https://cag.gov.in/webroot/uploads/download_audit_report/2021/Report%20No.%209%20of%202021_GWMR_English-061c19df1d9dff7.23091105.pdf.

¹⁹ Government of Punjab (India), Department of Water Resources (2017). Categorization of Blocks. Available at

http://irrigation.punjab.gov.in/PDF/WaterResources/10072015/CATEGARISATION OF BLOCK 3 00715.pdf

The stage of groundwater development is a ratio of Annual Groundwater Draft and Net Annual Groundwater Availability in percentage. For details, *see*, Central Ground Water Board's FAQs, available at http://cgwb.gov.in/faq.html

²¹ Central Ground Water Board (CGWB) (2020). Ministry of Jal Shakti, Department of Water Resources, River Development and Ganga Rejuvenation, Govt. of India. Faridabad. Groundwater Year Book- India 2019-20.

²² See, CAG Report, supra note, 18, at 12.

²³ India witnessed an increasing use of groundwater to an extent that many parts of the country were recling under groundwater stress due to excessive abstraction. Amidst this scenario and in the absence of any state legislation, a public interest litigation (PIL) was filed in the Supreme Court of India. The apex court mandated the federal government to regulate groundwater (despite it falling in the jurisdiction of the state legislatures). The government of India used the provisions of the Environmental Protection Act, 1985 (which is a federal statute), and established a groundwater regulatory authority called the Central Ground Water Authority (CGWA). Additionally, the federal government drafted model bills on groundwater regulation and circulated to the states for legislation. There are still many states which have not legislated on groundwater and for such states, the regulations notified by the CGWA are applicable. For details, *see*, Notification S.O. 3289 (E). (Sept, 2020). Ministry of Jal Shakti, Department of Water Resources, River Development and Ganga Rejuvenation, Central Ground Water Authority at 32.

2. Electric Vehicles

Transport is listed in List-III (Concurrent list). Therefore, both the Parliament and the state legislatures can legislate on transport matters including EVs, though the term 'electric vehicles' is not mentioned in the Concurrent list. This dissertation focuses on the federal regulations on EVs because the federal government of India and the federal agencies are driving most of the regulations in this evolving sector.

3. Health data

In India, health data presents a peculiar situation in law-making. Health is a State list subject and data per se is not mentioned in any of the three lists of the India's Constitution. Information technology (IT), the subject that could be considered closest to data, also finds no mention in the three lists of the Constitution. However, the Parliament of India has been legislating on IT related issues including the National Data Protection bill 2019. This could be attributed to the Parliament's residuary powers vested by the Union list subject at serial number 97 (List I), 'Any other matter not enumerated in List II or List III including any tax not mentioned in either of those Lists,' could be legislated by the Parliament of India.²⁴ This dissertation focuses on the federal regulations on health data because the federal government of India through its agencies is driving most of the regulations in this nascent sector.

The idea of analyzing the laws and policies in such differently placed sectors is to understand the extent of application of adaptive regulation and/or its need altogether. In addition, this could help in understanding if the decision-makers in three sectors are considering different ways to update their regulatory processes, or adopting new tools to deal with such salient issues, and/ or designing their laws and policies in adaptive ways.

The law and policy documents analyzed in this study are public documents and are available in public domain. The sector-wise list is collated. (See Table 2)

Table 2. India's Law and Policy documents

 Sector
 Law and Policy documents

 GROUNDWATER
 1)
 Guidelines to regulate and control ground water extraction in India (September 2020)

 2)
 National Groundwater Management Improvement Scheme (Atal Bhujal Yojana) (2020)

²⁴ Ministry of External Affairs, Govt. of India (undated). Seventh Schedule (Article 246). Available at https://www.mea.gov.in/Images/pdf1/S7.pdf

| | Model Bill for the Conservation, Protection, Regulation and Management of Groundwater, (2016) |
|-------------|---|
| | 4) Provisions pertaining to Groundwater in the following documents: |
| | a) Draft National Water Framework Bill, (2016) |
| | b) National Water Policy (2012) |
| | 5) Punjab Water Resources (Management and Regulation) Act, (2020) |
| | 6) Punjab Guidelines for Groundwater Extraction and Conservation (Draft), (2020) |
| | 7) Punjab Preservation of Subsoil Water Act (2009) |
| | 7) I unjab i reservation of Subson water Act (2009) |
| ELECTRIC | 1) Production Linked Incentive (PLI) Scheme for Automobile and Auto |
| VEHICLES | Components Industry in India (September 2021) |
| | 2) Production Linked Incentive scheme, 'National Programme on Advanced |
| | Chemistry Cell (ACC) Battery Storage' (June 2021) |
| | 3) Guidelines and Standards-Charging Infrastructure for Electric Vehicles (June |
| | 2020, October 2019, and December 2018) |
| | 4) Measures relating to the Safety and Electric Supply Regulations- Safety Provisions |
| | for EV Charging Stations (June 2019) |
| | 5) Amendments in Model Building Bye-Laws (2016) for Electric Vehicle Charging |
| | Infrastructure (2019) |
| | 6) Scheme for Faster Adoption and Manufacturing of (Hybrid &) Electric Vehicles |
| | in India, (FAME India) Phase II (2019) and operational guidelines |
| | 7) Scheme for Faster Adoption and Manufacturing of (Hybrid &) Electric Vehicles |
| | in India, (FAME India) Phase I (2015) |
| | 8) National Electric Mobility Mission Plan (2012) |
| | 9) Gazette notifications on e- vehicles: e-rickshaws, 2-wheelers, 3- wheelers, and e- |
| | buses, Ministry of Road Transport and Highways (issued from time to time- 2014 |
| | to 2021) |
| НЕАІТН ДАТА | 1) The Personal Data Protection Bill (2019) |
| | 2) Ayushman Bharat Digital Mission (Guidelines) (Aug 2020) |
| | 3) Ayushman Bharat Digital Mission - Data Privacy Policy (2020) |
| | 4) Ayushman Bharat Digital Mission - Health Data Management Policy (2020) |
| | |

II. Adaptive Regulation in the US: Groundwater, Electric Vehicles, and Health data

Ayushman Bharat Digital Mission - Strategy Overview (2020)

Provisions pertaining to health data in the National Health Policy (2017)

A. Why US?

The concept of adaptive regulation is developed and practiced in the US and other western countries such the UK and EU. Therefore, there is plenty of literature on adaptive regulation in US, UK, and many European countries. However, studying law at the US law school and getting exposure to a variety of US federal and state laws as a part of legal research projects, increased familiarity with the US laws and their regulatory landscape. This made US a preferred option over other western countries and I believe this factor facilitated better understanding and analysis of the US regulations. However, the relevant

literature of EU is also reviewed while developing the normative framework in the last chapter of the dissertation.²⁵

Further, adaptive regulation is applied in many US settings with ample examples of regulatory experimentation and learning.²⁶ Thus, reviewing the literature and analysing the US regulations in three sectors offered interesting lessons in adaptive regulation in general and for India in particular. In addition to answering the research questions on the adaptability of India's regulations, this dissertation did a comparative analysis of the US and India's regulations informed by the six-features, and identified few lessons where both countries could learn from each other.

B. Why the three sectors: Groundwater, Electric Vehicles, and Health data?

1. Groundwater

While doing the comparative analysis of the law/ policies of the two countries, it is helpful to keep the level of law-making jurisdictions similar. In India's context, the law-making on groundwater is the prerogative of the states, hence two of the most impacted states vis-à-vis groundwater depletion, are the focus of study. Similarly, in the US context, groundwater regulation is mostly in the purview of the state governments. Thus, the groundwater laws of two states- California and Texas, are analyzed.

These states are among the largest users of groundwater in the US. As a percentage of all groundwater withdrawals, California with 16% is the largest user of groundwater, followed by Texas at 10 %.²⁷ Also, two of three most impacted aquifer systems of the US fall in these states- the High Plains (Texas) and the Central Valley of California (California). ²⁸ Further, the groundwater laws of the two states offer an opportunity to study different groundwater regimes: Texas, where the common law doctrine of 'absolute ownership,' is

Administrative Conference of The United States (ACUS) (2017) Adoption of Recommendations.
 Learning From Regulatory Experience. Federal Register / Vol. 82, No. 249 / Friday, December 29, 2017 / Notices (61738-42). Also, see, Gubler, Zachary J. (2017). Regulatory Experimentation. Final Report (ACUS), and Gubler, Zachary J. (2014) Experimental Rules, 55 Boston College Law Review 129.
 American Geosciences Institute (AGI) (2017). Groundwater use in the United States. Factsheet 2017-

²⁷ American Geosciences Institute (AGI) (2017). Groundwater use in the United States. Factsheet 2017-002. Available at

https://www.americangeosciences.org/sites/default/files/CI Factsheet 2017 2 groundwater 170309.pd f. Also, see, Water Science School. (2018). Groundwater Use in the US. United States Geological Survey, Available at https://www.usgs.gov/special-topic/water-science-school/science/groundwater-use-united-states?qt-science_center_objects=0#qt-science_center_objects.

²⁵ For details, see, Chapter 6 titled 'Descriptive and Normative Analysis.'

²⁸ For details *see*, Konikow, Leonard F. (2015). Long-term Groundwater Depletion in the United States. Vol. 53, No.1-Groundwater (pg 2 -9). National Center, U.S. Geological Survey.

largely driving the groundwater extraction in the form of the 'rule of capture,' and California, which moved away from the 'absolute ownership' of groundwater a century ago. In California, a variety of common law principles are in action including its recently developed state-wide statutory framework on groundwater management.²⁹

2. Electric Vehicles

The U.S. has many federal laws and incentives that are designed to encourage EV adoption. For example, tax incentives to encourage the purchase of EVs and to encourage construction of EV infrastructure, like charging stations. Similarly, the federal government makes investment in the research and development of batteries to reduce the production costs, increase the range of EVs, and reduce the charging times.³⁰ Beyond these federal laws and incentives, there are many incentives and programs initiated by the states and electric utilities to promote vehicle electrification. In India's context, the federal laws/policies on EVs are the focus of study and the state EV policies are analysed summarily. Therefore, for comparative analysis, in the US context, the federal regulations on EVs are the main focus of study.

3. Health data

US Federal laws have played a significant role in shaping the use of health IT at various levels of governance including the state, tribal, and local. There are many federal laws that could be interpreted to regulate individually identifiable health information in certain circumstances, for example, the Gramm-Leach-Bliley Financial Services Modernization Act, Family Educational Rights and Privacy Act, the Children's Online Privacy Protection Act, or the Privacy Act. ³¹ However, four major federal laws with most elaborate provisions

²⁹ Perrone, Debra et al., Water in the West, Stanford University. Available at http://groundwater.stanford.edu/dashboard/index.html.

³⁰ Graham, John D. (2021). The Global Rise of the Modern Plug-in Electric Vehicle-Public Policy, Innovation and Strategy. Also *see*, Cattaneo, Lia. (2018). Plug-in Electric Vehicle Policy- Evaluating the Effectiveness of State Policies for Increasing Deployment. Energy and Environment. Center for American Progress. Also *see* Congressional Research Service (CRS). (2019). Vehicle Electrification: Federal and State Issues Affecting Deployment. 3.

^{31 &}quot;GLBA, Title V of the Financial Services Modernization Act of 1999, Pub. L. No. 106-102, 113 Stat. 1338 (Nov. 12, 1999) (codified at 15 U.S.C. §§ 6801, 6809, 6821, and 6827); 16 C.F.R. Part 313 (implementing privacy rules pursuant to GLBA and regulates information about individuals that may derive from financial transactions related to health, such as a health savings account); Family Educational Rights and Privacy Act (FERPA), 20 U.S.C. § 1232g, 34 C.F.R. Part 99 (may apply to student health centers); The Children's Online Privacy Protection Act of 1998 ("COPPA"), 515 U.S.C. §§ 6501 -6506 and 16 C.F.R. Part 312, (COPPA Rule); The Privacy Act, 5 U.S.C. § 552a (applies to data held by the United States)." For details, see U.S. Department of Health and Human Services (HHS) (2016). Examining Oversight of the Privacy & Security of Health Data Collected by Entities Not Regulated by HIPAA, footnote 50 at 11.

on health data and health IT are the focus of this study. In India's context also, the federal laws/policies on health data are analyzed.

Table 3. US Law and Policy documents

| Sector | Law and Po | olicy documents |
|-------------|-----------------|---|
| Groundwater | i. Su | stainable Groundwater Management Act (2014), California and |
| | | oundwater related chapters in Texas Water Code and Texas Water |
| | | evelopment Board Rules as identified on the official website of the Texas |
| | | ater Development Board. |
| Electric | i. | Congestion Mitigation and Air Quality (CMAQ) Improvement Program |
| VEHICLES | ii. | Clean Cities Coalition Network |
| , milene | iii. | State Energy Program (SEP) Funding |
| | iv. | Clean Construction and Agriculture |
| | | Ports Initiative |
| | v. vi. | Vehicle Incremental Cost Allocation |
| | | |
| | V11. | Vehicle Acquisition and Fuel Use Requirements for State and Alternative |
| | | Fuel Provider Fleets |
| | viii. | Vehicle Acquisition and Fuel Use Requirements for Federal Fleets |
| | 1X. | Vehicle Acquisition and Fuel Use Requirements for Private and Local |
| | | Government Fleets |
| | х. | Voluntary Airport Low Emission (VALE) Program |
| | xi. | High Occupancy Vehicle (HOV) Lane Exemption |
| | xii. | Aftermarket Alternative Fuel Vehicle (AFV) Conversions |
| | xiii. | Improved Energy Technology Loans |
| | xiv. | Qualified Plug-In Electric Vehicle (PEV) Tax Credit |
| | XV. | Advanced Technology Vehicle (ATV) and Alternative Fuel Infrastructure |
| | | Manufacturing Incentives |
| | xvi. | Procurement Preference for Electric and Hybrid Electric Vehicles |
| | XV11. | Alternative Fuel Labeling Requirements |
| | xviii. | Advanced Energy Research Project Grants |
| | xix. | Airport Zero Emission Vehicle (ZEV) and Infrastructure Incentives |
| | XX. | Alternative Fuel Infrastructure Tax Credit |
| | xxi. | Alternative Fuel and Advanced Vehicle Technology Research and |
| | 7.71. | Demonstration Bonds |
| | XX11. | Qualified Two-Wheeled Plug-In Electric Drive Motor Vehicle Tax Credit |
| | XXII. XXIII. | Low and Zero Emission Public Transportation Research, Demonstration |
| | XXIII. | <u> •</u> |
| | | and Deployment Funding |
| | XXIV. | Electric Vehicle Charging on Federal Property |
| | XXV. | National Alternative Fuels Corridors |
| | XXV1. | Natural Gas Vehicle (NGV) and Plug-In Electric Vehicle (PEV) Weight |
| | | Exemption |
| НЕАІТН ДАТА | i. | Health Insurance Portability & Accountability Act (HIPAA), 1996 |
| | (a) | Title-II, Subtitle F- Administrative Simplification- established national |
| | | standards for the electronic transmission of certain health information. |
| | (b) | 45 CFR Sub Chapter C- Administrative Data standards and related |
| | | requirements |
| | (c) | The HIPAA Privacy Rule, 45 CFR Part 160 and Subparts A and E of Part |
| | | 164 |
| | (d) | HIPAA Security Rule, 45 CFR Part 160 and Subparts A and C of Part 164 |
| | (e) | Health Insurance Portability and Accountability Act of 1996 (HIPAA) |
| | (-) | (Pub. L. 104–191), added a new part C to title XI of the Social Security |

- Act (sections 1171–1179 of the Social Security Act, 42 U.S.C. 1320d–1320d–8).
- ii. The Health Information Technology for Economic and Clinical Health (HITECH) Act, 2009-All provisions
- iii. The Cures Act, 2016
 - (a) Title IV—Delivery (amended portions of the HITECH Act)
- iv. Section-5 of the Federal Trade Commission (FTC) Act

III. Methodology

A. Systematic review of literature

The frameworks are considered useful tools to understand the basic components of a concept. This study began with a systematic review of literature to identify the frameworks related to adaptive regulation. The literature review of frameworks helped in identifying several features of adaptive regulation propounded by different scholars. The search strategy used the terms that are closely related to adaptive regulation such as adaptive policy, adaptive management, adaptive law, adaptive governance, and dynamic law, to name a few. Though the scholars have defined these terms differently, there are many similarities and overlap. The objective of this review is to understand adaptive regulation in a holistic manner and gain from the literature of closely related concepts.³²

1. Process

The following process is adopted for systematic literature review:

- (a) Research question- The research question for the systematic review was- What are the different frameworks on adaptive regulations published between 2010 and 2020? 33
- (b) Broad search strategy- Key words and Boolean operators³⁴ were used in the broad search strategy:

³² There are a few limitations in the process adopted for systematic literature review (e.g. choosing a ten-year period in the research question and concomitantly in the search process, applying filters in the search process, choosing two databases and not more, etc). However, an effort is made to conduct the literature review in a structured and transparent manner, describing all the steps undertaken, and providing rationale for the choices made, including details of various filters.

³³ The time period of a decade was chosen to represent a reasonable time frame that could fetch adequate number of articles for review with a focus on finding the latest literature on the research topic. However, acknowledging that a lot of literature on the topic is published before 2010, the SJD reading list (that also includes articles published before 2010) have additionally been analysed.

³⁴ Boolean search enables faster and more precise results. Boolean search uses operators, such as AND, OR, and NOT. These operators enable the search engines in narrowing down or broadening the search results.

("Adaptive regulation" OR "adaptive law" OR "adaptive governance" OR "adaptive policy" OR "adaptive rulemaking" OR "adaptive management" OR "planned adaptive regulation" OR "adaptive policy-making" OR "dynamic rulemaking" OR "dynamic adaptive policies" OR "adaptive decision-making" OR "dynamic law") AND ("Framework")

(c) Legal databases- In this study, two legal databases with an extensive array of law review or journal articles, were searched.

Heinonline- Based on the key words search, 1203 results were generated for the publications between 2010-2020. To narrow down the scope of research, following filters were applied in the given sequence: (1) Articles published by the United States, United Kingdom, and England,³⁵ (2) Articles with full-text availability,³⁶ (3) Articles related to subject sectors that are broadly relevant to the dissertation.³⁷

LexisNexis- Based on the key words search on LexisNexis, 1898 results were generated. To narrow down the scope of research, following filters were applied in the given sequence: (1) Law review and Journals,³⁸ (2) Jurisdiction-United States, states of the United States, and Europe,³⁹ (3) Timeline- 2010 to 2020, ⁴⁰ and (4) Key word- Adapt.⁴¹

- (d) In social sciences, while doing the systematic literature review, multiple databases are referred. This ensures that the literature on the research topic is adequately identified. Due to time constraint, 2 legal databases were searched in this literature review. However, to strengthen the base of identified literature, articles recommended in the SJD reading list are also analyzed.⁴²
- (e) Title and abstract review- The title and abstract review of 618 articles of Heinonline and 176 of LexisNexis, was done to find frameworks related to adaptive regulation. The title and abstract review looked for the terms "adaptive/ adapt/ adaptation" and "framework" in the title and/or abstract of

³⁵ This filter reduced the number of results to 951.

³⁶ This filter reduced the number of results to 875.

³⁷ This filter reduced the number of results to 618. The subject sectors are: environmental law, environmental policy, climate change, water law, natural resources law, regulation, science and technology, technology, and groundwater.

³⁸ This filter reduced the number of results to 1720.

³⁹ This filter reduced the number of results to 1587.

⁴⁰ This filter reduced the number of results to 962.

⁴¹ This filter reduced the number of results to 176.

⁴² The SJD reading list is prepared under the guidance of eminent domain experts.

the identified articles. Accordingly, total 66 articles were identified from both databases, out of which 7 articles were found to be duplicate.

2. Six-features of adaptive regulation

Based on the review of literature and the SJD reading list, six broad features that have been repeatedly propounded by the scholars are identified.⁴³ These six features are not claimed to be the sine qua non of adaptive regulation, nevertheless, their presence is likely to reflect the adaptability of regulations. These are: (a) Assessing risk and uncertainty, (b) Broader and fuller impact assessment, (c) Monitoring, evaluation, and feedback, (d) Iterative decision- making and policy adjustment, (e) Public participation, and (f) Adaptive governance structures. These features form the basis of both document and interview analysis. Further, an attempt is made to capture additional feature(s) during these analyses.

B. Qualitative Research

Qualitative research methods capture expressive information such as beliefs, perspectives, values, which are not elicited using the quantitative methods. In qualitative inquiry, context is important and the information is gathered directly from the people.⁴⁴ In this dissertation, the focus is to understand if the laws and policies in India are adaptive i.e. keeping pace with changing circumstances and adapting to new requirements. To study such a dynamic and evolving topic, both context and people are important. Further, qualitative research is considered appropriate when there is a need to explore a problem or an issue in depth such as identifying factors that cannot be easily measured, listening to peoples' perspectives and experiences that are unimpeded by what the literature says or what a researcher expects.⁴⁵

Considering there is limited literature on 'adaptive regulation in India' and to understand the adaptability of laws on the books, there is a need to analyze the law and policy documents. However, analyzing the documents alone would not give a complete

⁴³ Detailed description of the six-features may be seen in Chapter 1 under the section, 'Broad features of Adaptive Regulation.'

⁴⁴ Berkwits M, and Thomas, Inui S. (1998). Making use of qualitative research techniques. Journal of General Internal Medicine. 13(3):195-199.

⁴⁵ Creswell, John W. and Poth, Cheryl N. (2018). Qualitative Inquiry & Research Design-Choosing Among Five Approaches. Chapter-3 at 84. Fourth Edition.

picture. To understand how adaptive are India's regulations in practice and to gain from multiple perspectives of the stakeholders, it is important to talk to people and listen to their views. Therefore, in this study, two qualitative research methods are combined- document analysis and interviews, thus, enabling triangulation. Triangulation is the 'combination of methodologies in the study of the same phenomenon.²⁴⁶ This technique enables a comprehensive understanding of the phenomenon by converging and corroborating information from different data sources and methods.⁴⁷

1. Document Analysis

Document analysis is a systematic process of reviewing and evaluating documents. These documents could be printed or electronic.⁴⁸ In document analysis, the data is examined and interpreted to "elicit meaning, gain understanding, and develop empirical knowledge."49

In this study, the documents are analysed using qualitative content analysis.⁵⁰ In particular, 'directed content analysis' approach is used – it is a structured process in which existing theory or prior research informs the key concepts as initial coding categories. This coding scheme is developed prior to the data analysis process. And, as analysis begins, the initial coding scheme could be revised including identifying and forming new category or sub-category of existing codes.⁵¹

The strength of using 'directed content analysis' approach is that the process is structured compared to the conventional approach, in which coding is developed during analysis and not prior. Further, this analysis helps to add to or refine the existing literature. However, its limitation is that the researcher approaches the data with a

⁴⁶ *Id*.

⁴⁷ Bowen, Glenn A. (2009). Document Analysis as a Qualitative Research Method. Qualitative Research Journal, vol. 9, no. 2, at 28.

⁴⁸ Electronic includes computer-based and Internet-transmitted material.

⁴⁹ See Bowen, supra note 47, at 27.

⁵⁰ Content analysis is defined as a research method for the subjective interpretation of the content of text data through the systematic classification process of coding and identifying themes or patterns. For details, see Hsieh. H. F. and Shannon S, E. (2005). Three Approaches to Qualitative Content Analysis. Qualitative Health Research. 15(9), at 1278.

⁵¹ The basic coding process in content analysis is to organize large quantities of text into much fewer content categories (Weber, 1990). See, Hsieh & Shannon, supra note 50, at 1281, 86.

strong bias and likely to see information supportive of the theory rather than the contrary. Over-emphasising on theory could also blind the researcher to the context of the phenomenon being studied.⁵²

To overcome these limitations, codes based on the six key features are identified in advance and the scope to add another feature(s) during coding process is retained. The information that seemed contrary to the theory, is identified and coded. Further, care is taken to identify the contextual factors that could be unique to the setting under investigation. The overall objective of analysis has been to present as holistic understanding of the phenomenon under study as possible.

a. Content analysis

Following are the steps followed in the content analysis⁵³ of the law and policy documents as well as the interview transcripts:

- (i) The level of analysis- In content analysis, the level could be a word, phrase, word sense, sentence, or themes. In this dissertation, 'theme' has been chosen as the level of analysis. The objective of analysis is to understand the phenomenon under study, which could best be achieved by analyzing the documents at the level of theme instead of adopting word frequency, etc. Further, most of the law and policy documents are detailed, therefore, theme level analysis is feasible as well as relevant. This choice is also in sync with the six features, which are akin to themes and are informed by literature review. In this dissertation, for consistency, the word 'feature' is used instead of 'theme.'
- (ii) Initial coding categories- Based on the six features identified in the literature review, the initial coding categories are developed. Considering, new features could emerge during the analysis, the flexibility to add categories through coding process is retained.
- (iii) Operational definitions- The operational definitions of the features and initial codes⁵⁴ are outlined in advance. The features for document analysis as well as

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⁵² See, Hsieh & Shannon, supra note 50, at 1283.

⁵³ Columbia Public Health, Population Health Methods, 'Content Analysis.' Columbia University Mailman School of Public Health. Available at https://www.publichealth.columbia.edu/research/population-health-methods/content-analysis

⁵⁴ In this dissertation, for consistency, the word 'feature' has been used instead of 'theme.' Features and codes do not differ much in their meaning. Features are the broader concepts and are explained in phrases or sentences. Whereas, codes are the labels that depict the essence of the features, succinctly, in a few words. For details, *see* Saldana, J. (2013). The Coding Manual for Qualitative Researchers. Chapter-1, An

- interview analysis are similar (with an addition of one feature for the interview analysis). However, there is a little variation in the codes. (See Table 4 and 8)
- (iv) Rules for coding- Coding is a process of reading the text and assigning it to different features/ codes. The following rules were decided to enable a structured coding process: (1) Categorizing the text according to the pre-determined features, (2) Adding new features if they emerge during the coding process, (3) Coding on the basis of the 'existence' of code/ feature, not merely the frequency or the occurrence of the feature/code, (4) Coding on the basis of the manifest meaning of the content and not its latent or hidden meaning, (5) Distinguishing the relevant information from the irrelevant information based on judgment (Example-participant response to the rapport-building questions (sharing personal background, education, designations held, etc.), or sharing a personal anecdote as a side note during the interview, etc. are considered irrelevant information).
- (v) Using software for coding- In this study, the PDF files of the law and policy documents and interview transcriptions are coded using NVivo. It is a qualitative-data analysis software program commonly used in social-science research.⁵⁵
- (vi) Analysis and the results- To draw conclusions, based on the six-feature analysis, additional feature(s), and the emergence of patterns and general trends.

Table 4. Prior identified features/ codes for document analysis

| | O 1D C | C 1 | 0 1 1D 6 11 |
|---|--|-------------------------------------|---|
| Features | Operational Definition | Codes | Operational Definition |
| Acknowledging risk, uncertainty, and change | Provisions acknowledging the risks and uncertainties related to the policy issue | Risk | e.g. risk assessment |
| | | Uncertainty and change | e.g. post-policy reviews due to uncertainty or expected change |
| Broader/ fuller impact assessment | Provisions related to holistic impact assessment of law/policy choice(s). e.g. considering multiple factors-socio, economic, technical, scientific, cultural, etc. | Costs and benefits | e.g. cost-benefit analysis, cost- effectiveness, etc. |
| | | Distributional equity Science | e.g. distributional impact of the law/policy e.g. considering scientific evidence, best available science, etc. |

Introduction to Codes and Coding at 3. (Second Edition) Sage. Also, see, NVivo QSR International guide on 'Themes and Case nodes' available at http://help-

nv11.qsrinternational.com/desktop/concepts/about_nodes.htm#MiniTOCBookMark3.

⁵⁵ Bringer, J. D. et al., (2004). Maximizing transparency in a doctoral thesis: the complexities of writing about the use of QSR NVIVO within a grounded theory study. Qualitative Research 4(2): 247-265. Also, *see*, Bazeley, P., and K. Jackson. (2013). Qualitative Data Analysis with NVivo. Second edition.

| Monitoring, Evaluation, and feedback | Provisions related to monitoring and evaluating the key indicators (policy outputs/ outcomes), or taking feedback from stakeholders on policy performance | Policy alternatives Data provisions | e.g. considering impact of various policy alternatives e.g. data relevance, data analysis, data quality, data to inform future law/policymaking, etc. e.g. related to M&E and feedback processes in general |
|--|---|--|--|
| Iterative decision- making and policy adjustment | Provisions related to the review or updating the policy/ law | Examples of Review | e.g. periodic review, sunset clause, retrospective review |
| adjustificht | | Examples of Regulatory learning | e.g. Pilot programs, phased roll-outs, policy variance over time and space, experimental rules |
| Public participation | Provisions related to public involvement in the law/policymaking process | Public outreach Capacity | e.g. public outreach mechanisms, the time period for inviting public comments/ feedback, etc. e.g. education and awareness |
| | | building Grievance redressal | generation on the policy issue e.g. conflict / grievance redressal mechanisms |
| Adaptive governance structures | Provisions related to inter-agency coordination and multiple levels of decision-making | Polycentricity Inter-agency coordination | e.g. multiple centers of decision-making at federal, state, local level; public-private partnerships, etc. e.g. inter-agency coordination vertical (across levels of governance- federal, state, local) and horizontal (at the same level of governance) |

b. Actual coding process

The coding process has been quite iterative. To start with, the analysis was feature-wise and the text was coded under relevant pre-identified codes. However, three new broad categories were created to understand the presence of adaptive features in different stages of a regulatory cycle i.e. pre-implementation, implementation, and post-implementation. The text was recoded under these categories though maintaining the six features. In addition to the existing codes, a few new codes were added which in some cases vary from sector to sector depending on the nature of provisions in the analyzed documents. Summary of added codes given in Table 5.

Table 5. New broad categories and codes for document analysis

| New Broad categories | Existing Features | Existing Codes | Added Codes |
|-------------------------|--------------------------------------|---|---|
| Pre- implementation | Assessing risks and uncertainties | Risk | - |
| mplementation | uncertainties | Uncertainty | - |
| | Broader and fuller | Costs and benefits | - |
| | impact assessment | Distributional | - |
| | | equity Science | - |
| | | Policy alternatives | - |
| | Public Participation | Public outreach | - |
| Implementation | Monitoring, Evaluation, and Feedback | Data provisions | 'Structure-based monitoring' and 'Process-based monitoring' (EV sector) 'Monitoring and compliance' (Groundwater and health data) |
| | Public Participation | Other provisions Capacity building | Public engagement in implementation (Added to all three sectors) |
| Post- Implementation | Iterative decision- making | Grievance redressal Examples of Review | 'Provisions acknowledging change' and 'Revising laws/policies' (Added to all three sectors) |
| | | Examples of Regulatory learning | - |
| Overarching feature | Adaptive governance structures | Polycentricity | - |
| | | Inter-agency coordination | 'Vertical coordination' and 'Horizontal coordination' (Added to all three sectors) |

2. Interview Analysis

An interview is described as 'an exchange with an informal character, a conversation with a goal.⁵⁶ According to Brinkmann and Kvale (2015), an interview is where "knowledge is constructed in the interaction between the interviewer and the interviewee" (p. 4).⁵⁷ To supplement the document analysis, semi-structured interviews of key stakeholders are conducted in India. The interview research aims to understand the gap between theory and action i.e. between the adaptability of laws and policies on books (based on the document

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⁵⁶ Hijmans, E., & Kuyper, M. (2007). Het halfopen interview als onderzoeksmethode. In L. PLBJ & H. TCo (Eds.), *Kwalitatief onderzoek: Praktische methoden voor de medische praktijk*. [The half-open interview as research method (pp. 43–51). Also, *see*, Busetto, L. et al., (2020). How to use and assess qualitative research methods. Neurological Research and Practice 2 (14), 1-10.

⁵⁷ See, Creswell & Poth, supra note 45, at 230.

analysis) and the law in practice (based on the information and perspectives gathered from interview participants).

a. Sampling of participants

Purposeful sampling is used for selecting interview participants⁵⁸ i.e. the participants who could best inform the research questions and enable understanding of the phenomenon under study are selected.⁵⁹ In purposeful sampling, a researcher intentionally samples individuals or a group of people who can best inform the central phenomenon being examined.⁶⁰ Further, the following qualitative sampling strategies are used:

(i) Maximum variation- This sampling strategy aims to document diverse variations of individuals or sites based on specific characteristics.⁶¹ In the beginning of this study, five categories of participants were identified to maximize the differences. This increases the likelihood that the findings would reflect diverse perspectives attributable to different interests, ideologies, and professional goals of the stakeholders. Also, the identified stakeholder categories are expected to have the experience and/knowledge related to the phenomenon under research. The categories are:

Political leaders/Elected representatives- In a democracy, political leaders are the elected representatives of the people. They play a crucial role in law and policy-making by voicing the demands of their constituents in the lawmaking bodies (Parliament at the federal level and Legislative Assembly at the state level). Knowing the views and perspectives of lawmakers could be very useful to assess the practice and feasibility of adaptive regulation in India.

Government officials in the concerned Ministry/ Department – In India, at the federal and the state levels, typically the department's Minister and the Secretary take key policy decisions. However, they are assisted by a range of officers and staff varying from

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⁵⁸ Purposeful sampling is a technique widely used in qualitative research for the identification and selection of information-rich cases for the most effective use of limited resources (Patton 2002). For details *see*, Palinkas, Lawrence A. et al., (2015). Purposeful Sampling for Qualitative Data Collection and Analysis in Mixed Method Implementation Research, Administration and Policy in Mental Health, 42 (5), 533-544.

⁵⁹ Sargeant J. (2012). Qualitative Research Part II: Participants, Analysis, and Quality Assurance. Journal of Graduate Medical Education, 4(1), 1–3.

⁶⁰ See, Creswell & Poth, supra note 45, at 223. (Chapter 7)

⁶¹ Id. at 225.

section officers to the additional secretaries. In particular, the officers at the rank of deputy secretary and above have significant work experience (experience of working at the state/ federal government between 10 to 15 years) and their opinions are a part of the formal decision-making process. These officers are well-informed and have the experience of participating in key decision-makings, therefore, well-situated to be the participants for the research study. A representative organization chart of a ministry in the federal government of India may be seen in Figure-2.

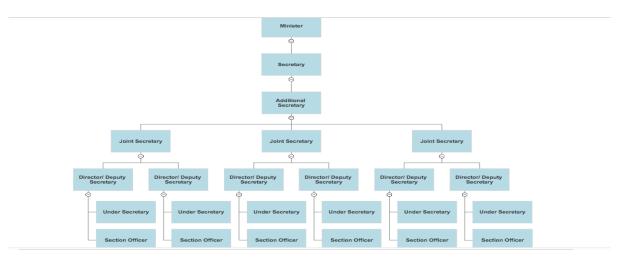


Figure 2. Representative Organization chart of a Ministry in India (at the federal level)

Experts from academia- Academic researchers and scholars have domain knowledge along with cutting-edge research experience in a specific sector. Based on their expertise, they are well-placed to contribute to the research study.

Non-profit organizations- These organizations are unique as they perform diverse roles including working with the communities, conducting field research, capacity building, involving in policy advocacy, and representing people's voice on important matters of governance. Thus, their views are valuable for research study.

Representatives of Industry- The industry sector makes huge investments based on the prevailing law and policy requirements. Any change in the law/policy is likely to impact this sector the most. Therefore, the views of industry representatives are valuable to inform the suitability of adaptive regulation.

(ii) Criterion- This sampling strategy requires the cases/ potential participants to meet some pre-determined criteria.⁶² In this study, the individual participants in the five categories are selected based on a criterion established in advance. The criteria is mentioned in Table 6.

Table 6. Selection criteria of potential interview participants

| Stakeholder category | Criteria to select potential participant | Rationale |
|-----------------------------------|--|--|
| Lawmakers/Elected representatives | Serving or the former Member of the Parliament (MP) or Serving or the former Member of the state Legislative Assembly (MLA) or Serving or the former district-level elected representatives | -People's representatives -Key role in law and policy formulation |
| Government officials | Middle-level officers in the Federal / State government having work experience in the sector (Serving/ former Deputy Secretary and above) And/or District-level officers- Serving/ former head of the department at the district level having work experience in the sector | -Key informants -Involved in formal decision-making process |
| Experts from academia | Associate Professor and above (University level/ National Institutes/ State level Educational and Research Institutes) And Preferably the ones with experience of participating in law/policy making process as an expert in the sector Or Having publications related to law/ policy making in the relevant sector Or Conducting field research in the sector | Knowledge and expertise in the sector |
| Non-profit organizations | Experience of working at the grassroots (community level) in one state or multiple states in the relevant sector Or Conducting research activities/programmes in the sector And Policy advocacy in the relevant sector | -Experience and perspective; knowing what works on the ground and what does not -Voice concerns of the people |
| Representatives of Industry | People at relevant managerial positions in the business entity at a micro or macro level in the relevant sector Or Representatives of industrial bodies/ unions in the relevant sector | Industry (including manufacturing and services) makes huge investments based on the prevailing law and policies. |

(iii) Snowball or chain- This sampling strategy enables identification of cases of interest from the people who know people with required information and experience.⁶³ In addition to the above two strategies, some of the participant selection is based on

⁶² *Id*.

⁶³ *Id*.

the snowball strategy. However, the selection criterion has been followed while identifying participants through this sampling strategy.

b. Sample Size

While conducting the semi-structured interviews, the principle of 'saturation' is followed i.e. to collect information till no new substantive information is received from the participants.⁶⁴ The sample size is deemed sufficient when the data saturation is reached, i.e. when no new substantive information is resulting while conducting the interviews.⁶⁵ In this context, the interview questions have been designed to cover different aspects of adaptive regulations based on the six features and the tentative number of interview participants was expected to be 30. This included six lawmakers/ elected representatives (not sector-specific) and 24 key stakeholders with two persons per category of stakeholder per sector, i.e. eight persons per sector.

In this study, total 33 interviews are conducted. During data analysis, in each sector, many commonalities and repetitions were found in the responses of different stakeholder categories. Before starting the data analysis, there were six main themes (i.e. the six broad features of adaptive regulation) and prior determined codes. As analysis began, additional codes were created to categorize the new information available in interview transcripts. However, as data analysis progressed beyond a point, no new code was created to categorize the information and the existing codes were sufficient to capture the information. This indicates that the themes were saturated.

c. Interview questions

The interview guide comprised of 11 questions. Of these, two questions are introductory, and the remaining nine questions cover various aspects of adaptive regulation including the six features. The feature-wise mapping of 11 interview questions is summarized in table 7 and the detailed questions are mentioned in Appendix I.

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⁶⁴ See Palinkas et al., supra note 58. (Primary emphasis in qualitative is on saturation i.e., obtaining a comprehensive understanding by continuing to sample until no new substantive information is acquired).

⁶⁵ See Sargeant supra note 59.

Table 7. Thematic mapping of features and interview questions

| Sr.no. | Feature of Adaptive Regulation | No. of interview Questions | Sr. No. of the Question |
|--------|---|----------------------------|-------------------------------|
| i. | Acknowledging risk, uncertainty, and change | 1 | 4 |
| ii. | Fuller and broader impact assessment | 1 | 3 |
| iii. | Monitoring, evaluation, and feedback | 1 | 7 |
| iv. | Iterative decision-making and Policy adjustment | 2 | 5, 6 |
| v. | Public participation | 2 | 8, 9 |
| vi. | Adaptive governance structures | 1 | 10 |
| vii. | Adaptive regulation in India | 1 | 11 |
| | Sub total | 8 | |
| | Introductory questions | 2 | 1, 2 |
| | Total | 11 | |

d. Data storage and data cleaning

- (i) Storage- Most of the interviews are conducted on Zoom and a few conducted inperson. To ensure the safety and security of data, and in compliance with the IRB protocol, the audio files of all interviews and their transcripts are stored on Duke Box.⁶⁶
- (ii) Audio files and transcription- As a first step, software called otter.ai has been used for machine- enabled transcription. The interviews range between 35 minutes and 1 hr 50 minutes. Most of the interviews are around 1-hour duration.
- (iii) Data cleaning- Each audio file and the machine generated transcription has been reviewed. Total 33 interview transcriptions have been reviewed, finalized, and their PDF copies prepared for NVivo analysis.

e. Data analysis

The data in the interview transcripts has been analysed following the steps outlined in the section on content analysis. Details of prior identified features/ codes are in Table-8.

Table 8. Prior-identified features/ codes for Interview analysis

| Features | Operational Definition | Codes | Operational Definition |
|---|--|---------------------------------|---|
| Assessing risk, uncertainty, and change | Whether in the law and policymaking process, there is an acknowledgement/assessment of the risks and uncertainties | Risks and uncertainties | e.g. Practice of risk assessment |
| ū | | Policy response to change | How does the policy respond to the changes in |

⁶⁶ Duke's Box is a cloud-based storage and collaboration service of Duke University. With Box, users can access, store and share content securely with Duke and non-Duke users.

| Broader/ fuller impact assessment | Whether in the law and policymaking process, holistic impact assessment of law/policy choice(s) carried out. e.g. considering multiple factors- socio, economic, technical, scientific, cultural, etc. | Broader assessment Skewed assessment | circumstances (post- policy formulation)? -Considers factors like, cost-benefit analysis, distributional Equity, best available science, etcConsiders various policy alternatives Absence of above, Driven by political interests/Stakeholder interests (populist in |
|--|--|---|--|
| Monitoring, Evaluation, and feedback | The ways in which the regulatory bodies/ agencies monitor and evaluate the key indicators (policy outputs/ outcomes), or gather feedback from various stakeholders on policy performance. | Quality | nature) Overall assessment of the M&E and feedback processes of the agencies |
| | 1 71 | Capacity | Issues related to staff skills, training, resources, etc. |
| | | Data | Issues related to data quality, data analysis, data planning, etc |
| Iterative decision- making and policy adjustment | Whether there are provisions for reviewing or updating the law or policy. | Examples of Review | e.g. periodic review, sunset clause, retrospective review |
| aujustinent | | Examples of Regulatory learning | e.g. Pilot programs, phased roll-outs, policy variance over time and space, experimental rules |
| Public participation | Public involvement in the law/policymaking process | Level of public participation | Overall assessment of the level of public participation in the law/policymaking process |
| | | Accessibility | Types of government platforms available, adequacy of existing platforms, ease of retrieving public |
| | | Transparency | documents, etc. Response to public comments and feedback, availability of documents |
| | | Stakeholder participation | in public domain, etc Stakeholder groups that participate in the law/policymaking |
| Adaptive governance structures | Whether the agencies coordinate in law and policymaking process and the level(s) of governance for regulating a particular | Inter-agency coordination | process more than others Inter-agency coordination in law and policymaking, how effective it is, any |
| | sector | Scale of governance | gaps, etc. Most appropriate level (s) of governance to regulate a particular sector, e.g. |
| Adaptive Regulation | General thoughts on the value and applicability of adaptive regulations in India | For | federal, state, local. Favouring the application of adaptive regulation in India |

| Against | Not favouring the application of adaptive regulation in India |
|------------|---|
| Challenges | The challenges in implementing adaptive regulation in India |

f. Actual coding process

The coding process has been quite iterative. To start with, the analysis was feature-wise and the text was coded under relevant pre-identified codes. However, three new broad categories were created to understand the presence of adaptive features in different stages of a regulatory cycle i.e. pre-implementation, implementation, and post-implementation. The text was recoded under these categories though maintaining the six features. In addition to the existing codes, a few new codes were created which in some cases vary from sector to sector depending on the nature of responses given by the participants. Summary of added codes given in Table 9.

Table 9. New broad categories and codes for Interview analysis

| New Broad | Existing Features | Existing Codes | Added Codes |
|-------------------------|--|--|--|
| Pre- implementation | Assessing risks and uncertainties | Risk and Uncertainty | Limited assessment' Detailed assessment' (EV sector) 'Limited assessment' Detailed assessment' 'No assessment' (Groundwater and Health data) |
| | Broader and fuller impact assessment | Broader assessment | 'Structured assessment' 'Unstructured assessment' (EV sector) |
| | Public Participation | Skewed assessment Level of public participation Accessibility Transparency Stakeholder participation | - 'Effective participation' (Groundwater) |
| Implementation | Monitoring, Evaluation, and Feedback | Quality Capacity Data | 'Formal and structured' 'Informal and less structured' 'Metrics' 'Transparency (EV sector) 'Resource monitoring' and 'Policy monitoring' (Groundwater) 'Monitoring and feedback' (Health data) - 'Use of data' (All three sectors) |
| | Public Participation | Level of Public participation | - |
| Post- Implementation | Iterative decision- making | Examples of Review | 'Policy response to change' (Shifted from the 'Assessing risks and uncertainty' feature and added to all three sectors) |

| | | Examples Regulatory learning | of | |
|---------------------|--------------------------------------|------------------------------------|----|---|
| Overarching feature | Adaptive governance structures | Inter-agency coordination | | 'Effective coordination' and 'Lack of coordination' (All three sectors) |
| | | Scale governance | of | |
| | Need of Adaptive Regulation | For | | 'Existing Law and policy processes' (All three sectors) |
| | | Against Challenges | | |

g. IRB approval

Prior to conducting the interviews, approval from the Duke Institutional Review Board (IRB) has been taken. The IRB granted an expedited approval as the proposed research study does not pose any risk to the participants. Further, the IRB approved the interview guide, the consent form and the templates for reaching out to the participants. During the study, all measures were taken to protect the participant's privacy, such as clearly communicating the consent process (including the right to withdraw from the study any time), permission to record the interviews, and explaining the intended purpose of the study. All interview responses are confidential and anonymous. At no stage of the dissertation research, the identity of the participants has been disclosed.

IV. Conclusion

The methodology described in this chapter is applied in analyzing the data in the following chapters. Each of the next three chapters is dedicated to a specific sector of study- electric vehicles (EVs), groundwater, and health data. In each chapter, stage-wise analysis reflects the adaptability of the sector in a regulatory cycle and is based on the six features, pre-identified codes, as well as the newly added codes. Further, for the US, the regulatory stage-wise analysis is informed by the document analysis. Whereas, for India, the regulatory stage-wise analysis is presented in two parts- one informed by the document analysis and another informed by the interview analysis. Each chapter concludes with a summary comparative assessment and high-level recommendations for India.

Chapter-3

Groundwater Regulations in India- An analysis

Summary: This chapter presents the analysis of Groundwater laws and policies of several states within the US and India. The analyzed documents include relevant statutes, rules, and policies. Though the case laws play an important role in the evolution of the legal framework of groundwater in both countries, their analysis is beyond the scope of this chapter. However, summary references of the seminal case laws are mentioned at suitable places. The overall analysis is anchored on the adaptive regulatory cycle which has six adaptive features embedded in three stages of the cycle. Based on the relative presence or absence of the adaptive features, stage-wise adaptiveness is inferred for the groundwater sector. For India, this inference is based on the review of selected states' (Punjab and Rajasthan) groundwater law and policy documents and semistructured interviews of ten key stakeholders. For the US, this inference is based only on the review of selected states' (California and Texas) groundwater laws. In the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments), India's regulatory cycle indicates moderate to high adaptiveness on the books whereas moderate adaptiveness in practice. In the implementation stage (monitoring and evaluation), India's regulatory cycle indicates high adaptiveness on the books and low adaptiveness in practice. And in the post-implementation stage (iterative decision-making), India's regulatory cycle indicates medium adaptiveness on the books but high adaptiveness in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the inference is mixed. Public participation shows high presence both on the books and in practice. Whereas, the inter-agency coordination shows moderate presence both on the books and in practice. Considering the variation in the groundwater regulatory processes of the four states, it is difficult to draw conclusions at the level of regulatory cycle. Instead, feature-wise comparative analysis is done which suggests that (i) in assessing risks and uncertainties, all four states indicate similar adaptiveness (on the lower side); (ii) in broader impact assessments, California and Texas are more adaptive than Rajasthan, and Punjab is the least adaptive; (iii) in monitoring and evaluation, all four states seem similarly adaptive; (iv) in iterative decision-making, California and Texas are more adaptive than Rajasthan and Punjab; (v) in public participation, California, Texas, and Rajasthan are more adaptive than Punjab, and (vi) in adaptive governance structures including inter-agency coordination, California, Texas, and Rajasthan are more adaptive than Punjab. Based on the comparative analysis, potential lessons are identified where the four states could learn from one another. Further, this study recommends that to assess the effectiveness of the laws/policies and to improve regulatory learning, the agencies in all four states should emphasize on conducting retrospective regulatory reviews and introduce multi-policy reviews. The chapter concludes with specific recommendations for India.

Groundwater and Adaptive Regulation

Groundwater provides almost 50 % of all drinking water, 40 % of irrigation water, and about one-third of all water for industrial use worldwide. It maintains the base flow of rivers, sustains ecosystems, and prevents seawater intrusion and land subsidence. In the early twentieth century, groundwater extraction increased exponentially for irrigation purposes in the United States, Mexico, Spain, and Italy. It was followed by an increased extraction in parts of South Asia, North China, parts of the Middle East, and North Africa in the 1970s, a period also called the second wave of groundwater development. The third wave comprises increased extraction in parts of Africa and other countries like Vietnam and Sri Lanka.² This worldwide boom in groundwater development has been called the silent revolution.³ The revolution ushered economic development in many parts of the world but also placed significant stress on the groundwater system. It modified the hydrogeological regimes of many aquifers in an unprecedented and unsustainable way, especially affecting aquifers with little or no recharge.⁴ The most heavily impacted aquifers are spread over various parts of the globe, including the Californian Central Valley⁵ and the High Plains aguifer ⁶ in the United States, the majority of aguifers in Spain ⁷, the North-Western Sahara Aquifer System⁸ and the Nubian Sandstone Aquifer System in North Africa,9 the Yemen Highland basins10, extensive aquifer systems of the Indus basin, especially in the Indian states of Rajasthan, Gujarat, Punjab, Haryana, and Delhi, 11 the

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¹ International Groundwater Resources Assessment Centre. (2018). UN Water- Ground Water Overview: Making the Invisible Visible, at 1.

² Shah et al., (2007). Groundwater: A global assessment of scale and significance. In D. Molden (Ed.) Water for Food, Water for Life: A Comprehensive Assessment of Water Management in Agriculture. Chapter 10. (pp. 395–423). International Water Management Institute.

³ Llamas, M. and Martínez-Santos, P. (2005). Intensive groundwater use: a silent revolution that cannot be ignored. Water Science and Technology Series, 51 (8), 167–74.

⁴ Gun, Jac V. D. (2012). Groundwater and Global Change: Trends, opportunities, and challenges. United Nations World Water Assessment Programme.

⁵ Famiglietti et al., (2009). Water storage changes in California's Sacramento and San Joaquin river basins, including groundwater depletion in the Central Valley. American Geophysical Union Press Conference. ⁶ Sophocleus, M. (2010). Review: Groundwater management practices, challenges and innovations in the

High Plains aquifer, USA: lessons and recommended actions. Hydrogeology Journal, 18 (3), 559-75.

Custodio, E. (2002). Aquifer overexploitation: What does it mean? Hydrogeology Journal, 10 (2), 254–77.
 Mamou et al., (2006). North Western Sahara Aquifer System. In S. Foster and D. Loucks (eds). Non-

Renewable Groundwater Resources: A Guidebook on Socially-Sustainable Management for Water-policy Makers. Series on Groundwater No. 10, UNESCO/IAH, 68–74.

⁹ Bakhbakhi, M. (2006). Nubian Sandstone Aquifer System. In S. Foster and D. Loucks (eds). Non-Renewable Groundwater Resources: A Guidebook on Socially-Sustainable Management for Water-policy Makers. Series on Groundwater No. 10, UNESCO/IAH, 75–81.

¹⁰ Gun, Van D. et al. (1995). The Water Resources of Yemen: A Summary and Digest of Available Information. Delft and Sana'a, WRAY-Project.

¹¹ Rodell, M. et al., (2009). Satellite-based estimates of groundwater depletion in India. Nature, 460.

North China Plain aquifer, ¹² and Great Artesian Basin in Australia. ¹³

Studies suggest that excessive groundwater extraction could lead to the rising cost of groundwater (due to the additional cost of drilling deeper), contamination due to possible salinization, decreased base-flows, depletion of groundwater storage, land subsidence, rise in the sea level, and other adverse environmental impacts. ¹⁴ Similarly, there are several risks associated with groundwater stress, including risks to food production, livelihoods, industrial production, and the overall economy. ¹⁵

Thus, it is relevant to understand how the impacted countries/states' governments are regulating this invisible but finite resource. Do laws acknowledge the uncertainties surrounding the resource's availability and use? Are there mechanisms of data collection and monitoring built-in the laws/policies? Are the laws/policies changing with new information and changing environment? Is it challenging to regulate groundwater which not only fulfills the basic human needs but also impacts the economy of many sectors? Are there provisions to assess the impact of such laws and policies? This chapter is an attempt to find answers to similar questions.

I. Adaptive Regulatory Cycle

Typically, a policy or regulatory cycle can be divided into three basic stages i.e. preimplementation, implementation, and post-implementation.¹⁶ In the adaptive regulatory cycle, each stage has adaptive features which enable learning and improvement over the lifecycle of a policy or regulation. The adaptive regulatory cycle is informed by the six features of adaptive regulation (based on the literature review). ¹⁷ These features are (i) Assessing the risks and uncertainties, (ii) Broader and fuller impact assessment, (iii) Monitoring, evaluation, and feedback, and (iv) Iterative decision-making and Policy adjustment. These features are shown in different stages of the regulatory cycle.

¹² Jia, Y. and You, J. (2010). Sustainable groundwater management in the North China Plain: Main issues, practices and foresights. Extended abstracts No. 517, pp. 855–62 prepared for 38th IAH Congress, Krakow.

¹³ Habermehl, M. (2006). The Great Artesian Basin, Australia. In S. Foster and D. P. Loucks (eds). Non-Renewable Groundwater Resources: A Guidebook on Socially-Sustainable Management for Water-policy Makers. Series on Groundwater No. 10, UNESCO/IAH, 82–8.

¹⁴ Konikow, L. and Kendy, L. (2005). Groundwater depletion: A global problem. Hydrogeology Journal, 13, 317–20.

¹⁵ National Institute for Transforming India (NITI). (2019). Composite Water Management Index at 13 -

¹⁶ For details, see, Section VIII 'Adaptive Regulatory Cycle' in Chapter 1.

¹⁷ For details, see Chapter 1.

Additionally, there are two overarching features: (v) Public participation and (vi) Adaptive governance structures, which play an important role in all stages of the cycle.

A. Pre-Implementation

Adaptive regulations acknowledge the importance of assessing the risks and uncertainties and responding to them directly. In adaptive regulatory cycle, this implies that while formulating the regulations/policies, the agencies undertake risk assessment. Another feature is the fuller impact assessment of the policy/ regulatory alternatives. The objective is to avoid the perils of narrow decision-making. This implies that the decision-makers assess the full portfolio of impacts such as the costs, benefits, and distributional effects, including the co-benefits and the countervailing risks. Lastly, adaptive regulations acknowledge the importance of planning relevant data collection. This implies there is adequate planning to identify the relevant information to be collected so that it could result in meaningful monitoring and reviews.

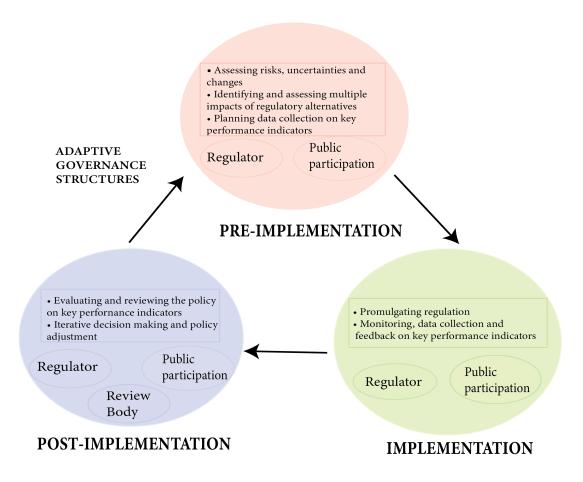


Figure 1. Adaptive Regulatory Cycle

B. Implementation

In this stage, the regulation/ policy is implemented. Adaptive regulations have built-in mechanisms of monitoring and feedback that enable policy adjustments. This implies relevant data collection and analysis take place; policy outcomes and key performance indicators are monitored, and the outcomes of monitoring and feedback are fed back into the regulatory process i.e. inform future policies and regulations.

C. Post-Implementation

In adaptive regulations, the decision-making is not a one-time binary yes/no but a continuous process where new information and post-implementation experience inform the future decisions. This implies there are built-in provisions of policy learning and iterative decision-making, such as periodic review, retrospective review, and sunset clause. In this stage, the regulations are reviewed/ evaluated such as by comparing the ex-post assessments with the ex-ante assessments. Thus, the policy changes or improvements are based on the evaluation of policies.

D. Overarching features

Public participation and adaptive governance structures are the overarching features which play an important role in all stages of the regulatory cycle.

Public Participation- Public participation has a very broad meaning. Often the terms community participation, public participation, community involvement, community engagement, stakeholder participation, citizen participation, etc., are used interchangeably. In adaptive regulatory cycle, the term public participation implies the right of the affected public to participate in the decision-making processes (regulatory/policy-making). The word public includes both general public and the stakeholders/right holders.

Adaptive Governance Structures- Adaptive governance structures represent the larger ecosystem that enables the implementation of adaptive regulations. A decentralized and polycentric approach facilitates adaptive approaches and allows for risk diversification, policy experimentation, and innovation across jurisdictions. In the adaptive regulatory

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¹⁸ National Environmental Justice Advisory Council (NEJAC), Model Guidelines for Public Participation (2013), at 1.

cycle, these include the presence of polycentric structures and the inter-agency coordination both vertical (across different levels of government) and horizontal (at the same level of government).

The analysis of the law and policy documents and the interviews in the following sections builds on the adaptive regulatory cycle and its three stages.¹⁹

II. Groundwater in the US- Analysis of state laws (California and Texas)

A. Groundwater use in the US

Groundwater is a critical component in fulfilling domestic and agricultural water needs in the country. In 2015, approximately 149 million people (46 % of the population) relied on groundwater for domestic water supply while irrigation accounted for the greatest volume of groundwater use (69%). Other groundwater uses include thermoelectric power, oil and gas development, livestock, mining, and industrial processes. California and Texas are among the largest users of groundwater in the US. As a percentage of all groundwater withdrawals, California with 16% is the largest user of groundwater, followed by Texas at 10 %. In general, the drier western states, rely more on groundwater than the eastern states, which have more access to surface water.

B. Groundwater Laws in the US

There is no overarching national framework for groundwater management in the United States. States have the powers to regulate water within their boundaries and in setting goals for water use and water pollution. In general, United States' laws on water use (for humans and the environment), water quantity, and water quality have developed separately and with wide variability between states.

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¹⁹ For details, see, Chapter 1.

²⁰ Congressional research Service (CRS). (2018). The Federal Role in Groundwater Supply: Overview and Legislation in the 115th Congress.

²¹ American Geosciences Institute (AGI) (2017). Groundwater use in the United States. Factsheet 2017-002. Available at

https://www.americangeosciences.org/sites/default/files/CI Factsheet 2017_2_groundwater_170309.pd f. Also, see, Water Science School. (2018). Groundwater Use in the US. United States Geological Survey, Available at https://www.usgs.gov/special-topic/water-science-school/science/groundwater-use-united-states?qt-science_center_objects=0#qt-science_center_objects.

1. Surface water laws- Riparian and Prior appropriation

In general, the 100th meridian separates the surface water allocation laws in the United States- the eastern states are wetter and have adopted riparian²² or regulated riparian laws,²³ and the western states are drier and tend to use prior appropriation. However, groundwater laws do not neatly fit into these divides and vary within a state. There are multiple doctrines of groundwater law, most of which are less developed when compared to the heavily-regulated, well-litigated, and established surface water doctrines.²⁴

2. Groundwater laws- Five doctrines

As is the case with surface water laws, the states choose the rules and regulations for groundwater use and allocation. However, unlike the surface water laws that fall into two broad categories, the groundwater laws in the United States could be classified into five categories. Two of these five doctrines (prior appropriation and the rule of capture) are quite distinct and the differences in the remaining are subtle and sometimes overlapping.

a. Rule of capture

It is the oldest doctrine of groundwater in the United States. According to this rule, one does not own groundwater under one's property but once the groundwater is lawfully pumped, it becomes the personal property of the owner.²⁵ Further, pumping of the groundwater if harms another person (e.g. due to drilling by one person, the well of another dries up), does not result in legal liability.²⁶ This doctrine though gives absolute right to pump groundwater, in practice, has witnessed a few exceptions. These include malicious pumping with a purpose of causing harm, wanton and willful wastage of water,

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²² Riparianism limits the use of water to only those landowners with riparian land. In order to be classified as a riparian landowner, the landowner must own the parcel of land adjacent to the watercourse, i.e. a river, stream, lake, or pond, from which the landowner plans to use the water. Even then, the water may only be put to a reasonable use. National Agricultural Law Center. Water Law: Overview. Undated. Available at https://nationalaglawcenter.org/overview/water-

 $[\]underline{law/\#:} \sim : text = \underline{Under\%20 the\%20 regulated\%20 riparian\%20 system, water\%20 is\%20 ever\%20 actually\%20 use}\underline{d}.$

²³ *Id.* (Under the regulated riparian system, a central state agency controls who may use the water, how much they can use, and when they can use. Regulated riparianism departs from common law riparianism by looking at the projected use before any water is ever actually used).

²⁴ Dellapenna, Joseph W. (2013). A Primer on Groundwater Law, Idaho Law Review, 49, 265.

²⁵ Craig et al., (2017). Allocating Groundwater: The Five Doctrines Used in the United States. In Water law (Concepts and Insights), Chapter 4, pp-67-68.

²⁶ Acton v. Blundell. 152 Eng. Rep. 1223 (Ex. Ch.), 12 Mees. & W. 324 (1843).

and/or negligence that proximately causes land subsidence.²⁷ This rule is not widely prevalent and persists only in a few states like Texas and Maine.²⁸

b. Reasonable Use

This doctrine allows a landowner to pump unlimited amount of groundwater as long as the landowner puts the water to reasonable use on the overlying land.²⁹ However, if he uses this water off-tract (e.g. selling to others at different location) he/ she incurs more liability. It is also true that any use cannot interfere with the reasonable use of groundwater by the neighboring property owners.³⁰ There is no clear definition of "reasonable use" and unlike the "reasonable use" in riparian rights law, in the groundwater there is no balancing of interests and there is no scrutiny of the nature and purpose of on-tract use. As long as the on-tract uses are not overtly wasteful or causing harm to others, these are viewed as "reasonable."³¹ However, most of the reasonable use states have changed their groundwater laws to incorporate either correlative rights or the Restatement second of Torts.³²

c. Correlative Rights

This doctrine is considered to have originated in California and later spread to other states. In a seminal case, *Katz v. Walkinshaw*, the court determined that the landowners overlying aquifers can put that groundwater to a reasonable and beneficial use on the overlying land, but the groundwater should be shared equitably between the overlying landowners i.e. in proportion to their land holdings (hence the term "correlative" rights).³³ There are a few states that apply this doctrine 'purely.' Even California has replaced it with a comprehensive groundwater management regulation in 2014.³⁴

d. Restatement (Second) of Torts

This doctrine has elements of two doctrines- reasonable use and correlative rights and it recognizes the connection between surface water and groundwater. Restatement test

²⁷ See, Craig et al., supra note 25 at 68.

²⁸ See, e.g. Sipriano v. Great Spring Waters of America Inc., 1 S.W. 3d 75 (Tex.1999) (The court reaffirmed applicability of the rule of capture in Texas in absence of legislative action).

²⁹ See, Craig et al., supra note 25 at 69.

³⁰ See Meeker v. City of East Orange, 74 A. 379 (N.J. 1909).

³¹ See, Craig et al., supra note 25 at 69.

³² *Id.* at 70.

³³ Katz v. Walkinshaw, 74 P. 766 (Cal. 1903).

³⁴ See, Craig et al., supra note 25 at 71.

assumes the ownership of groundwater that is pumped from one's overlying land and presumes against any liability for groundwater pumping. However, there are three exceptions to this presumption: (a) "unreasonable harm" caused to the neighbor due to pumping (e.g. lowering the water table or reducing artesian pressure), (b) groundwater withdrawal exceeding the landowner's reasonable share of storage or annual supply, and (c) groundwater withdrawal "directly and substantially" impacting the nearby water body (lake or stream) and unreasonably causing harm to its users.³⁵ The Restatement relies on the factors of balancing used in the riparian rights law to determine "reasonable use."³⁶

e. Prior Appropriation

The doctrine includes four key elements- diverting water and applying it to a beneficial use (establishing the water right and the beneficial use), excluding others from using the same water, using the water distant from the source, and selling the water to third parties.³⁷ Majority of the western states applied the prior appropriation to regulate their groundwater resources.³⁸ In the context of groundwater, seniority is based on the order in which water is extracted from the aquifer and put to beneficial use.³⁹ The basis, measure, and the limit of the right is beneficial use of groundwater. In the prior appropriation system, most groundwater rights are relatively junior to the surface water rights. The groundwater rights holders have to compensate for their impacts on the senior rights holders and in times of water scarcity, it could lead to termination of groundwater pumping. 40 Like with surface water prior appropriation, the groundwater version of the doctrine retains its features of "use it or lose it" and of avoiding unnecessary wastage. However, there are many complexities while applying this doctrine in groundwater context. For example, how to address the challenges of 'aquifer mining' where withdrawals (existing plus proposed) deplete the aquifer at levels that exceed the rate of recharge. Such a scenario could be addressed by limiting the approval of appropriative rights to the level of estimated recharge

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³⁵ Sections 858. Restatement (2d) of Torts.

³⁶ These factors include the "purpose of the use; the suitability of the use to the place; the economic value of the use; the social value of the use; the extent and the amount of harm caused; the practicality of avoiding harm by adjusting the means of use or the use itself; the practicality of adjusting the amount of use by each landowner; protection of existing uses, land value, and investments; and the "justice of requiring the user causing harm to bear the loss." Sections 850- 850 A. Restatement (2d) of Torts.

³⁷ Ross, Andrew. (2016). Groundwater Governance in Australia, the European Union and the Western USA. In Jakeman et al., (eds.). Integrated Groundwater Management- Concepts, Approaches and Challenges. Chapter 6, 155-156. National Centre for Groundwater Research and Training (Springer).

³⁸ Schlager E. (2006). Challenges of governing groundwater in US western states. Hydrogeology Journal, 14, 350–360.

³⁹ See, Craig et al., supra note 25 at 73.

⁴⁰ See, Ross, supra note 37 at 155- 156.

rate of the aquifer.⁴¹ But such a limiting approach has not been adopted by many states, resulting in groundwater mining and lowering of water table over time in different parts of the country.⁴²

The application of the five doctrines varies from state to state and also within states. It is difficult to categorize the states fitting in one of these doctrines as the states have chosen different aspects of these doctrines suitable to their context. Further, many states are moving away from the common law doctrines and creating statutory frameworks for groundwater management.

C. Groundwater laws of California and Texas

California and Texas are among the largest users of groundwater in the US. As a percentage of all groundwater withdrawals, California with 16% is the largest user of groundwater, followed by Texas at 10 %.⁴³ Two of the three aquifer systems of the US most impacted by groundwater depletion fall in these states- the Central Valley of California (California) and the High Plains (Texas).⁴⁴ The groundwater laws of the two states offer an opportunity to study different groundwater regimes: Texas, where the common law doctrine of 'absolute ownership,' is largely driving the groundwater extraction in the form of the 'rule of capture,' and California, which moved away from the 'absolute ownership' of groundwater a century ago. In California, a variety of common law principles are in action including its recently developed state-wide statutory framework on groundwater management.

1. California groundwater law

In California's groundwater regulation, the case laws played a crucial role in changing the nature of associated rights and usage. It originally followed the rule of absolute ownership before adopting the rule of "correlative rights" in *Katz v. Walkinshaw* (1903). ⁴⁵ Later cases decided that once the needs of all overlying pumpers have been met, the surplus water

⁴⁴ For details *see*, Konikow, Leonard F. (2015). Long-term Groundwater Depletion in the United States. Vol. 53, No.1-Groundwater (pg 2 -9). National Center, U.S. Geological Survey.

⁴¹ See, e.g., Baker v. Ore-Ida Foods, Inc., 513 P. 2d 627 (Idaho 1973) (Held that the Idaho statute prohibited groundwater mining).

⁴² See, Craig et al., supra note 25 at 73, 74.

⁴³ See, AGI, supra note, 21.

⁴⁵ California State Water Resources Control Board. The Water Rights Process. (undated). Available at https://www.waterboards.ca.gov/waterrights/board info/water rights process.html#rights.

could be appropriated by the non-overlying landowners under the rules of prior appropriation.⁴⁶ The courts later ruled that the pumpers may acquire prescriptive rights for the groundwater. Through these rights, the appropriators may acquire equal priority to pump groundwater in situations of groundwater pumping keeps the basin in overdraft for five years or more.⁴⁷

Additionally, California has managed groundwater regulation in various ways: (a) creating "adjudicated" basins- the parties in dispute over groundwater could initiate the formal adjudication and the equitable apportionment of water would be determined by a court or the State Water Resources Control Board, (b) creating 12 Special Act districts with legal powers to limit the extractions, (c) regulating groundwater by creating local groundwater ordinances,⁴⁸ and (d) allowing groundwater management by local agencies.⁴⁹ In 2014, California passed the Sustainable Groundwater Management Act (SGMA), mandating sustainability for groundwater basins in the state. It established a state-wide mandate for creating Groundwater Sustainability Agencies (GSAs) in high and medium priority basins, which will develop and implement the Groundwater Sustainability Plans (GSPs) for achieving groundwater sustainability in a period of 20 years.⁵⁰ Of the total 515 groundwater basins in the state, GSP development is required for 94 basins.⁵¹ However, in combination with the adjudicated areas which have governance and oversight in place, these basins account for 98 percent of the pumping, 83 percent of the population, and 88 percent of all irrigated acres within the state's groundwater basins.⁵²

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⁴⁶ Perrone, Debra et al., Water in the West, Stanford University. Available at http://groundwater.stanford.edu/dashboard/index.html.

⁴⁷*Id*.

 $^{^{48}}Id.$

⁴⁹ AB 3030, passed in 1992, allowed local agencies to voluntarily create groundwater management plans. SB 1938, passed in 2002, required that public agencies looking for state money for groundwater projects submit a groundwater management plan. AB 359, passed in 2011, required that public agencies prepare and implement a groundwater management plan and additionally focus on identifying groundwater recharge areas. For details, *see*, California Department of Water Resources. Non-SGMA Groundwater Management. (Undated). Available at https://water.ca.gov/Programs/Groundwater-Management/Non-SGMA-Groundwater-Management.

⁵⁰ Lubell, Mark, et al., (2020). Sustainable Groundwater Management in California: A Grand Experiment in Environmental Governance, Society and Natural Resources, 33:12, 1447-1467.

⁵¹ SGMA required Department of Water Resources to prioritize the state's 515 groundwater basins. 2015 basin prioritization identified 127 high and medium priority basins, which were reduced to 94 in 2019. Mostly the adjudicated basins were removed. For details, see, California Department of Water Resources. Basin Prioritization. (Undated). Available at https://water.ca.gov/programs/groundwater-management/basin-prioritization.

⁵² *Id*.

2. Texas groundwater law

In Texas, the surface water belongs to the state, while the groundwater is held to be the property of the overlying landowner in contrast. In 1904, the courts adopted the 'rule of capture' and allowed unlimited pumping of groundwater without incurring liability from neighboring property owners.⁵³ In 1917, the constitution of Texas was amended to include section on 'conservation and development of natural resources' that gave the state legislature powers to pass "all such laws as may be appropriate." With respect to the rule of capture, the legislature has not abrogated it. In deference to this legislative framework, the courts have decided not to alter the property rights rules arising from the rule of capture.

The rule of capture is still in practice and allows a landowner to drill a well and pump the water without any permit. However, derived from the common law and state legislation, there are a few limitations on the rule of capture, such as capturing groundwater for beneficial use without waste, pumping water without malice, and without causing subsidence of the land of a neighboring property.⁵⁵ In *Sipriano v. Great Spring Waters of America Inc.*,⁵⁶ the court reaffirmed the applicability of the rule of capture in Texas in absence of legislative action.

Other limitations on groundwater extraction are placed through the Groundwater Conservation Districts (GCDs) created by the state legislation in 1949. The GCDs regulate the well spacing, groundwater production, and permits along with developing the groundwater management plans.⁵⁷ There are almost 100 GCDs in the state having power to regulate groundwater extraction within their boundaries, such as granting permit to a landowner for drilling a new well or altering the existing one.⁵⁸ However, one-third of Texas is not regulated by the GCDs.⁵⁹

⁵³ Houston.C. Ry. Co. v. East. 81 S.W.279 (Tex.1904). Supreme Court of Texas.

⁵⁴ The Texas Constitution. Article 16. General provisions. Section 59. Conservation and Development of Natural Resources and Parks and Recreational facilities; Conservation and Reclamation Districts.

⁵⁵ Liebert, T. (2020). Texas Water Law: A Legal Research Guide. Vol 84. P-6.

⁵⁶ Sipriano v. Great Spring Waters of America Inc., 1 S.W. 3d 75 (Tex.1999)

⁵⁷ Russell, C. Texas Water Issues: Groundwater Conservation Districts' Rules and Regulations and other Legal obstacles awaiting unsuspecting landowners. Chapter 19.2. State Bar of Texas. 15th Annual Changing Face of Water Rights Course. February 27 - 28, 2014. (p-2-4).

⁵⁸ See, Liebert, supra note 55 at 12,13.

⁵⁹ *Id.* at 6.

D. Analysis of the select Groundwater laws of California and Texas

To explore if the regulatory cycle in groundwater is adaptive or not, the following section analyzes the general law and policy making process in California and Texas along with the select groundwater laws of these states. For California, it is the Sustainable Groundwater Management Act (2014) and related provisions (as chaptered including provisions of California Water Code and California Government Code), and for Texas, these are the groundwater related chapters in Texas Water Code and Texas Water Development Board Rules.⁶⁰

1. Pre-Implementation

The rulemaking processes of California and Texas require the agencies to conduct regulatory and economic impact assessment of the proposed regulations though there is no explicit requirement for risk assessment. However, the process mandates assessment of adverse economic impact of the proposed regulations. In this regulatory stage, the law making and the rulemaking process of both states are consultative and participatory.

a. Assessing risk and uncertainty

In both states, the rulemaking process of major/ significant rules requires agencies to conduct regulatory impact analysis (RIA). The California's Administrative Procedure Act (APA) requires the assessment of potential adverse economic impact of proposed regulation on business enterprises and individuals.⁶¹ Similarly, the Texas APA requires assessment of potential adverse economic effect on small businesses or rural communities.⁶² In this context, assessing risks could be considered a part of RIA, though there is no explicit requirement of conducting risk assessment.

Designation of River and Coastal Basin). Available at

https://www.twdb.texas.gov/groundwater/rules_statutes/index.asp.

⁶⁰ As identified on the official website of the Texas Water Development Board (TWDB) (*Texas Water Code*-Chapter 16: Provisions Generally Applicable to Water Districts; Chapter 35- Groundwater Studies;

Chapter 36- Groundwater Conservation Districts; Chapter 49- Provisions Applicable to All Districts; And *TWDB Rules*: Chapter 356- Groundwater Management; Chapter 357- Regional Water Planning Guidelines; Chapter 358- State Water Planning Guidelines; Chapter 359- Water Banking; and Chapter 360-

⁶¹ Cal. Gov't Code § 11346.3(a).

⁶² Texas Gov't Code §§ 2006.001-.002 and Tex. Gov't Code § 2006.002(d)(1).

Additionally, there are examples of risk and uncertainty assessment in the analyzed groundwater laws. The California's groundwater law provides for addressing the 'undesirable results' through groundwater sustainability plans (GSPs). The undesirable results include chronic lowering of groundwater levels, significant and unreasonable reduction of groundwater storage, significant and unreasonable- seawater intrusion, degraded water quality, and land subsidence, and depletion of interconnected surface water. ⁶³ It requires the GSP to include activities that could create risks to groundwater quality or quantity ⁶⁴ and in prioritizing the groundwater basins, the department is required to consider the adverse impacts on the local habitat and local stream flows among other factors. ⁶⁵

Similarly, the Texas law provides for identifying, designating, and delineating 'priority' groundwater management areas. Such priority areas include the areas that are experiencing or expected to experience critical groundwater problems in the immediate 50-year period. Examples of critical problems include, groundwater shortages, land subsidence from groundwater withdrawal, and groundwater supply contamination. ⁶⁶ California law requires the state auditor to conduct risk assessment while determining if a district is operational (i.e. its performance in achieving the objectives of the district management plan) ⁶⁷ and the development board to assess the projected impacts of brackish groundwater production in terms of significant aquifer level declines, negative effects on water quality, and subsidence while granting permits in brackish groundwater production zones. ⁶⁸

b. Broader and fuller impact assessment

The state legislative committees play an important role of reviewing and analyzing the proposed legislations. In both, California and Texas, the proposed legislative actions are referred to the legislative committees for review and hearing.⁶⁹ The committees submit

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⁶³ The law defines "Undesirable result" as one or more of the specified effects caused by groundwater conditions occurring throughout the basin. For details, see, Sustainable Groundwater Management Act (SGMA) § 10721. Definitions (x). Also, *see*, § 10727.2.

⁶⁴ SGMA, § 10727.4 (l).

⁶⁵ SGMA, § 10933 (b) (8).

⁶⁶ Tex. Water Code. § 35.007(a).

⁶⁷ Tex. Water Code. § 36.302 (d).

⁶⁸ Tex. Water Code. § 36.1015 (j)

⁶⁹ For California, see, Legislative Council. State of California. (Undated). Official California Legislative Information- Overview of Legislative Process. Available at http://www.leginfo.ca.gov/bil2lawx.html. For Texas, see, Texas House of Representatives. How A Bill Becomes a Law. Available at https://house.texas.gov/about-

detailed reports based on the testimonies and written submissions of a variety of stakeholders, research studies, practices in other states, and reports of experts.⁷⁰ Thus, these committees could be considered an important forum to assess broader impacts of the proposed legislation/bill.

In rulemaking, California's APA requires the state agencies to publish 'initial statement of reasons' while proposing a regulation or change therein.⁷¹ For 'major' regulations, it requires standardized regulatory impact analysis,⁷² and for 'non-major' regulations, it requires the economic impact assessment.⁷³ The standardized regulatory impact assessment has elaborate provisions of assessing the costs and benefits of the proposed regulatory, the proposed regulatory alternatives, along with the distributional effects.⁷⁴

Similarly, in the proposed rule, Texas APA requires the state agencies to publish detailed information including the benefits and costs of the rule for each of the first five years when the rule will be in effect;⁷⁵ impact assessment on local economies (if applicable),⁷⁶ and for certain major environmental rules, regulatory analysis and draft impact analysis.⁷⁷ If the proposed rule have an adverse economic effect on the small or micro businesses or rural communities, the agency must prepare the economic impact assessment along with regulatory flexibility analysis.⁷⁸ Further, the office of Governor has authority to review the rules of select agencies to see if the proposed rules would affect market competition in the state by creating a barrier to market participation, resulting in price rise, or reducing competition.⁷⁹

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us/bill/#:~:text=If%20the%20governor%20neither%20vetoes,become%20law%20without%20a%20sign ature. Also, see, Texas Legislative Council. (2021). The legislative Process in Texas. Available at https://tlc.texas.gov/docs/legref/legislativeprocess.pdf.

⁷⁰ For example, House Committee on Natural Resources. Interim Report to the 87th Texas Legislature. December 2020. Available at https://lrl.texas.gov/scanned/interim/86/n218h.pdf.

⁷¹ Cal. Gov't Code § 11346.2 (b).

⁷² Cal. Gov't Code § 11346.3 (c). Also, *see*, California Code of Regulations, § 2002. Available at https://www.dgs.ca.gov/Resources/SAM/TOC/6000/6600

⁷³ Cal. Gov't Code § 11346.3 (b).

⁷⁴ Cal. Gov't Code § 11346.36 (b). Also, see, California Code of Regulations, § 2003. Methodology for Making Estimates.

⁷⁵ Tex. Gov't Code § 2001.024(a).

⁷⁶ I.J

⁷⁷ Tex. Gov't Code § 2001.0225.

⁷⁸ Tex. Gov't Code § 2006.002.

⁷⁹ Tex. Occ. Code §§ 57.105(d).

Additionally, the analyzed groundwater laws have several provisions reflecting broader and fuller impact assessment in regulating groundwater. For example, California's state policy acknowledges that groundwater resources should be managed sustainably to have economic, social, and environmental benefits for current and future beneficial uses.⁸⁰ Other examples include requiring the groundwater sustainability agencies (GSAs) to consider the interests of all beneficial uses and users of groundwater; ⁸¹ requiring comprehensive analysis of multiple elements while preparing the groundwater sustainability plans (GSPs),⁸² and requiring the department to consider multiple factors while prioritizing groundwater basins and sub-basins.⁸³

Texas law requires the groundwater conservation districts (GCDs) to consider a variety of factors including environmental impacts, socio-economic impacts, impacts on subsidence, impacts on the interests and rights in private property, before voting on the desired future conditions of aquifers;⁸⁴ to consider all groundwater use and needs, public interest in conservation, and goals of district management plan while making and adopting a rule,⁸⁵ and to consider water availability in the district, projected effect on aquifer conditions, depletion, subsidence, effects on existing permit holders, along with the approved regional water plan and district management plan while reviewing a proposed transfer of groundwater out of district.⁸⁶ Other examples include, elaborate assessments before granting the permit to operate in the brackish groundwater production zone;⁸⁷ considering 25 guidance principles for developing state water plans;⁸⁸ undertaking studies of underground water supply to investigate its occurrence, quantity, and quality along with

⁸⁰ Cal. Water Code § 113.

⁸¹ Such as agricultural, domestic, municipal, public water systems, local land use planning agencies, environmental users, surface water users, federal government, native American tribes, disadvantaged communities, and groundwater monitoring entities. For details, see, SGMA § 10723.2.
82 SGMA § 10933 (b).

⁸³ SGMA § 10727.2. (Such as historical data related to water/ aquifer data, groundwater levels, subsidence, groundwater-surface water interaction, historical and projected demand and supply of water, potential recharge areas of the basin, consideration of applicable county and city general plans, related water resources plans and programs). Also, see, SGMA § 10727.4. (Additional elements include control of saline water intrusion, well construction policies, efficient water management practices, review land use plans and assess activities that could potentially create risks to groundwater quality or quantity, and overall impact on groundwater dependent ecosystems).

⁸⁴ Tex. Water Code. § 36.108(d). Also, see, Tex. Admin. Code. Rule § 356.10. Definitions (9). (Desired Future Conditions- "The desired, quantified condition of groundwater resources within a management area at one or more specified future times as defined by participating groundwater conservation districts with a groundwater management area as a part of the joint planning process").

⁸⁵ Tex. Water Code. § 36.101 (a).

⁸⁶ Tex. Water Code. § 36.122 (f).

⁸⁷ These include the simulation of the projected effects of the proposed production on water levels and quality. For details, *see*, Tex. Water Code. § 36.1015. Also, *see*, Tex. Admin. Code. Rule § 356.71.

⁸⁸ Tex. Admin. Code. Rule § 358.3.

finding feasible methods to preserve, conserve, improve and supplement the resource;⁸⁹ and considering a variety of impacts while developing the Regional Water Plans (RWP) including the potential impacts on public health, safety, and welfare⁹⁰ and a quantitative description of the socio-economic impacts of not meeting the identified water needs in the RWP.⁹¹

c. Public participation

In both states, the legislative and rulemaking processes are participatory in nature.

In California, the legislative committee hearings are generally public in nature where the citizens can testify before the committee. ⁹² In preliminary rulemaking activities, ⁹³ it is discretionary for the agency to include public. However, the agency is required to involve the stakeholders /parties who would be subjected to such regulations. ⁹⁴ For the proposed regulation, the public comment period is 45 days. ⁹⁵ The agency must respond to all comments and include the summary and response to comments in 'Final statement of reasons' as a part of the rulemaking document. ⁹⁶ However, in the events of 'emergency rulemaking' there is a brief public comment period of five calendar days. ⁹⁷ Another practice which keeps a check on agency following the APA procedures relates to 'underground regulations.' It encourages public to challenge the agency regulatory action where the agency bypasses APA procedures in rulemaking by filing a petition with the Office of Administrative Law. ⁹⁸

https://www.assembly.ca.gov/legislativeprocess.

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 $^{^{89}}$ Tex. Water Code. \S 16.015. Also, see, \S 16.012.

⁹⁰ Tex. Admin. Code. Rule § 357.22.

⁹¹ Tex. Admin. Code. Rule § 357.40.

⁹² California State Assembly. Legislative Process. (Undated). Available at

⁹³ Preliminary rulemaking-where the agency is researching and gathering material required for formal APA rulemaking.

⁹⁴ Cal. Gov't Code § 11346.45 (a). Also, *see*, Office of Administrative Law (OAL). About the Regular Rulemaking Process. (Undated). Available at https://oal.ca.gov/rulemaking-participation/

⁹⁵ Cal. Gov't Code § 11346.4 (a).

⁹⁶ Cal. Gov't Code § 11346.9 (a) (3). Also, see, OAL, supra note 94.

⁹⁷ Cal. Gov't Code § 11346.1 (2). Also, see, Office of Administrative Law (OAL). About the Emergency Rulemaking Process. (Undated). Available at

https://oal.ca.gov/emergency_regulations/Emergency_Regulation_Process/.

⁹⁸ Office of Administrative Law (OAL). Underground Regulations. (Undated). Available at https://oal.ca.gov/underground regulations/.

In Texas, the legislative committee hearings are generally public in nature allowing citizens to present arguments on different aspects of the bill.⁹⁹ In preliminary/ contemplated rulemaking, the agencies can appoint expert committees or public representatives or interested persons to advise the agency.¹⁰⁰ Such committees may assist the agency by providing inputs on rules and assisting in rule drafting. In the proposed rulemaking, the agency must provide public notice and comment for 30 days.¹⁰¹ The agency must respond to all public comments (written and oral) in its formal order of adopting the rule.¹⁰² Further, any interested person may petition an agency to adopt a rule¹⁰³ and the agency must accept or deny the petition within 60 days.¹⁰⁴ The law also provides for 'negotiated rulemaking' where the initial rule is developed by a committee of representatives of interested persons who will be affected by the rule, followed by the agency adopting the rulemaking process including public notice and comment.¹⁰⁵ While drafting the proposed rules, the Texas State Soil and Water Conservation Board may engage in negotiated rulemaking.¹⁰⁶

Additionally, the analyzed groundwater laws encourage public participation in the preimplementation stage. California's law provides for public participation before adopting the regulations to evaluate the proposed revisions of basin boundaries. It requires notice and comment period of 30 days and conduct at least three public meetings.¹⁰⁷ In Texas, while exercising rulemaking power, the district should publish the proposed rule and hold a public hearing.¹⁰⁸ Similarly, prior to the preparation of regional water plan, the Regional Water Planning Group (RWPG) shall hold at least one public meeting to gather public recommendations and suggestions.¹⁰⁹

⁹⁹ See, Texas Legislative Council, supra note 69, at 2,3.

¹⁰⁰ Tex. Gov't Code § 2001.031(b).

¹⁰¹ Tex. Gov't Code § 2001.023(a).

¹⁰² Tex. Gov't Code § 2001.033.

¹⁰³ Tex. Gov't Code § 2001.021(a). An "interested person" must be: 1. A resident of the State of Texas; 2. A business entity located in the State of Texas; 3. A governmental subdivision located in the State of Texas; or 4. A public or private organization located in the State of Texas that is not a state agency. For details, *see* Tex. Gov't Code § 2001.021(d).

¹⁰⁴ Tex. Gov't Code § 2001.021(c).

¹⁰⁵ Tex. Gov't Code § 2008.053(a). (The federal government enacted the Negotiated Rulemaking Act of 1990 and established a statutory framework for the agency to use the process. Negotiated rulemaking has been used by many federal agencies, including the EPA, as well as the state governments). For details, see, University of Texas School of Law. (1996). Texas Negotiated Rulemaking Deskbook. Center for Public Policy Dispute Resolution. P- 50,51. Available at https://law.utexas.edu/wp-

content/uploads/sites/30/2015/10/Texas-Negotiated-Rulemaking-Deskbook-web.pdf.

¹⁰⁶ Texas State Soil & Water Conservation Board. Negotiated Rulemaking Policy. Available at https://www.tsswcb.texas.gov/negotiated-rulemaking-policy.

¹⁰⁷ SGMA, § 10722.2 (d).

¹⁰⁸ Tex. Water Code. § 36.101 (d), (e) and (f).

¹⁰⁹ Tex. Water Code. § 16.053 (h) (1).

Key Points:

- Both California and Texas rulemaking processes do not mandate assessing risks of proposed regulations, except the assessment of adverse economic impact.
 However, the state groundwater laws have examples of assessing such risks in groundwater management.
- Both California and Texas rulemaking processes mandate regulatory impact assessment of major/significant rules. State groundwater laws have several examples of assessing multiple factors in groundwater management with more examples in Texas law.
- In both states, the rulemaking processes at pre-implementation stage are participatory. Public notice and comment, and response to comments is a mandatory requirement.

2. Implementation

Both California and Texas groundwater laws have detailed provisions on data collection, reporting and monitoring. Also, the groundwater management in both states is participatory.

a. Monitoring, Evaluation, and Feedback

California- State groundwater law acknowledges the importance of improving data collection and understanding on groundwater.¹¹⁰ There are timelines for implementing groundwater sustainability plans (GSPs) in high and medium priority basins.¹¹¹ As a part of 'required elements' the GSPs must have measurable objectives, including interim milestones to achieve the sustainability goal within 20 years of plan's implementation.¹¹² The GSPs also have components relating to monitoring and management of groundwater.¹¹³

¹¹¹ SGMA, § 10720.7.

¹¹⁰ SGMA, § 10720.1.

¹¹² SGMA, § 10727.2. (b) (1).

¹¹³ SGMA, § 10727.2. (d), (e), (f). ("including the type of monitoring sites, type of measurements, frequency of monitoring for each location, and monitoring protocols for detecting changes in groundwater levels, quality, subsidence, and flow and quality of surface water).

Other examples include authorizing the GSAs to investigate monitoring compliance including inspecting the property or facilities of entities or persons, ¹¹⁴ requiring installation of water measuring devices for groundwater extraction in the management areas and filing annual statement of yearly extraction, ¹¹⁵ annually reporting of groundwater elevation data by the GSAs, ¹¹⁶ and reporting of groundwater extraction for probationary basins and basins without a GSA. ¹¹⁷

In addition to the GSAs, the law authorizes several entities to assume responsibility for monitoring and reporting the groundwater elevations such as a watermaster, groundwater management agency, local agency, county, and voluntary cooperative groundwater monitoring association.¹¹⁸ Other provisions include the department monitoring the groundwater elevation within each basins and sub-basins¹¹⁹ and taking action if monitoring is not pursuant to the statutory requirements.¹²⁰ Every five years, the department must report its findings on identifying groundwater basins subject to critical conditions of overdraft to the Governor and the state legislature.¹²¹

Texas- State groundwater law provides for conducting district level groundwater surveys for determining the quantity of available water and determining improvement, development and recharge. Similarly, there are provisions for collecting information by a district on the use of groundwater, water conservation, and practicability of recharging a groundwater reservoir; conducting annual surveys of groundwater and surface water use for long-term water supply planning, and providing training on basic data collection methodology and reporting to the interested districts.

The groundwater management plans are time-based and quantifiable, ¹²⁶ along with management goals, performance standards, ¹²⁷ management objectives, and the

¹¹⁴ SGMA, § 10725.4.

¹¹⁵ SGMA, § 10725.8.

¹¹⁶ SGMA, § 10728.

¹¹⁷ Cal. Water Code § 5203.

¹¹⁸ Cal. Water Code § 10927.

¹¹⁹ Cal. Water Code § 10933 (a).

¹²⁰ Cal. Water Code § 10933 (c), (d), and (e).

 $^{^{121}}$ Cal. Water Code \S 12924.

 $^{^{122}}$ Tex. Water Code. \S 36.106.

¹²³ Tex. Water Code. § 36.109.

¹²⁴ Tex. Admin. Code. Rule § 358.5.

¹²⁵ Tex. Admin. Code. Rule § 356.6.

¹²⁶ Tex. Admin. Code. Rule § 356.51.

¹²⁷ Sec 36.1071. TWC. Also, see, Tex. Admin. Code. Rule § 356.52.

methodology to track a district's progress on annual basis.¹²⁸ Through annual meetings, the district representatives review the management plans in terms of achieving the goals, effectiveness of measures, and degree of achievement of desired future conditions.¹²⁹

There are several reporting requirements such as, biennial report on designating the priority groundwater management areas;¹³⁰ reporting by the owner/ operator of wells regarding drilling, equipping, and completing of water wells and the production and use of groundwater;¹³¹ annual reporting by the permit holders in brackish groundwater production zones;¹³² biennial progress reporting on desalination studies by the board;¹³³ reviewing water conservation plan and annual reporting to determine compliance with statutory requirements;¹³⁴ and water loss auditing at specified time intervals by the public utilities providing potable water.¹³⁵

b. Public Participation

In California, the groundwater law provides for public participation in implementing the statutory provisions. For example, before deciding to become a GSA, the local agency shall hold public hearing in the counties overlying the basin;¹³⁶ in developing the groundwater sustainability plans (GSPs), the GSAs must notify the public;¹³⁷ while evaluating the GSPs, the department must publish the plan on its website and provide 60 days for public comments;¹³⁸ for amending the GSPs, the GSAs must hold public hearing and provide notice of at least 90 days;¹³⁹ in developing the best management practices for sustainable management of groundwater, the department must involve public;¹⁴⁰ and while designating

¹²⁸ *Id*.

¹²⁹ Tex. Water Code. § 36.108 (c).

¹³⁰ Tex. Water Code. § 35.018.

¹³¹ Tex. Water Code. § 36.111 and § 36.112.

¹³² Tex. Water Code. § 36.1015.

¹³³ Tex. Water Code. § 16.060. (to be submitted to the Governor and Speaker, House of Representatives).

¹³⁴ Tex. Water Code. § 16.402.

¹³⁵ Tex. Admin. Code. Rule § 358.6.

¹³⁶ SGMA, § 10723 (b).

¹³⁷ SGMA, § 10727.8. (It may appoint advisory committees of interested persons to participate in the development and implementation of these plans).

¹³⁸ SGMA, § 10733.4. (a) and (c).

¹³⁹ SGMA, § 10728.4.

 $^{^{140}}$ SGMA, § 10729 (d) (1) and § 10729 (d) (2). (The statute specifies at least four geographical locations where the public meetings must be conducted).

probationary basins and adopting interim plans, the board must provide public hearing with at least 90 days' notice.¹⁴¹

In Texas, in addition to the general statute requirements of the agencies providing 'internet access to rules' ¹⁴² and holding open meetings, ¹⁴³ there are specific provisions in the Texas groundwater laws/rules mandating public participation. For example, while designating and delineating the priority groundwater management areas, the commission must publish the notice of hearing and give at least 30 days of notice; ¹⁴⁴ requiring public hearing on the proposed 'desired future conditions' and preparing summary of comments by each GCD; ¹⁴⁵ requiring public notice and public hearing on consolidation of districts; ¹⁴⁶ requiring public notice and public hearing on permit or permit amendment applications; ¹⁴⁷ requiring the approval of a majority of voters before an area is included in a GCD; ¹⁴⁸ rulemaking hearing by the GCD after giving at least 20 days' public notice; ¹⁴⁹ encouraging public participation in groundwater management process within groundwater management area not represented by a GCD; ¹⁵⁰ while designating the brackish groundwater production zone, the agency¹⁵¹ shall work with the GCDs and the stakeholders; ¹⁵² increasing public awareness by GCDs by sharing plans and information on groundwater use; ¹⁵³ and developing and implementing state-wide water conservation public awareness programs. ¹⁵⁴

There are similar provisions of public participation while reviewing and updating the designations of the regional water planning areas;¹⁵⁵ identifying potentially feasible water management strategies by the Regional Water Planning Group (RWPG);¹⁵⁶ and creating a

¹⁴¹ SGMA, § 10736 (b), (c), and (d).

 $^{^{142}}$ Tex. Gov't Code § 2001.007(b). (Each state agency must make their rules publicly available on the internet and provide opportunity to the public to electronically send their questions on the rules to the agency and receive the agency answers electronically).

¹⁴³ Tex. Gov't Code § 551.002. (Unless specified, all meetings of a governmental body shall be open to the public).

¹⁴⁴ Tex. Water Code. § 35.009 (a).

¹⁴⁵ Tex. Water Code. § 36.108(d-2).

¹⁴⁶ Tex. Water Code. § 36. 353.

¹⁴⁷ Tex. Water Code. § 36. 403.

¹⁴⁸ Tex. Water Code. § 36.012 (e).

¹⁴⁹ Tex. Water Code. § 36.101.

¹⁵⁰ Tex. Water Code. § 35.020.

¹⁵¹ Texas Water Development Board.

¹⁵² Tex. Admin. Code. Rule § 356.70.

¹⁵³ Tex. Water Code. § 36.110.

¹⁵⁴ Tex. Water Code. § 16.401.

¹⁵⁵ Tex. Admin. Code. Rule § 357.11.

 $^{^{156}}$ Tex. Admin. Code. Rule \S 357.12 (b).

website by RWPG for posting public notices along with important information for public knowledge and participation. 157

Key Points:

- Groundwater management/sustainability plans in both states have measurable objectives and time frames.
- Both states have elaborate monitoring and reporting requirements for a variety of stakeholders and agencies at local as well as state level.
- Groundwater law of both states have several provisions mandating public participation in implementing the law, such as in California while creating GSAs and GSPs, and in Texas while creating the GCDs, designating priority management areas, proposing 'desired future conditions', and in GCD's rulemaking.

3. Post-Implementation

General statutes of both states contain provisions for reviewing the existing rules and regulations. Additionally, there are a few examples of post-implementation review in the select groundwater law of California and Texas.

a. Iterative Decision-making and Policy Adjustment

i. Provisions acknowledging change

In California's groundwater law, there are several provisions acknowledging the potential of future changes. For example, updating the groundwater plans and programs based on best available science, 158 extending the GSPs up to five years beyond 20-year sustainability time frame including granting second extension up to five years, ¹⁵⁹ amending the GSPs, ¹⁶⁰ updating regulations by incorporating best management practices, 161 and revising the boundaries of groundwater basins. 162

¹⁵⁷ Tex. Admin. Code. Rule § 357.21.

¹⁵⁸ Cal. Water Code § 113. (This section outlines the state policy of sustainable groundwater management to be achieved through local management and updating of the plans based on best available science).

¹⁵⁹ SGMA, § 10727.2 (b). (The extension may be granted at the request of the Groundwater Sustainability Agency (GSA) subject to conditions, such as demonstrating a need for extension, making progress towards meeting the sustainability goal, and adopting a feasible work plan).

¹⁶⁰ SGMA, § 10728.4. (A GSA may adopt or amend a groundwater sustainability plan (GSP) after holding a public hearing and providing notice to the city/county within the area of proposed plan or amendment).

¹⁶¹ SGMA, § 10733.2. (Pursuant to Section 10729, the department to develop the best management practices for the sustainable management of groundwater by holding public meetings at designated places).

¹⁶² Cal. Water Code § 12924. Also, see, SGMA, § 10722.2 (a).

Examples from Texas groundwater law include altering the boundaries of designated management areas as required by future conditions and factual data, ¹⁶³ amending the management plans subject to notice and hearing, ¹⁶⁴ and amending a designated brackish groundwater production zone on agency's own initiative or on the request by a GCD. ¹⁶⁵

ii. Provisions of review/evaluation

In California, the APA provides for reviewing the existing regulations if any standing, select or joint legislative committee considers that a regulation does not meet specified statutory standards. ¹⁶⁶ Examples from California's groundwater law include periodic review and assessment of GSPs by the GSAs; ¹⁶⁷ periodic review of GSPs at least every five years by the department; ¹⁶⁸ and adopting regulations for evaluating GSPs, their implementation, and evaluating coordination agreements. ¹⁶⁹

In Texas, the state law requires agencies to review and consider re-adoption of all rules every four years. The review must include an assessment of the changed circumstances post rule adoption.¹⁷⁰ In Texas groundwater law, the examples include annually reviewing the need for additional designated priority areas of groundwater management;¹⁷¹ reviewing and readopting the management plan every five years (with or without revisions);¹⁷² proposing and adopting the desired future conditions every five years based on the

¹⁶³ Tex. Water Code. § 35.004

¹⁶⁴ Tex. Water Code. § 36.1071 (g).

¹⁶⁵ Tex. Admin. Code. Rule § 356.70.

¹⁶⁶ Cal. Gov't Code. § 11349.7. Also, *see*, § 11349.1 (a). (The standards are - Necessity, Authority, Clarity, Consistency, Reference, and Non-duplication).

¹⁶⁷ SGMA, § 10728.2. (Based on changing conditions in the basin warranting a change/ modification in the plan) (An evaluation of the plan shall focus on determining whether the actions under the plan are meeting the plan's management objectives and whether those objectives are meeting the sustainability goal in the basin).

 $^{^{168}}$ SGMA, § 10733 and § 10733.8. The department assessments may include recommendations for corrective actions to address the deficiencies identified by the department. (To evaluate whether a plan conforms with relevant sections and is likely to achieve the sustainability goal for the basin covered by the GSP)

¹⁶⁹ SGMA, § 10733.2. (The regulations shall identify appropriate methodologies and assumptions for baseline conditions concerning hydrology, water demand, ... The baseline for measuring unreliability and reductions shall include the historic average reliability and deliveries of surface water to the agency or water users in the basin).

¹⁷⁰ Tex. Gov't Code § 2001.039(b), (c), and (e). (As a part of rule review, an agency must determine if the reasons for initially adopting the rule continue to exist). Also, *see*, The Office of the Attorney General of Texas. Administrative Law Handbook 2020, at 52. Available at

https://www.texasattorneygeneral.gov/sites/default/files/files/divisions/general-oag/adminlaw_hb.pdf. 171 Tex. Water Code. § 35.007(a).

¹⁷² Tex. Water Code. § 36.1072 (e). (The district may review the management plan annually).

groundwater availability models and other data for the relevant aquifers;¹⁷³ reviewing the amount of groundwater that may be transferred out of district under the permit;¹⁷⁴ and requiring legislative audit review every seven years to determine GCD's achievement of the objectives of management plan.¹⁷⁵

Texas' water code has other examples of planned reviews such as state water planning guidelines requiring the state water plan to include evaluation of all water management strategies and projects recommended in the previous state water plan;¹⁷⁶ reviewing and updating the regional water planning areas as necessary but at least every five years;¹⁷⁷ amending the adopted regional water plan due to changed conditions or new information;¹⁷⁸ and updating the guidance principles for the state water plan as necessary but at least every five years.¹⁷⁹

Key points

- California APA requires review of existing regulations if they don't fulfil specified statutory standards. Whereas, Texas state law requires all state agencies to review the rules every four years.
- Both states provide for periodic review of their respective groundwater management/ groundwater sustainability plans (GSPs) every five years along with updating and amending these plans based on science or other grounds.
- California groundwater law requires regulations for evaluating the GSPs and their implementation.
- Texas groundwater law has additional periodic review provisions, such as annual review of the designated priority areas of groundwater management, adopting desired future conditions every five years, and legislative audit review every 7 years.

4. US groundwater laws and Adaptive governance structures

The governance structures in California and Texas reflect polycentrism as well as interagency coordination. In California, the law authorizes the local agencies to manage

¹⁷³ Tex. Water Code. § 36.108 (d).

¹⁷⁴ Tex. Water Code. § 36.122. (k) (The district shall consider: the availability of water in the district and in the proposed receiving area; the projected effect of the proposed transfer on aquifer conditions, depletion, subsidence, or effects on existing permit holders or other groundwater users within the district, and the approved regional water plan and approved district management plan).

¹⁷⁵ Tex. Water Code. § 36.302. (This review must be done and the state auditor to report findings of review to the legislative audit committee and to the commission).

¹⁷⁶ Tex. Admin. Code. Rule § 358.4. Also, *see*, Tex. Water Code. § 16.051. (For the high-priority projects of the previous state water plans, an assessment of the extent of their implementation and analysis of any impediments to implementation).

¹⁷⁷ Tex. Admin. Code. Rule § 357.11.

¹⁷⁸ Tex. Water Code. § 16.054. Also, see, Tex. Admin. Code. Rule § 357.51 (a).

¹⁷⁹ Tex. Water Code. § 16.051 (d).

groundwater and in Texas, the management is at the district level. There are examples of horizontal as well as vertical coordination in the groundwater laws of both states.

a. Polycentric governance

The US Constitution does not mention about the local government and different states vary in the level of authority they delegated to the local governments. The Home Rule states delegate power to the local government bodies (villages, counties, towns, municipalities, etc.) and create local autonomy by limiting relative state interference in local affairs. However, the delegated power is generally limited to specified fields. The other hand, the Dillon Rule states are more restrictive and their the local bodies could exercise only the explicitly granted powers. In case there is a reasonable doubt whether the power is granted to a local government, that implies that the power is not granted. California's Constitution provides for Home Rule as a self-executing power and the Dillon Rule applies to certain local governments. Whereas, Texas is an example of Dillon Home-Rule combination. Texas Constitution recognizes Home Rule and requires an enabling legislation/statute.

California's groundwater law provides authority to the local governments to manage groundwater by establishing the Groundwater Sustainability Agencies (GSAs) at the local level. Additionally, there is the role of counties, the Department of Water Resources, and the State Water Resources Control Board in groundwater management. Other examples include provisions enabling a water corporation or a mutual water company to participate in a GSA through a memorandum of agreement;¹⁸⁸ a GSA entering into agreements with private parties to facilitate implementation of the GSPs,¹⁸⁹ and a GSA appointing advisory

https://nebraskalegislature.gov/pdf/reports/research/snapshot_localgov_2020.pdf.

¹⁸⁰ Moore, Travis. (2020). Legislative Research Office. Dillon Rule and Home Rule: Principles of Local Governance. Available at

¹⁸¹ Id. Also, see, National League of Cities (NLC). Cities 101- Delegation of Power.

¹⁸² Id.

¹⁸³ Article XI. Local Government. Section 5. California Constitution.

¹⁸⁴ See, Moore, supra note, 180.

¹⁸⁵ Id.

¹⁸⁶ Article 11. Municipal Corporations. The Texas Constitution.

¹⁸⁷ To obtain local autonomy, a city is required to go through the process of adopting a home rule charter. This is possible when a city's population exceeds 5,000. For details, *see*, McDonald, J. V. (2000). An analysis of Texas' municipal home rule charters since 1994. Masters of Public Administration, Texas State University, San Marcos, Texas. Also, *see*, Moore, *supra* note, 180.

¹⁸⁸ SGMA, § 10723.6 (f).

¹⁸⁹ SGMA, § 10726.5

committees of interested persons to participate in the development and implementation of these plans. 190

Similarly, in Texas, the law establishes the Groundwater Conservation Districts (GCDs) for groundwater management. Additionally, there is role of the Texas Water Development Board and the Texas Commission on Environmental Quality in groundwater conservation and management. Other examples include the GCDs appointing non-voting advisory subcommittees representing social, governmental, environmental, or economic interests. These sub-committees assist in developing the desired future conditions in groundwater management areas. ¹⁹¹ Other examples include the Regional Water Planning Group (RWPG) to have at least one representative of interested entities as voting members, such as the public, industry, persons or entities with environmental interests, persons or entities with agricultural interests, small businesses, water utilities, groundwater management areas among others; ¹⁹² and consulting stakeholders committee regarding regional prioritization of projects by RWPG. ¹⁹³

b. Inter-agency coordination

There are examples of agency coordination both horizontally (between agency at the same level of government) and vertically (between agencies at different levels of government).

i. Horizontal coordination

California's groundwater law recognizes the importance of close coordination between water supply/ management agencies and the land use approval agencies for effective water supply and management planning.¹⁹⁴ Other provisions include requiring all state agencies to consider the groundwater policies and GSPs when adopting or revising policies, regulations or issuing orders;¹⁹⁵ facilitating multiple local agencies to form a GSA through joint-powers agreement or a memorandum of agreement;¹⁹⁶ and GSAs implementing multiple GSPs by coordinating with other agencies within the basin.¹⁹⁷

¹⁹⁰ SGMA, § 10727.8.

¹⁹¹ Tex. Water Code. § 36.1081 (b).

¹⁹² Tex. Admin. Code. Rule § 357.11 (d).

¹⁹³ Tex. Water Code. § 15.436 (c).

¹⁹⁴ Cal. Gov't Code § 65352.5 (a).

¹⁹⁵ SGMA, § 10720.9.

¹⁹⁶ SGMA, § 10723.6 (e).

¹⁹⁷ SGMA, § 10727.6. (to ensure that the plans use the same data and methodologies in preparing the plan).

In Texas groundwater law, examples include the Texas Water Development Board (TWDB) coordinating with the Department of Agriculture, and the Parks and Wildlife Department while adopting the rule guidance principles for the state water plan;¹⁹⁸ the executive administrator, TWDB coordinating with GCDs and RWPGs while obtaining or developing groundwater availability models for major and minor aquifers;¹⁹⁹ the GCDs within the same/ adjacent management areas coordinating their efforts and jointly conducting studies or research under mutually beneficial terms and conditions; and ²⁰⁰ the inter-regional planning council improving coordination among the Regional Water Planning Groups (RWPGs).²⁰¹

ii. Vertical coordination

In California's groundwater law, examples include recognizing the key role of local agencies in groundwater management while providing state support where necessary;²⁰² the department or the GSA providing technical assistance to entities that extract or use groundwater for promoting groundwater conservation; ²⁰³ and the department providing technical assistance to GSAs in developing and implementing GSPs.²⁰⁴

In Texas' groundwater law, examples include the Texas Commission on Environmental Quality (TCEQ) and the TWDB providing technical assistance to the interested GCDs in developing the management plans including training on data collection methodology;²⁰⁵ each GCD sharing the approved management plan with the RWPGs;²⁰⁶ the executive administrator, TWDB leading a state-wide effort of collecting and disseminating water-related information in coordination with federal, state, and local governments including higher education institutions;²⁰⁷ and the TWDB, the TCEQ, the Department of

¹⁹⁸ Tex. Water Code. § 16.051 (d).

¹⁹⁹ Tex. Water Code. § 16.012 (l).

²⁰⁰ Tex. Water Code. § 36.1086.

²⁰¹ Tex. Water Code. § 16.052 (b) and (c).

²⁰² SGMA, § 10720.1 (h).

²⁰³ SGMA, § 10729 (g).

²⁰⁴ SGMA, § 10729 (h).

²⁰⁵ Tex. Water Code. § 36.1071 (c)and (d).

²⁰⁶ Tex. Admin. Code. Rule § 356.57.

²⁰⁷ Tex. Water Code. § 16.012 (b) (8).

Agriculture, and the Parks and Wildlife Department providing inputs and assistance in local water planning.²⁰⁸

California and Texas Regulatory cycle in groundwater- Summary analysis

The above analysis suggests that the law and rulemaking processes in both states are quite similar in terms of requiring impact assessment of proposed regulations, emphasizing relevant data collection and monitoring, being participatory, and having strong decentralized agencies for groundwater management. Regarding the review of regulations in general, Texas mandates all state agencies to review the rules once every four years whereas, such a general periodic review provision is not there in California. However, in groundwater law, both states require periodic review of their groundwater sustainability/management plans along with California law providing for regulations to evaluate the plan's implementation. Thus, broadly, the groundwater laws of both states seem to have most of the adaptive features in the three stages of their regulatory cycle. However, the states could improve by having explicit mandate to assess risks of the proposed regulations as well as by having provisions of retrospective review of the regulation.

Further, California's SGMA is a state-wide framework, whereas, the GCDs of Texas do not cover one-third of its geographical area. To understand how adaptive these laws are in practice, it is important to interview key stakeholders, which is beyond the scope of this research.

Key points

- On the books, the groundwater laws seem adaptive in both states.
- The rulemaking/lawmaking could be improved by mandating assessing the risks and uncertainties of proposed laws/regulations.
- The groundwater law/regulations could be improved by having built-in provisions of retrospective review of the law/regulation with a specified time period.
- To understand how adaptive these laws are in practice, it is important to interview key stakeholders which is beyond the scope of this research.

²⁰⁸ Tex. Water Code. § 16.054 (a).

III. Groundwater in India- Analysis of state laws and policies (Punjab and Rajasthan)

A. Groundwater in India

India extracts the largest percentage of groundwater annually (28.9 %) in the world, followed by the US and China (whose combined groundwater extraction is less than India's). Groundwater is considered the backbone of India's water and food security as it fulfils 85 % of drinking water needs in rural areas, 45% of drinking water needs in urban areas, and 62% of total irrigation needs of the country. Of the annual groundwater draft, 89% is used for irrigation and the remaining 11% for domestic and industrial purposes. However, this resource is fast depleting in India.

In 2017, out of 6,881 groundwater assessment units all over India, 1,186 are categorised as over-exploited, 313 as critical, 972 as semi-critical, and 4,310 units as safe. There are 100 assessment units which are completely saline. These units are categorized based on the stage of groundwater extraction. The stage of groundwater extraction at the national level is 63%. In 13 states/union territories, the percentage is higher than the national average. These include 4 states/ union territories- Punjab, Rajasthan, Delhi, and Haryana with stage of extraction more than 100 percent, implying the groundwater extraction has surpassed the groundwater recharge in these states.

Table 10. Criteria for categorizing groundwater assessment units in India

| Stage of Groundwater Extraction | Category | | |
|---------------------------------|---------------|--|--|
| ≤70% | Safe | | |
| >70% and ≤90% | Semi-critical | | |

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²⁰⁹ Giordano, Mark. (2009). Global Groundwater? Issues and Solutions. 34 Annual Review of Environment and Resources, 34:153, 158.

²¹⁰ Report of the Comptroller and Auditor General (CAG) of India on Groundwater Management and Regulation. (2021). Union Government. Ministry of Jal Shakti. Department of Water Resources, River Development, and Ganga Rejuvenation. Report no. 9 (Performance Audit). Available at, https://cag.gov.in/webroot/uploads/download_audit_report/2021/Report%20No.%209%20of%202021 _GWMR_English-061c19df1d9dff7.23091105.pdf. Also, *see*, The World Bank. (2012). India Groundwater: a Valuable but Diminishing Resource. Retrieved from

https://www.worldbank.org/en/news/feature/2012/03/06/india-groundwater-critical-diminishing ²¹¹ See, CAG Report, supra note, 210, at 13. (The Annual Ground Water Draft (i.e. extraction of ground water) of the entire country for the reference year 2017 is estimated as 249 bcm, of which 221 bcm (89 %) is for used for irrigation. The remaining 28 bcm (11 %) is used for domestic and industrial purposes). ²¹² Id. at iii. (Ground water resources are estimated assessment unit wise. The Central Ground Water Board (CGWB) is the national agency to assess, manage, and develop ground water resources in the country). ²¹³ The stage of groundwater development/ extraction is a ratio of Annual Groundwater Draft and Net Annual Groundwater Availability in percentage. For details, see, Central Ground Water Board's FAQs, available at http://cgwb.gov.in/faq.html

| >90% and ≤100% | Critical |
|----------------|----------------|
| > 100% | Over-exploited |

Source: Dynamic Ground Water Resources of India 2017

In addition to the groundwater quantity overdraft, there are serious concerns about its quality as well. Based on 2015 data of 15,165 locations in 32 states/union territories, groundwater contamination is found in alarming proportions. For example, major contaminants are found in higher than permissible limits in groundwater, such as arsenic (697 locations), fluoride (637 locations), nitrate (2015 locations), iron (1389 locations), and salinity (587 locations).²¹⁴

NITI, India's national think tank in its recent report acknowledges the impending water crisis as 600 million Indians face high to extreme water stress.²¹⁵ By 2030, India's water demand is projected to be twice the available supply, which could severely hit the water needs of millions of people as well as result in ~6% loss of the country's GDP.²¹⁶

B. Complexities surrounding groundwater in India

["Groundwater is a subject on which there is a lot of science. And there's a lot of society, and economic action..."]. - Participant A

1. Groundwater rights

The applicable groundwater rights in India have their genesis in the English case laws. Most of the English cases that were central to the development of groundwater rules primarily arose out of the land use disputes. In *Acton v. Blundel*, the court gave ownership-like rights to the landowners i.e. the right to extract unlimited groundwater.²¹⁷ In *Chasemore v. Richards*, the court determined that separate rules would apply to the surface water and the groundwater.²¹⁸ The surface water rules were quite restrictive for the landowners; limiting their rights to appropriate water flowing on their land. Whereas, the groundwater

²¹⁴ See, CAG Report, supra note, 210, at 18.

²¹⁵ NITI Aayog. (2018). Composite Water Management index- A Tool for Water Management, at 15,16.

²¹⁷ [1843] 152 ER 1223, 1235.

²¹⁸ [1859] 7 HLC 349, 374. (The water 'percolating through underground strata, which has no certain course, no defined limits, but which oozes through the soil in every direction in which the rain penetrates' is not subject to the same rules as flowing water in streams or rivers")

rules were very permissive; allowing unlimited extraction with very few limitations.²¹⁹ For example, the landowners were barred from accessing the groundwater where it could not be accessed without touching the surface water flowing in a defined channel.²²⁰

The 19th century cases made distinction between the 'percolating groundwater' and the groundwater flowing in a 'defined channel.' The courts ruled that in the latter case, the surface water rules would also apply which effectively meant a limitation on the use of water.²²¹ Despite the difficulty of ascertaining the underground defined channels, the courts in the early 20th century applied the concept of 'defined channel' in several cases, such as to the water flowing down the river bed²²² or in an underground man-made trench.²²³ However, the potential of this concept remained untapped as the groundwater rules remain unchanged in the 21st century despite the evolution of scientific and hydrological understanding.²²⁴ Further, the Indian Easements Act, 1882 provides the major statutory mention of groundwater rights in the form of "user" or "easementary" rights for the landowners.²²⁵ However, these rights of use cannot be equated as full groundwater ownership rights. Thus, the groundwater rights have always been interpreted in the context of land owners' rights but not on their own i.e. assuming that only landowners have stake in groundwater and indirectly excluding people who do not own land.²²⁶

2. Groundwater access and equity

For more than a century and a half, the land rights and the groundwater rights have not been delinked and the legal framework on groundwater has not been updated. In India, the number of landless people is estimated to be a staggering 484.8 million.²²⁷ The

²¹⁹ Cullet, P. (2014). Groundwater Law in India – Towards a Framework Ensuring Equitable Access and Aquifer Protection. Journal of Environmental Law, 26 (1), p. 55-81.

²²⁰ Grand Junction Canal Company v Shugar [1870-71] LR 6 Ch App 483.

²²¹ See, Cullet, supra note 219, at 58,59. Also, see, BB Katiyar, Law of Easements and Licences (13th edn, Universal Law Publishing 2010) 797.

 $^{^{222}}$ Malyam Patel Basavana Gowd (dead) v Lakka Narayana Reddi AIR 1931 Mad 284 (High Court of Madras 1930).

²²³ The landowner built an underground trench from a point 14 feet away from the outlet of a spring. For details, *see*, Babaji Ramling Gurav v Appa Vithavja Sutar AIR 1924 Bom 154 (High Court of Bombay 1923).

²²⁴ See, Cullet, supra note 219, at 59.

²²⁵ Indian Easements Act 1882, § (7) (g): "The right of every owner of land to collect and dispose within his own limits of all water under the land which does not pass in a defined channel and all water on its surface which does not pass in a defined channel." Also, *see*, Environmental Law Institute. (2013). Regulating Groundwater in India. (October-December); Vol.4, Issue 4, at 1.

²²⁶ Cullet, P. (2018) Model Groundwater (Sustainable Management) Bill, 2017: a new paradigm for groundwater regulation, Indian Law Review, 2:3, 263-276.

²²⁷ Ranjan R. (2021). Impact of COVID-19 on Migrant Labourers of India and China. Critical Sociology; 47(4-5):721-726. ("The Socio-Economic and Caste Census of 2011 shows the 'households with no land' at

groundwater has become a major source of drinking water and irrigation, and the Supreme Court has recognized the right to pollution free water as a fundamental right.²²⁸ In this context, the existing groundwater framework makes water access difficult for the landless, raises serious concerns of equity, and complicates the potential exercise of remedies for the violation of the fundamental right.²²⁹

3. Food- energy- water nexus

In India, the period of 1960's and 1970's is called 'Green Revolution' when the country introduced modern technologies in agriculture to increase food production. There was large scale adoption of hybrid high yielding seeds, fertilizers, and intensive irrigation. ²³⁰ The pace and volume of groundwater extraction started rapidly rising in the 1970s. ²³¹ Accessibility and reliability of groundwater based irrigation than canal irrigation, resulted in the success of green revolution in India. ²³² Thus, groundwater depletion in parts of India is attributed to food and energy policies of 1960's and 70's, when food security was a national priority and the government kept the agricultural input prices low including electricity. ²³³ Government policies such as of subsidized electricity, food procurement guaranteeing a minimum support price for rice and wheat, and easy credit availability for buying pumps and constructing groundwater wells, ²³⁴ over decades resulted in severe groundwater stress in many parts of India, in particular the Green revolution states of north-west (such as Punjab). However, these policies remain unchanged despite change in the socio-political conditions.

4. Competitive deepening of wells

With reducing groundwater levels, the well owners are competing with each other to access the limited available resource. Receding water levels increase the cost of deepening the wells. People with money and resources win this competition whereas the ones with limited

²³⁰ Srivastava et al., (2017). Revisiting groundwater depletion and its implications on farm economics in Punjab, India. Current Science, 113 (3): 422-429.

^{56.41} per cent of total rural households or 10 crores (101 million) households. The Census takes 4.8 mean size per household, totalling 48.48 crores (484.8 million) people are landless.")

²²⁸ Subhash Kumar V State of Bihar (1991) 1 SCC 598.

²²⁹ See, Cullet, supra note at 226.

²³¹ Mukherji, Aditi. (2022). Sustainable Groundwater Management in India Needs a Water-Energy-Food Nexus Approach. Applied Economic Perspectives and Policy, 44 (1), at 395.

²³² *Id.* Also, *see*, Shah T. (1993). Groundwater Markets and Irrigation Development: Political Economy and Practical Policy (Bombay: Oxford University Press).

²³³ See, Mukherji, supra note at 231.

²³⁴ Rural Electrification Corporation Limited was established in 1969 to promote pump electrification. For details, see, https://recindia.nic.in/corporate-profile. Also, see, Shah, supra note at 221.

resources are pushed out.²³⁵ This often results in losses for the small and marginal famers who are unable to sustain the unsuccessful investments in digging and deepening of wells, as well as the impact of droughts. In many cases, the competitive deepening results in pauperization of farmers, pushing many farmers into a deep debt trap.²³⁶

5. Agriculture and groundwater

India has more than 20 million irrigation wells, the highest number of any nation in the world.²³⁷ Majority of wells (87.86%) are owned by marginal, small and semi-medium farmers with land holding up to 4 hectares.²³⁸ Of the annual groundwater draft, 89% is used for irrigation.²³⁹ However, agriculture sector remains exempt, thus, outside the purview of groundwater regulation in the latest federal government guidelines. The guidelines suggest that considering the huge number of groundwater extraction structures in the country, a participatory approach could be more productive for sustainable groundwater management than the one based on command and control.²⁴⁰ Further, 82% of Indian farmers are small and marginal²⁴¹ thus, contributing to strong political economy underpinnings of regulating this resource.

C. Groundwater and Law making in India

According to the Constitution of India, law-making can happen in three ways- at the federal level, at the state level, and both at the federal and the state level. The 7th schedule of the Indian Constitution distributes the legislative subjects into three lists- the Union list having subjects of national importance on which the Parliament can legislate, the State list

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²³⁵ Janakarajan, S. and Moench, Marcus. (2006). Economic and Political Weekly, 41 (37), pp. 3977-3987.

²³⁷ Government of India. Ministry of Water Resources, River Development and Ganga Rejuvenation, Minor Irrigation (Statistics Wing). (2017). Report of the 5th Census of Minor Irrigation Schemes. New Delhi. Available at http://jalshakti-dowr.gov.in/sites/default/files/5th-MICensusReport 0.pdf. Also, *see*, Mukherji, *supra* note at 220.

²³⁸ Notification. S.O. 3289 (E). (2020). Ministry of Jal Shakti. Department of Water Resources, River Development and Ganga Rejuvenation. (Central Ground Water Authority). New Delhi, 24th September, 2020.

²³⁹ See, CAG Report, supra note, 210, at 13. (The Annual Ground Water Draft (i.e. extraction of ground water) of the entire country for the reference year 2017 is estimated as 249 bcm, of which 221 bcm (89 %) is for used for irrigation. The remaining 28 bcm (11 %) is used for domestic and industrial purposes).. ²⁴⁰ See, Notification, supra note, 238, Para 3.0.

²⁴¹ Food and Agriculture Organization of the United Nations. FAO in India. (Undated). Available at https://www.fao.org/india/fao-in-india/india-at-a-glance/en/#:~:text=Agriculture%2C%20with%20its%20allied%20sectors,275%20million%20tonnes%20(MT).

having subjects of local importance on which the state legislatures can legislate, and the Concurrent list having subjects on which both the federal and the state governments can legislate.²⁴² Water is listed in List II (State list). Therefore, the state legislatures can legislate on the matters related to water including groundwater.

Additionally, the Parliament has the authority to pass a law if two or more states pass resolutions to that effect in their state legislatures.²⁴³ Adopting this process, the Parliament passed the Water (Prevention and Control of Pollution) Act in 1974 which established a pollution control board in every state to regulate water quality and waste water. The Water Act does not have explicit provision to control groundwater pollution. However, the Act prohibits discharging sewage or trade effluent in a stream or well or drain or on a property without prior approval of the state pollution control boards.²⁴⁴ This provision brings groundwater contamination within the jurisdiction of the pollution control boards.²⁴⁵

In the 1960's and 70's, the government of India introduced modern technologies in agriculture (Green Revolution) which demanded intensive irrigation practices. This coupled with other government policies such as in the food and energy sector, resulted in rapid increase of groundwater extraction. In 1970, the federal government drafted a model bill on groundwater regulation and circulated to the states for adoption but there was limited response. In 1980's India started witnessing receding groundwater levels in many parts of the country including the national capital territory. Amidst this scenario and in the absence of any state legislation, a petition was filed in the Supreme Court of India. In 1996, the apex court mandated the federal government to regulate groundwater (despite it falling in the jurisdiction of the state legislatures). In 1997, the government of India using provisions of the Environmental Protection Act, 1985 (which is a federal statute), established a groundwater regulatory authority called the Central Ground Water Board as

²⁴² Schedule VII. Constitution of India.

²⁴³ Constitution of India. Article 252. (Power of Parliament to legislate for two or more States by consent and adoption of such legislation by any other State).

²⁴⁴ Water (Prevention and Control of Pollution) Act 1974. Section 25.

²⁴⁵ Jithin V.J. (2016). Legal Impediments of Groundwater Conservation and Water Law Reforms in India. International Journal of Economics and Socio-legal Sciences, 2(3), 1-21.

²⁴⁶ See, Srivastava et al., supra note, 230. Also, see, Mukherji, supra note, 231.

²⁴⁷ See, Cullet, supra note 219. (In mid-1980s and late 1990s a few states legislated on drinking water specific groundwater laws. It was only in the beginning of the century when many states legislated on groundwater).

²⁴⁸ MC Mehta Vs Union of India & Others. (1997) 11 SCC 312.

Authority to regulate and control ground water development and management.²⁴⁹ Since then the Central Ground Water Authority (CGWA) has been issuing guidelines on groundwater regulation from time to time.

In 2015, the National Green Tribunal (NGT) issued directions that any person operating tube-well or extracting groundwater by any means shall obtain permission from CGWA even if such a unit is existing unit or is yet to be established.²⁵⁰ The NGT directed all industrial units which are members of the Common Effluent Treatment Plants (CETPs) to approach the CGWA through state pollution control board for obtaining 'no objection certificate' in accordance with the law.²⁵¹

In *MC Mehta v. Kamal Nath*, the Supreme Court of India held that the state is the trustee of all natural resources which are by nature meant for public use and enjoyment.²⁵² Further, in *Subhash Kumar V State of Bihar*, the Supreme Court of India held that the right of enjoyment of pollution- free water is a part of right to life as enshrined in Art. 21 of the Constitution of India.²⁵³ These landmark rulings have yet to become a part of the formal legislative framework on groundwater. In 2016, the federal government's latest model bill on groundwater integrated all major legal developments related to water including the decentralization reforms, recognising water as a public trust, and recognizing right to water as a fundamental right.²⁵⁴

As of Nov 2021, of 36 states/union territories in India, 19 have passed groundwater legislation, 255 however, most state legislations are based on the earlier model bills

²⁴⁹ CGWA issues 'No Objection Certificates' for ground water extraction to industries or infrastructure projects or Mining Projects etc.

²⁵⁰ National Green Tribunal. New Delhi. Order dated the 15th April 2015 in OA Nos. 204/205/206 of 2014.

²⁵¹ National Green Tribunal. New Delhi. Order dated the 09th July, 2015 in OA Nos. 34 and 37 of 2014. ²⁵² MC Mehta v. Kamal Nath (1997) 1 SCC 388. ("Our legal system includes the public trust doctrine as part of its jurisprudence"). Also see, Intellectual Forum v. State of A.P (2006) 3 SCC 549 (It "must make a distinction between the Government's general obligation to act for public benefit, and the special, more demanding obligation which it may have as a trustee of certain public resources"). Also see, Fomento Resorts & Hotels Ltd. v. Minguel Martins (2009) 3 SCC 571 ("The public interest doctrine is a tool for exerting long established public rights over short term public rights over private gain").

²⁵³ Subhash Kumar V State of Bihar (1991) 1 SCC 598 ("Right to live is a fundamental right under Art 21 of the Constitution of India and it includes the right of enjoyment of pollution- free water and air for full enjoyment of life"). Also see, (2004) 12 SCC 118 ("The natural sources of air, water and soil cannot be utilized if the utilization result in irreversible damage to the environment").

²⁵⁴ See, Cullet, supra note at 226.

²⁵⁵ Press Information Bureau. Government of India. Ministry of Jal Shakti. (2021). Legislation to Regulate Ground Water. 2nd December, 2021. Available at https://pib.gov.in/Pressreleaseshare.aspx?PRID=1777337.

(1970/2005) which were largely top-down in their approach.²⁵⁶ For the states that have not legislated on groundwater, the federal regulations apply. All new/existing industries, infrastructure projects and mining projects abstracting ground water, unless specifically exempted are required to seek 'no objection certificate' from CGWA or, their concerned State authority.

The federal government also drafted a national water framework bill and circulated to all states and union territories to pass suitable legislations in the state legislative assemblies in support of the framework law.²⁵⁷ Like the model groundwater bill 2016, this national framework has incorporated all major legal pronouncements of the Supreme Court on water including the public trust doctrine and the right to water.

D. Groundwater Laws of Punjab and Rajasthan

Considering, water is a state list subject, two states: Punjab and Rajasthan have been chosen for this research. These states are amongst the worst affected in the country, in terms of groundwater depletion and offer an opportunity to study regulations of two different jurisdictions. Punjab has recently legislated on water including groundwater; hence its two legal documents are analyzed- The Punjab Water Resources (Management and Regulation) Act, 2020 and Draft Punjab Guidelines for Groundwater Extraction and Conservation (2020). However, Rajasthan has not passed any law on groundwater. Federal government scheme called 'Atal Bhujal Yojana' (ABY) is implemented in seven states of India, including Rajasthan.²⁵⁸ Further, for the states that have not legislated on groundwater, the federal guidelines apply. Therefore, in addition to the ABY scheme (2020), the latest federal guidelines (2020)²⁵⁹ are analyzed in Rajasthan's context. Additionally, the Model

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²⁵⁶ See, Cullet, supra note at 219.

²⁵⁷ See, Constitution of India, supra note 243.

²⁵⁸ Government of India (GOI). Ministry of Jal Shakti. Department of Water Resources, River Development and Ganga Rejuvenation. Atal Bhujal Yojana (ABY). (2020). Program Guidelines. Version 1.1.March, 2020. (The major objective of the Scheme is to improve the management of groundwater resources in select water stressed areas in identified states viz. Gujarat, Haryana, Karnataka, Madhya Pradesh, Maharashtra, Rajasthan and Uttar Pradesh).

²⁵⁹ See, Notification, supra note, 238.

Groundwater Bill (2016),²⁶⁰ the draft National Water Framework Bill (2016),²⁶¹ and the national water policy (2012)²⁶² are analyzed.

1. Punjab- Groundwater situation and law

Punjab, a north-western state of India is a hotspot with the highest non-renewable groundwater extraction of 34.66 km³ in the country, whereas its renewable groundwater volume is only 20.35 km.³ Of the non-renewable groundwater extraction (34.66 km³), 92 % (33.97 km³) is used for irrigation only, which is twice that of the High Plain aquifer of the U.S.²63 Out of 138 assessment units in Punjab, only 22 units (16 per cent) are safe and five units (four per cent) are semi-critical.²64 The remaining 111 units (80 per cent) are critical and over-exploited.²65 The scenario has worsened since 2011 with more than 40 units exceeding groundwater development greater than 200 % and a few exceeding 400%.²66

Studies using dynamic general equilibrium model predict aquifer depletion in Punjab (the point where withdrawal of water cannot exceed the recharge profitably) that could result in the decline of farm employment and sharp fall in agricultural profits impacting the state's economy.²⁶⁷

Punjab has been one of the few states in India that did not favour adopting a comprehensive groundwater regulation. However, due to over-exploitation of

²⁶⁵ See, CAG Report, supra note, 210, at 12.

²⁶⁰ Model Bill for the Conservation, Protection, Regulation and Management of Groundwater, 2016 (Draft of 17 May 2016). Available at http://jalshakti-

 $dowr.gov.in/sites/default/files/\overline{M}odel_Bill_Groundwater_May_2016_0.pdf.$

²⁶¹ Draft National Water Framework Bill, 2016 (Draft of 18 July 2016). Available at http://jalshaktidowr.gov.in/sites/default/files/Water_Framework_18July_2016%281%29.pdf.

²⁶² National Water Policy. (2012). Government of India. Ministry of Water Resources. Available at http://jalshakti-dowr.gov.in/sites/default/files/NWP2012Eng6495132651_1.pdf.

²⁶³ Panda, D.K. and Wahr. J. (2016). Spatiotemporal evolution of water storage changes in India from the updated GRACE-derived gravity records. Water Resources Research, 52, pp. 145,146. Also, *see*, Dangar, Swarup et al., (2021). Causes and implications of groundwater depletion in India: A review, Journal of Hydrology, Volume 596, *and* Central Ground Water Board (CGWB). (2014). Ministry of Water Resources Govt. of India. Faridabad Groundwater Year Book- India 2013-14.

²⁶⁴ For details, see, supra Table-1.

²⁶⁶ Government of Punjab (India), Department of Water Resources (2017). Categorization of Blocks. Available at

 $[\]underline{\text{http://irrigation.punjab.gov.in/PDF/WaterResources/10072015/CATEGARISATION~OF~BLOCK~3~00715.pdf}.$

²⁶⁷ Nelson et al., (2013). The shadow value of Groundwater in Punjab, India" An analysis in an Economy – wide context. Institute on the Environment, University of Minnesota, 9, at 29,30. Available at http://efi.eng.uci.edu/papers/efg 152.pdf.

groundwater and alarmingly receding groundwater levels, the state began its regulatory action by enacting a specific legislation prohibiting the farmers from sowing and transplanting paddy crop before the date notified in the Act.²⁶⁸ The Act's objective was to reduce water use by delaying the sowing of paddy, thus, escaping higher evapotranspiration²⁶⁹ that happens in the relatively hotter months prior to the notified date. Later, in 2020, the state legislature passed a statute on regulating water including groundwater.²⁷⁰ The draft Punjab guidelines for groundwater extraction and conservation, 2020 (draft guidelines) permit all non-agricultural water users to extract groundwater subject to metering and volumetric charging.²⁷¹ The draft guidelines provide for water conservation credits. In case a groundwater user opts to implement water conservation measures on his own, he will be eligible for a water conservation rebate (credit) that will be reduced from his groundwater charges.²⁷² Compared to the Model Groundwater Bill 2016, Punjab's latest Water Resources Act could not be considered a comprehensive legislation. It misses out on several components including groundwater management and conservation through decentralized planning; the right to water as a fundamental right, and the periodic review of groundwater management. Details are mentioned in the stage-wise analysis in the following sections.

2. Rajasthan- Groundwater situation and law

Rajasthan is located in semi-arid western part of India and geographically is the largest state of the country. Rajasthan has the second highest percentage of the stage of groundwater development of 140 % (after Punjab's 166 %), whereas the national average is 63%.²⁷³ Out

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²⁶⁸ Punjab Preservation of Subsoil Water Act, 2009. Available at

 $https://prsindia.org/files/bills_acts/acts_states/punjab/2020/Act\%20No.\%202\%20of\%202020\%20Punjab.pdf$

²⁶⁹ Evapotranspiration is the sum of evaporation from land surface and transpiration from plants.

²⁷⁰ The Punjab Water Resources (Management and Regulation) Act, 2020. Available at https://prsindia.org/files/bills_acts/acts_states/punjab/2020/Act%20No.%202%20of%202020%20Punjab.pdf.

²⁷¹ Punjab Water Regulation and Development Authority (PWRDA). (2020). Punjab Guidelines for Groundwater Extraction and Conservation, 2020. (This draft proposes that permission of the Authority will be mandatory for extracting groundwater by every user in Punjab for commercial and industrial purposes. The Authority has exempted extraction of groundwater for Agriculture & related activities and for Drinking & Domestic usage. The Guidelines also propose charges for groundwater extraction which will be volumetric and based on water meters to be installed by all users).

²⁷³ Central Ground Water Board (CGWB) (2020). Ministry of Jal Shakti, Department of Water Resources, River Development and Ganga Rejuvenation, Govt. of India. Faridabad. Groundwater Year Book- India 2019-20.

of 292 assessment units in Rajasthan, only 45 units (15 percent) are safe, 29 are semi-critical (10 percent), and 218 are critical and over-exploited (75 percent).²⁷⁴

In 2011, in response to a public interest litigation, the Rajasthan High Court directed the state government to ban construction of all groundwater withdrawal structures except with the permission of the competent authority.²⁷⁵ In compliance of the court order, the state government authorized the district collectors as competent authorities to grant permission for constructing groundwater extraction structures in accordance with CGWA guidelines.²⁷⁶ Between 2006 to 2017, the state government's Ground Water Department and the State Water Resources Planning Department prepared five draft bills.²⁷⁷ However, none of these bills has been enacted.²⁷⁸ The state is relying on the federal groundwater regulations notified from time to time.²⁷⁹

On the non-regulatory side, Rajasthan has several examples of successful initiatives of community participation to conserve water. Rajasthan's 'Mukhya Mantri Jal Swavlambhan Abhiyan' is a multi-stakeholder programme based on participatory water management approach. This program aims to make villages water sufficient by converging various schemes²⁸⁰ and ensuring effective implementation of improved water harvesting and conservation initiatives.²⁸¹ This program uses drones to identify water bodies for restoration. Another example is of community-based successful groundwater recharge. A non-profit organization (Tarun Bharat Sangh) through traditional village governance structures initiated community-designed and maintained water harvesting structures. The approach anchored on applying local solutions based on economic and technical

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²⁷⁴ See, CAG Report, supra note, 210, at 12.

²⁷⁵ DB Civil Writ Petition (PIL) 628/2004 dated 20.1.2006 and 4754/10 dated 28.3.2011.

²⁷⁶ Public Health Engineering and Groundwater Department, Government of Rajasthan. No. F.12 (2) GWD/2011 Part. Dated 30.5.2013.

²⁷⁷ [These drafts are not available in public domain]. Retrieved from CAG Report 2021 (Details are: (i) The Rajasthan Regulation and Control of Development and Management of Ground Water Bill 2006 (ii) The Rajasthan Regulation and Control of Development and Management of Ground Water Bill 2011. (iii) The Rajasthan Ground Water (Regulation of Drinking Water Purpose) Bill 2012 (iv) Water Resources Management Bill 2012 (passed in Rajasthan legislation but not converted into act) and (v) Rajasthan Ground Water Regulation, Conservation and Management Bill 2016, 2017).

²⁷⁸ See, CAG Report, supra note, 210, at 23.

²⁷⁹ See, Notification, supra note, 238.

²⁸⁰ In India, the word, 'scheme' means a government sponsored plan or program to achieve policy objectives and sometimes used interchangeably with policy. In this context, this word does not have any negative connotation (as considered in American English).

²⁸¹ 'Mukhya Mantri Jal Swavlamban Abhiyan' (MJSA), Rajasthan Mukhya Mantri Jal Swawlamban Abhiyan. (2015). Available at http://mjsa.water.rajasthan.gov.in/.

efficiency, and resulted in enhanced seasonal groundwater recharge.²⁸² Managed Aquifer Recharge through Village-level Intervention (MARVI) in Rajasthan is another success story of participatory ground water management.²⁸³ This intervention involved measuring groundwater levels and improving water use efficiency based on data over a period of five years. Community-based volunteers with appropriate training monitored groundwater levels, groundwater quality, rainfall, and water levels of managed aquifer recharge infiltration basins (called check dams). The volunteers used this data in informing and guiding village people on groundwater situation and the best use of groundwater. The intervention resulted in improved cooperative decisions of sustainably using groundwater at the village level.²⁸⁴

E. Analysis of select Groundwater laws and policies of Punjab and Rajasthan To explore if the regulatory cycle in groundwater space is adaptive or not, I have analyzed eight law/policy documents along with ten interviews of key stakeholders. Additionally, state government sources on the law and policy making process are analyzed.

Regulatory context- In Rajasthan, there is no state level legislation. Therefore, the federal guidelines apply which primarily focus on the industry. Additionally, there is a federally sponsored scheme called 'Atal Bhujal Yojana' (ABY) which encourages the select states (including Rajasthan) to adopt a community-led participatory approach of groundwater management. In Punjab, the Water Resources (Management and Regulation) Act has recently been enacted. The state guidelines to regulate groundwater are in draft stage. However, these guidelines exempt the domestic and agricultural use of groundwater, and regulate other uses including industrial. Overall, of the eight analyzed documents, two are bills and one is in draft stage. Therefore, the identified examples from these documents are significant but may not be truly reflective of the law in action. In this context, the features of adaptive regulatory cycle are examined in the following paras.

²⁸² Everard, M. (2015). Community-based groundwater and ecosystem restoration in semi-arid north Rajasthan: Socio-economic progress and lessons for groundwater-dependent areas. Ecosystem Services, (16), 125–135.

²⁸³ Maheshwari,B. et al., (2021). MARVI: Securing groundwater supplies through engaging village communities. India Water Portal. Available at https://www.indiawaterportal.org/articles/marvi-securing-groundwater-supplies-through-engaging-village-communities.

²⁸⁴ Id.

1. Pre-Implementation

India's law and policy making processes at the federal and the state level are largely similar. Like the federal process, the state agencies have no legal mandate to assess the risks and conduct regulatory impact assessment of proposed regulations. However, the analyzed groundwater documents indicate the presence of these features. Like the federal government, there is no legal mandate to consult public in law and policymaking at the state level. Interview analysis suggests that risk assessment and impact assessment of laws and policies is not an integral part of governance. In limited ways, such assessments are considered in water law and policymaking. Further, public participation in policy making has increased over time but it is very limited in law making process. Participants also shared concerns of transparency and accessibility in public participation.

a. Documentary analysis

i. Assessing risks and uncertainties

Like the federal agencies, the state agencies have no mandate to assess the risks in law and policy making process. However, there provisions in the analyzed documents relating to risk assessment. For example, Atal Bhujal Yojana (ABY) a federal scheme requires environmental screening of the proposed works. The screening process is for identifying high-risk investments and their associated potential impacts on environment.²⁸⁵ It further requires environmental auditing of the scheme by an external agency twice during the period of scheme (year two and five) to assess substantial environmental risks.²⁸⁶

The federal groundwater guidelines require the entities engaged in infrastructure and industrial projects to submit report on environmental risks along with proposed management strategies for significant environmental issues including groundwater level decline, land subsidence, etc.²⁸⁷ Similarly, the Model Groundwater Bill 2016 requires the entities engaged in mining to submit groundwater protection plan along with risk minimization strategy of their prospective operations;²⁸⁸ the National Framework on Water Bill requires each state government to conduct risk and vulnerability assessment as a part

²⁸⁵ See, GOI, supra note at 258, Para 9.1.3. (The screening process will consider impacts on the downstream water users, ecological flows, flooding and submergence, water logging and stream erosion, community acceptance, chemical quality of recharging water...)

²⁸⁶ *Id.* Para 9.1.7.

²⁸⁷ See, Notification, supra note, 238, Para 4.3 and Annexure IV (para 7).

²⁸⁸ See, Model Bill, supra note, 260, Para 22.

of drought mitigation and management policy;²⁸⁹ and the draft guidelines of Punjab require risk assessment by any entity interested in extracting brackish/saline groundwater.²⁹⁰

NITI, India's apex policy thinktank in its latest composite water management index (CWMI) report has acknowledged and assessed multiple water risks along with their policy implications.²⁹¹ The identified water risks include (i) social and political risks- risk to food security, risk of acute water stress in cities and urban hubs; (ii) economic risks- risk to sustainable industrial activity, risk of energy shortages; and (iii) environmental risks- risk of biodiversity destruction and risk of desertification.²⁹²

ii. Broader and fuller impact assessment

Like the federal law and policymaking process, there is no mandate to conduct formal impact assessments of the proposed law or policy at the state level. There are a few mechanisms which could provide inputs for such assessments. For example, before a bill reaches the state legislature, the concerned department (with whom the bill is related) seeks comments and inputs from all departments of the government followed by the approval of the state law department. Similar process is generally followed in policymaking at the state level. Though not very structured, this process provides scope to multiple government agencies to assess different aspects of the proposed legislation/policy and give their comments.

Further, the proposed legislation could be discussed in a state legislature. Every bill goes through three readings (stages) - introducing and adopting the bill, discussing the bill clause by clause, and passing the bill. However, the evidence suggests that the state legislatures in India are in session for very limited days in a year, thus, may not have the time to debate and discuss every bill.²⁹³ For example, between 2016 and 2019, for 19 states for which data was available, the legislatures sat for an average of 29 days per year.

²⁸⁹ See, National Water Framework, supra note 261, Para 21.

²⁹⁰ See, PWRDA, supra note 271, Para 3.10.

²⁹¹ See, NITI, supra note 15 at 13-24.

²⁹³ Ramakrishnan, Anoop and Akhil, N.R. (2021). Annual Review of State Laws. PRS Legislative Research, at 1. Available at

https://prsindia.org/files/policy/policy_analytical_reports/Annual_Review_of_State_Laws_2020.pdf.

Whereas, in 2020, potentially affected by the COVID-19, the average for these states was reduced to 18 days in the year. In 2020, the Parliament met for 33 days.²⁹⁴

To address this problem, the state legislatures have legislative committees to scrutinize the proposed legislation. ²⁹⁵ In the state legislature, when a bill is introduced, the member incharge (who is introducing the bill) may make any of the three motions- (i) the bill be taken into consideration immediately or at a specified future date by the state legislature, (ii) it be referred to a select committee, or (iii) it be circulated for eliciting opinion by a specified date. ²⁹⁶ Thus, not every bill is referred to a legislative committee. Further, evidence suggests that the state legislatures pass most bills without detailed examination and scrutiny. In 2020, the 19 state legislatures (for which data was available) passed 59% of the bills on the same day they were introduced and passed 14% within a day of being introduced. Only 9% of the bills were passed after more than five days of being introduced (some of these were referred to a committee). ²⁹⁷ Thus, there seems very limited assessment of the proposed laws and policies at the state level.

However, the analysis of the groundwater law/policy documents indicates that there are several provisions related to impact assessments. For example, the federal groundwater guidelines require socio-economic impact assessment along with groundwater impact assessment in all industrial, mining, and infrastructure projects extracting groundwater.²⁹⁸ The ABY requires environmental impact assessment as a part of program action plan.²⁹⁹

Similarly, the Model Groundwater Bill 2016, requires the appropriate government to conduct environmental and social impact assessment for any use of groundwater, surface water, land and forest activity likely to have negative impacts on the local groundwater sources;³⁰⁰ the Gram panchayat (village-level elected body) to ensure that the right to water

²⁹⁴ *Id*.

²⁹⁵ In Punjab state legislature, there are 18 standing committees and in Rajasthan state legislature, there are 22 standing committees. For details, *see*, Punjab Legislative Assembly. Punjab Vidhan Sabha- Handbook for Members. (2022), at 76. Available at

http://www.punjabassembly.nic.in/images/docs/hand%20book%20final.pdf and see, Rajasthan Legislative Assembly. Introduction. (Undated). Available at https://rajassembly.nic.in/OverviewIntroduction.aspx.
²⁹⁶ Punjab Legislative Assembly. Rules of Procedure and Conduct of Business in the Punjab Vidhan Sabha, Rule 121(b). Available at http://www.punjabassembly.nic.in/images/docs/Rule-of-Procedure.pdf. For Rajasthan, see, Rajasthan Legislative Assembly. Rules of Procedure and Conduct of Business, Rule 66. Available at https://rajassembly.nic.in/RulesOfProcedure.aspx.

²⁹⁷ See, Ramakrishnan and Akhil, supra note, 293, at 3.

²⁹⁸ See, Notification, supra note, 238, Para 4.1 and Para 4.3.

²⁹⁹ Chapter 10, p-62.

³⁰⁰ See, Model Bill, supra note, 260, Para 7 (4).

for life is not jeopardized for anyone along with water for food security, sustenance agriculture, livelihoods, and ecosystem needs;³⁰¹ assess short-term and cumulative impacts of the projects on parameters including the right to water for life, drinking water sources, quantity and quality of groundwater, and impact on ecosystem;³⁰² create groundwater protection zones based on the latest dynamic resource assessment;³⁰³ and consider the social, environmental, and economic implications along with availability of other options or alternative measures while demarcating the groundwater protection zones.³⁰⁴

The National Framework on Water Bill requires considering the environmental, economic, and social impacts of inter-basin transfers of water;³⁰⁵ and Punjab's draft guidelines require the regulatory authority to determine water tariffs by considering principles of economy, efficiency, equity, and sustainability.³⁰⁶

iii. Public Participation

Public participation includes consultation and meaningful engagement in law and policymaking process, as well as enhancing participatory capacity of people. In India's law making, there is no legal mandate for pre-legislative public participation. It's based on the assumption that people's interests are voiced by their chosen elected representatives.³⁰⁷ In 2014, the federal government made a policy to formalize the pre-legislative consultation. But in the absence of a legal mandate, the same is not followed by the federal agencies. Similarly, in the state law and policymaking, there is no legal mandate for pre-legislative public participation.

The state legislatures may allow previous publication of the bills before these are introduced.³⁰⁸ However, the bill publication does not include inviting public comments. The state legislative committees may hear evidence from the experts, affected stakeholders, or may require any person to provide testimony to produce such records as necessary.

³⁰³ *Id.* Para 11.

³⁰⁴ Ia

³⁰¹ Id. Para 13 (5) (2) (b). Also, see, Para 19 (1) and (2)), and Para 10 (1).

³⁰² Id. Para 23.

³⁰⁵ See, National Water Policy, supra note 262, Para 5.5.

³⁰⁶ See, Punjab Water Resources Act, supra note 270, Sec. 17 (4).

³⁰⁷ Jain, Dipika. (2020). Law-Making by and for the People: A Case for Pre-legislative Processes in India. Statute Law Review. Vol. 41, No. 2, 189–206.

³⁰⁸ See, Punjab Vidhan Sabha Handbook, *supra* note, 295, at 47. For Rajasthan, *see* Rajasthan Legislative Assembly. Rules of Procedure, *supra* note, 291, Rule 58.

However, the proceedings and reports of these committees are confidential until their reports are presented to the House.³⁰⁹

The analysis of the groundwater law/policy documents indicate that the federal official notifications are published in the Gazette of India and generally mention a period of thirty days for inviting objections and suggestions from the public. The ABY scheme's guidelines require community consultation in the planning stage of various activities at the village panchayat level³¹⁰ such as in groundwater management investment plans, preparing water accounting/budgets, and water security plans.³¹¹ The Model Groundwater Bill 2016 requires public notification of the proposals for demarcating and declaring the groundwater protection zones³¹² and 60 days pre-hearing notice where the Act requires public hearing.³¹³

In Punjab, public comments were invited on the draft guidelines on groundwater extraction after 30 days' notice.³¹⁴ The guidelines provide for public hearing on the comments received³¹⁵ and publishing a summary of key objections raised in public comments along with the authority's response.³¹⁶

Key points:

- No legal mandate to assess risks or assess regulatory impact of proposed laws and policies.
- No legal mandate of public participation in the pre-legislative process.
- Very few bills are referred to the state legislative committees and bills could pass in the state legislatures without debate in the House.
- Groundwater law/policy documents have provisions requiring risk assessment and conducting environmental and social impact assessments while regulating groundwater extraction.
- Groundwater law/policy documents have examples of public notice and comment such as public consultation before finalizing the groundwater security plans or demarcating the groundwater protection zones.

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³⁰⁹ Id. For Punjab, see, Rule 126. And, For Rajasthan, see Rule 191, 200, and 223.

³¹⁰ A village council.

³¹¹ See, GOI, supra note at 258, Para 3.1.

³¹² See, Model Bill, supra note, 260, Schedule I (Para 4).

³¹³ Id. Schedule -III Para (1) (4).

³¹⁴ Punjab Water Regulation and Development Authority (PWRDA). Press Note.

Public Notice. Inviting objections against Draft Punjab Guidelines for Groundwater Extraction and Conservation, 2020. Available at https://punjab.gov.in/wp-content/uploads/2020/11/Public-Notice-Press-Note-regarding-Draft-Punjab-Guidelines-for-Groundwater-Extraction-and-Conservation-2020-1.pdf.

³¹⁵ See, PWRDA, supra note 271, Para 1.4.

³¹⁶ Id. Para 1.5.

b. Interview Analysis

i. Assessing risks and uncertainties

The interview analysis suggests that generally, the law and policy making processes do not include formal assessment or acknowledgement of the risks and uncertainties. Such processes are less formal such as assessing the threats or challenges or are absent.

• Limited acknowledgment or assessment of risks

Participant A- The participant gave an interesting perspective on why generally the formal risk assessment and scenario building does not happen in Indian law and policymaking.

["In India, the leaders imbibe the narratives and scenarios to articulate a preferred scenario, and build consensus around it. The leadership is mostly looking at its ability to manage the change before it decides"].

According to him, in a developed economy, the change is marginal, thus, it is easy to quantify the risks and build scenarios. However, in Indian context, the expected changes are massive, thus, uncertainty is deeper and could be radical. Even building scenarios could be debated ad infinitum leading to paralysis by analysis.

Participant B- The policy makers do not explicitly consider the risks and uncertainties. However, they broadly assess the future challenges.

Participant C- While drafting the latest national water policy, the drafting committee considered the uncertainties and climate change, to some extent. But he acknowledged that risk assessment is not yet an integral part of policymaking or the legal framework of water.

Participant D- In Rajasthan's context, the participant said the risks and environmental concerns are not addressed in the state level policymaking. However, the same are considered and addressed at the federal level.

Participant E- In Punjab's context, the participant said that the recent state water law acknowledges the risks of groundwater depletion in the state. The newly established regulatory authority is trying to assess and understand the impact of receding groundwater levels on agriculture and food production in the state.

No risk assessment

Participant F- Policymakers do not do risk and uncertainty assessment in advance and only talk about the damage subsequently. For example, he shared that nobody is thinking to analyze the impact if we hit the zero day.

["People in the government do not appreciate that there is risk in the first place"].

ii. Broader and fuller impact assessment

The interview analysis suggests that the impact assessments are conducted in a very limited manner; considering science and weighing different alternatives while formulating laws and policies is just beginning to happen and is not an institutionalized practice. A few participants also think that political factors greatly influence law and policymaking in the water sector.

Weighing different alternatives

Participant G- In policymaking, there is a practice of weighing different alternatives. However, in law making, it is just the beginning.

Participant C- To some extent, broader impact assessments take place in the water sector. For example, in drafting the latest national water policy, the committee started with an option which was least costly and more beneficial, and then assessed the water needs that could be met through this option, followed by other options.

Participant A- The practice of considering policy alternatives, weighing them, and taking a call is a very western and American practice. It is not much followed in India. The participant thinks that the answer lies in the degree of uncertainty one faces in India.

["If things are very uncertain, one would not spend energy in building scenarios because the probability of a particular scenario actually occurring is very small"].

• Science and policy-Gaps

Participant A- Science does not decide the debate in water sector. Because science makes forecasts and predictions which are always uncertain to some degree. It definitely puts some numbers, but depending on one's prior belief, these could be used either way.

Participant H- If one assumes that science is used in Indian policymaking, then policy approach to address policy issues should be different in different geographies. However, one does not find that difference. Many times the policies of different geographies are similar or even same.

["It seems the science is conveniently used to articulate the political interest or the political will, so that the policy looks scientific"].

Participant G- The participant shared an example of a dichotomy between science and the law. The Maharashtra Groundwater Act requires the minimum distance between a drinking well and an irrigation well to be 500 meters. Maharashtra is in a hard rock system where the typical zone of interference is in the range of 50 meters or maximum 200 meters. Thus, the gap of 500 meters is fine in the alluvial systems, not in the hard rock one.

Participant C- There is a disconnect between science and policy. The participant acknowledged that things are changing and the drafting committees are considering the latest science on the subject but this consideration could depend on the person heading the committee.

• Political factors

Participant B- Political factors and cost factors are very important in policymaking. For any new policy or policy modification, the government looks into the basic feasibility study and the cost-benefit analysis.

Participant I- Political factor determines policymaking in the water sector. The participant gave example of free electricity to the farmers, which is resulting in excessive water use in irrigation activities.

["No cost-benefit analysis will permit one to supply free electricity"].

The science and the policy alternatives are considered only on the paper because ultimately the political interests take over. The participant thinks that the government is not analysing deeper issues that are leading to over-exploitation of groundwater. The federal guidelines regulate the industry which is using hardly four to five percent of groundwater. Political interests are entwined with the use of groundwater in the agriculture sector, therefore, it is not being regulated.

iii. Public Participation

Interview analysis suggests that in the past 10-15 years, public participation has increased in the policymaking process with more experts, stakeholders, and public sharing their views and participating in consultations. However, it is not the same with the law making process. But overall, there is a huge scope to improve participation in both law and policymaking processes.

• Public participation-not mandatory

Participant A- The legislature has no legal mandate to consult. There are laws technically passed in India, with no examination by the legislative committees, no public consultation, and no debate in the house. And there are also example of laws with all three-legislative committee examination, public consultation, and debate in the house. So, it all depends on the legislature. Similarly, for policymaking, the government of India's executive order requires public notice and comments for 30 days but it is not codified in the law.

• General public participation-Low

Participant I- The general public does not participate in the policymaking process; it is the stakeholders impacted by the regulations, who participate, such as the industry.

Participant A- Low public participation is because the stakeholders are generally ignorant about the laws. In many ways, the education system in the country is biased towards technical education. Thus, liberal arts, social science, and law have suffered in the process.

• Stakeholder participation- increasing

Participant G- Over the years, stakeholder participation has increased and the composition of policy drafting committees has also become diverse. For example, the participant shared that in 2010, while being a member on one such drafting committee, there was heavy representation of lawyers, however in 2016, it was more balanced representing diverse interests. But there is a huge scope to improve stakeholder participation in the law making process than what it is now.

Participant C- The participant shared that before preparing the first draft of the latest national water policy, the committee heard a variety of stakeholders and asked them to make presentations before the committee. Thereafter, based on inputs, the first draft was prepared. This process indicates a positive change in policymaking. However, he feels there is ample scope to widen the stakeholder engagement such as by engaging the Panchayati Raj institutions³¹⁷ as they have a big role in local water management. Presently, their inputs are not formally taken in the policymaking.

Access

Participants shared the access issues due to the language of the draft law/policies.

Participant C- Most drafts are in English and Hindi, but not many people in India are conversant with these languages and would need the draft publication in vernacular languages.

Participant B- Another dimension of access relates to the tele-connectivity, some states have mobile penetration of 95% and high speed internet, which makes the access and

³¹⁷ Local government institutions in the villages.

participation easier but there are other states where mobile penetration is not high and there are internet connectivity issues.

Participant D- In the context of Rajasthan, the participant shared that most of the public meetings are conducted in big hotels where people are not comfortable going. So, the non-profit organizations first hold the meetings with public and then represent their views in such meetings. Additionally, he shared that the key information is buried in the state government's official websites and there is almost no practice of archiving the documents; any piece of information could be taken off the website anytime.

Participant I- Sometimes the draft is sent to the associations for their comments. However, not all associations receive these drafts. Also, the mechanism of newspaper publication seems inadequate. Thus, reach out to the public for increasing participation could be improved a lot.

• Transparency

Participant C- No one knows what happens to the comments; people do not get any acknowledgement or information of how the department considered the comments and what got accepted and rejected and why. Also, if one sends an email, there is no acknowledgement or response received. Thus, the process becomes selective and does not encourage people to participate.

• Participation- not effective

Participant F- Despite various ways of sharing one's views on the draft laws/policies, in his experience, these representations do not make any impact on the legislation. The public hearings are becoming routine business.

["We do not know how much of public inputs forms a part of policy or how many public hearing exercises have changed the laws"].

Participant D - Sometimes the stakeholders have limited capacities and worldviews. People participate merely by physical presence and not necessarily putting across their views. Instead, their representatives sometimes represent the political interests than the stakeholder interests.

["If as an expert you speak your mind strongly, you may not be invited again for sharing your views"].

Key points:

- Acknowledging and assessing risks in law and policymaking is not formally happening in both states. The challenges and threats are assessed broadly.
- Assessing impacts, including weighing policy alternatives is beginning to happen, but not institutionalized yet.
- There are many gaps in science and policymaking and, there is influence of political factors in regulating water.
- In policymaking, public participation has increased. However, the participation is not effective due to issues of access, transparency, and capacities.
- There is evidence of public participation while framing the Punjab's groundwater guidelines.

2. Implementation

In the implementation stage, the adaptive regulatory cycle emphasizes the need of relevant data collection and effective monitoring and evaluation (M&E) mechanisms to gauge policy performance. The documentary analysis suggests that there are several provisions related to data collection, reporting, and monitoring, along with a few examples of public consultation/ participation. Further, the interview analysis suggests that there are gaps in data collection, data quality, monitoring processes, and staff capacities at the state level.

a. Documentary analysis

i. Monitoring, evaluation, and feedback

• Data- collection, reporting, and sharing

The analyzed documents have provisions emphasising the importance of collecting data and building robust information systems. For example, the national water policy 2012 envisages establishing 'national informatics water center' to collect, collate and process hydrological data from all over the country³¹⁸ including various uses of surface and groundwater, water accounting, and water budgeting.³¹⁹ Similarly, the National Water

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³¹⁸ See, National Water Policy, supra note 262, Para 14.

³¹⁹ Id. Para 12.5.

Framework Bill provides for accessible and transparent water data sharing,³²⁰ and developing publicly available web-based water resources information system (IndiaWRIS) on GIS platform.³²¹ In the Model Groundwater Bill 2016, one of the functions of the rural groundwater sub-committees is collecting information on drilling of tube wells and construction of open wells;³²² the Block Groundwater Information and Monitoring Cell or Municipal Groundwater Information and Monitoring Cell is required to monitor compliance with the Bureau of Indian Standards specifications on water quality.³²³ Other examples include the Block panchayat to monitor and supervise the implementation of gram panchayat groundwater security plans;³²⁴ the Ward Groundwater Committee to register all wells and collectinformation on drilling of tube wells and construction of open wells within ward boundaries;³²⁵ the District Groundwater Council to monitor the implementation of panchayat and ward groundwater security plans,³²⁶ and register all drilling agencies;³²⁷ and the State Groundwater Advisory Council to maintain and monitor a database on the implementation of block and gram panchayat groundwater security plans.³²⁸

Additionally, NITI's Composite Water Management Index (CWMI) is the latest attempt to build a culture of data-based decision-making for water in India. It monitors key water-related metrics at a national level, ranging from piped water supply coverage to groundwater management and source protection.³²⁹ This index establishes a baseline data for measuring state performance on key water indicators, measuring progress over time, and identifying areas requiring deeper engagement and investment by the states.³³⁰ The report shows 80% of the states are displaying trends of improvement in their water management scores between 2015 to 2018, however, due to low scores, 16 of the 27 states are falling in the low-performance category.³³¹

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³²⁰ See, National Water Framework, supra note 261, Para 26.

³²¹ *Id.* Para 27.

³²² See, Model Bill, supra note, 260, Chapter VI. Para 13 (5) (2) (d). Also, see, Para 13 (5) (2) (c).

³²³ Id. Para 4 (3).

³²⁴ Id. Para 13 (6) (1) (c).

³²⁵ Id. Para 14 (7) (2) (e) (f) (g).

³²⁶ Id. Para 15 (9) (3) (g).

³²⁷ Id. Para 15 (9) (3) (k).

³²⁸ *Id.* Para 16 (10) (2) (f). Also, see, Para 16 (10) (2) (j).

³²⁹ See, NITI, supra note, 15 at 1.

³³⁰ *Id*.

³³¹ *Id.* at 5. (These states scored less than 50 points (out of 100) on the Index. These 16 states account for 48% of the population, 40% of agricultural production, and 35% of economic out of the country).

• Monitoring and compliance

The national water policy 2012 provides for monitoring by involving the users to identify problems and plan interventions; ³³² concurrent monitoring at the state and central level for water resource projects; ³³³ and establishing appropriate institutional arrangements for monitoring water quality of surface and groundwater for each river basin. ³³⁴ Similarly, the National Water Framework Bill has annual reporting requirements for the industries using large volumes of water. ³³⁵

The Model Groundwater Bill 2016 presents a multi-tiered structure of groundwater management at the village/ward, block, district, and the state level. It requires the appropriate government at each tier to monitor and supervise the implementation of groundwater security plans of the lower tier and maintain record of measures taken.³³⁶ Other examples include, establishing groundwater information and monitoring cells at block, municipal, and district levels;³³⁷ conducting annual water audit and filing annual water returns by the bulk users;³³⁸ annual social auditing by the village and ward level agencies,³³⁹ and requiring the drilling agencies to provide full details of the drilling activities (planned and undertaken).³⁴⁰

The federal groundwater guidelines also have several specific provisions on monitoring, such as requiring the state governments to register the drilling rigs, maintain the database of wells drilled, and share the data on the central groundwater authority (CGWA) portal.³⁴¹ Other provisions include annual water auditing by the commercial users of groundwater;³⁴² requiring the industries to reduce their groundwater use by 20% over next three years;³⁴³ installing digital water flow meters;³⁴⁴ constructing observation wells (piezometers) within

³³² See, National Water Policy, supra note 262, Para 6.7.

³³³ *Id.* Para 9.4.

³³⁴ *Id.* Para 12.6.

³³⁵ See, National Water Framework, supra note 261, Para 25 (2).

³³⁶ See, Model Bill, *supra* note, 260, Para 12, 15, 16.

³³⁷ *Id.* Para 4.

³³⁸ *Id.* Para 21.

³³⁹ Id. Para 26.

³⁴⁰ *Id.* Para 35 (2).

³⁴¹ See, Notification, supra note, 238, Para 1.1.

³⁴² *Id.* Para 4.0.

³⁴³ *Id.* Para 4.1 (iii).

³⁴⁴ *Id.* Para 9.0 (i).

commercial premises,³⁴⁵ mandatory monthly reporting of water level;³⁴⁶ and annual reporting of water quality data.³⁴⁷ To monitor the compliance, officers at the district level are authorized to do periodic inspections and take action including liability to pay penalties and imposing environmental compensation.³⁴⁸

ABY scheme's guidelines have detailed provisions on monitoring and evaluation (M&E). The scheme has two components to strengthen effective M&E in sustainably managing groundwater.³⁴⁹ One component is to strengthen institutional arrangements and capacity building in the states³⁵⁰ and the second incentivises state performance based on result indicators. Incentives are disbursed to the states based on their performance on 'disbursement linked indicators'³⁵¹ (DLIs). The guidelines emphasize data collection on specified indicators for evaluating scheme's progress, provide for citizen's feedback and grievance redressal, and reporting and auditing by the agencies at all levels of scheme implementation.³⁵² It further requires environmental auditing of the scheme by an external agency twice during the period of scheme (year two and five) to assess substantial environmental risks.³⁵³

At the state level, Punjab's Water Resources Act requires the regulatory authority to issue directions on installing and maintaining measuring instruments for groundwater quality and quantity; ³⁵⁴ conducting surveys, investigations, and research related to water conservation and use; ³⁵⁵ and submitting an annual report to be tabled in the state legislature. ³⁵⁶ The Punjab's draft groundwater guidelines mandate installing water meters along with specification; ³⁵⁷ maintaining and submitting the log of an entity's daily

³⁴⁵ *Id.* Para 9.0 (v).

³⁴⁶ *Id.* Para 4.1 (iv), Para 4.2 (ii), and Para 14.0.

³⁴⁷ *Id.* Para 9.0 (vi).

³⁴⁸ Id. Para 10.0 (b) and (d).

³⁴⁹ See, GOI, supra note at 258, Para 2.3.1.

³⁵⁰ *Id.* Includes installing groundwater level/ rainfall measurement instruments, training for using the equipment, and data collection.

³⁵¹ *Id.* For details, *see* Chapter 2. Para 2.4 and Chapter 5. (The scheme identified five DLIs out of which the first four DLIs incentivize the activities leading to sustainable management of ground water while the fifth DLI is related to the outcome of the four DLIs (i.e. Improvement in the rate of decline of groundwater levels).

³⁵² Id. For details, see Chapter 8.

³⁵³ *Id.* Para 9.1.7.

³⁵⁴ See, Punjab Water Resources Act, supra note 270, Section 15 (2) (v).

³⁵⁵ *Id.* Section 22.

³⁵⁶ Id. Section 37 (1) and (2).

³⁵⁷ See, PWRDA, supra note 271, Para 7.1. Also, see, Para 3.6.

groundwater extraction;³⁵⁸ installing piezometers and monitoring groundwater levels;³⁵⁹ registering the machinery, equipment, and vehicles related to water extraction/supply;³⁶⁰ assessing water conservation credits by a designated monitoring agency;³⁶¹ and water auditing and annual reporting by the bulk users of water.³⁶²

ii. Public Participation

The select law/policy documents examined here have a few examples where public participation is required in implementing the legal/policy provisions. For example, the Model Groundwater Bill 2016 requires public hearing with a notice of 60 days after publishing the social and environmental impact assessment report. The functions of district and state level groundwater advisory councils include conducting awareness enhancement programmes at village, block, and district level. Other examples include approval of the Panchayat Groundwater Security Plan by the gram sabha; approval of the Ward Groundwater Security Plan by the ward sabha; water user associations may levy and collect fees for groundwater use; gram sabha and ward sabha to conduct social audit of the groundwater management activities done within the gram panchayat or municipal ward; appropriate government to encourage independent audits by civil society or citizens' groups; and the State Groundwater Agency to demarcate groundwater protection zones in consultation with the appropriate government and the local communities.

³⁵⁸ Id

³⁵⁹ *Id.* Para 7.2. Also, *see*, Para 6.2 (The guidelines mention piezometer specifications, measuring protocols, and require the users to install machinery, equipment, and instruments of specifications as prescribed by the Authority).

³⁶⁰ *Id.* Para 7.4 (a) and (b).

³⁶¹ *Id.* Para 2.3 (The guidelines provide an option for the users to earn water conservation credits by implementing water conservation measures).

³⁶² *Id.* Para 8.2 and Para 8.3.

³⁶³ See, Model Bill, supra note, 260, Schedule III.

³⁶⁴ *Id.* Para 15 and 16.

³⁶⁵ *Id.* Para 13 (5) (2) (b). (Gram Sabha is the assembly of voters at the village level).

³⁶⁶ *Id.* Para 14 (7) (2) (b). (Ward Sabha is the assembly of voters at Ward level) (Ward is the smallest administrative unit of the local self-bodies/ the Panchayati Raj Institutions)

³⁶⁷ *Id.* Para 19 (6).

³⁶⁸ *Id.* Para 26. (1).

³⁶⁹ *Id.* Para 26. (4).

³⁷⁰ *Id.* Schedule I Para 1 (1).

Similarly, the National Water Framework Bill requires stakeholder consultation before reviewing the river basin master plans³⁷¹ and involving communities in managing the urban water resource projects and services.³⁷² The national water policy 2012 provides for local community participation while mapping the aquifers.³⁷³

The ABY scheme is based on the participatory approach to address groundwater challenges. It's the first federal scheme which provides for community-based planning, sharing and using groundwater data, capacity-building of stakeholders, and community-led groundwater management by combining supply and demand side measures. The scheme requires planning sustainable groundwater management with community participation;³⁷⁴ preparing the village water budget with participation of community water groups (water management committees/ village water and sanitation committee);³⁷⁵ preparing the water security plans with participation of community water groups ensuring participation of women and vulnerable groups through membership in these community groups;³⁷⁶ preparing and updating of water security plans by the district level implementation units using participatory processes;³⁷⁷ training and capacity building of the communities; ³⁷⁸ promoting social audit to assess ABY's impact, 379 and strengthening the water management committees/ village water and sanitation committees to function as Water User Associations.³⁸⁰ The scheme acknowledges the principle of 'inclusion' by ensuring inclusion of vulnerable sections of the community in the planning process³⁸¹ and mandatory participation of 33 percent women in the village level water user associations.³⁸²

The Punjab Water Resources Act requires public participation with 30 days' notice before finalizing the state's categorization into different zones³⁸³ as well as before enforcing the regulatory authority's directions on water conservation.³⁸⁴ Similarly, while determining the

³⁷¹ See, National Water Framework, supra note 261, Para 12.

³⁷² *Id.* Para 23.

³⁷³ See, National Water Policy, supra note 262, Para 5.3.

³⁷⁴ See, GOI, supra note at 258, Chapter 3. Para 3.

³⁷⁵ Id. Para 4.

³⁷⁶ Id. Para 5.

³⁷⁷ Activity (b) (Program Management and Implementation supervision). Table 3.2

³⁷⁸ Activity (d) and (e). (Institutional strengthening, Training and Capacity Building). Table 3.2.

³⁷⁹ *Id.* Para 9.2.5 (21).

³⁸⁰ Id. Para 4.4.1 (23).

³⁸¹ *Id.* Para 9.2.1.

³⁸² Id. Para 9.2.4.

³⁸³ See, Punjab Water Resources Act, supra note 270, Section 14. (Categorization based on the stage of groundwater development, groundwater quality, etc.).

³⁸⁴ *Id.* Section 15 (3).

tariff for water supply and management, the authority must seek public comments and objections, and may hold a common hearing to consider the objections.³⁸⁵ The regulatory authority may publish reports for disseminating water related information and scientific data to generate public awareness on water management.³⁸⁶

Key points:

- Analyzed documents have many provisions of collecting data and building robust information systems.
- There are elaborate reporting, monitoring, and compliance provisions.
- There are many provisions encouraging participatory approach in groundwater management.
- There are examples of higher levels of public participation (involvement and empowerment) in implementing key provisions, such as public hearing on social and environmental impact assessment of projects, community participation in preparing water security plans, approval of water security plans by gram sabha, social audits, and public notice and comment before finalizing directions on water conservation in the state.

b. Interview Analysis

i. Monitoring, evaluation, and feedback

The interview analysis suggests several gaps in data collection and monitoring mechanisms including capacity limitations of the staff working in government agencies. There are mixed views on groundwater estimation methodology.

• Monitoring – Programs not policies

Participant G- In the water sector, there is a practice of evaluations or third-party audits of the programs and projects. However, there is very less critical reflection on assessing if the policy has been successful or evaluating the policy impact per se.

Participant C- The participant shared that NITI's composite water management index is an interesting exercise in this direction but it is largely done by the governmental bodies, thus, could not be considered an independent assessment.

³⁸⁵ Id. Section 18 (6) and (7).

³⁸⁶ *Id.* Section 15 (7).

• Monitoring and assessing the groundwater

Participants shared that groundwater is a dynamic resource and monitoring its recharge is a challenging process.

Participant E- The monitoring agencies do not have precise measurements of groundwater level in every district across the country. 387 Regarding the methodology for estimating the groundwater, the participant shared that the methodology has been revised several times and is one of the best to calculate this resource worldwide.

Participant F- The central groundwater board assesses the groundwater availability at the national level through observation wells located at the block level. Their sample is very small and the data is inadequate. He shared that rainfall accounting protocol is an excellent way of water-budgeting and accounting. However, the same is not followed in India.

Participant G- The participant acknowledged that the revised methodology to estimate groundwater is better than before. But he thinks that their scale is wrong- aquifer mapping is happening at too regional a scale, whereas the assessment could improve if whole mapping is introduced (referring to the scale of the map i.e. the ratio of distance on the map and distance on the ground).

Participant J- At the federal level, every three years, the groundwater resource estimation committee prepares a report. In this report, the primary data is provided by the state governments and the central groundwater board monitors and cross checks the data on groundwater level. In the context of Rajasthan, the participant shared that the department prepares an annual report on groundwater in the state.

• Data availability and use- Gaps

Participant D and E- The participants shared that the government has the best data including excellent data set at the village level. However, they acknowledged that the emphasis is more on monitoring than evaluation.

³⁸⁷ Immediate gain of groundwater recharge can be measured if the water recorder is within the premises or say 50 or 100 meters where one is measuring. Beyond that it will disappear as groundwater is a dynamic resource. (Note from the interview).

Participant F- The available data may not be adequate but even this is not utilized well in policymaking.

Participant A – There are limited studies on water saving at the crop level. For a state like Punjab which has been growing rice on about three million hectares for more than four decades, there is not much data on water consumption variation for different cultivation practices. The studies are scattered and apparently not enough research is done.

Participant H - There is lack of availability of water data in public domain. This trend has increased in the past couple of years.

• Capacities

Many participants expressed concern on the capacities of government agencies.

Participant G - Agencies in the water sector must build their capacities and undertake institutional self-reform. Most institutions' roles still relate to the 1970's and 1980's when the water problems were very different than now. By institutional reform, the participant meant reforms in terms of principles, values, norms, laws, and human resources.

Participant B - The government departments are not skilled to analyze and interpret the data. Generally, the district level officers lack the skill of monitoring and evaluation. The government officials still have very traditional ways of developing their knowledge and improving skills, and the governments don't spend resources on capacity building.

Participant E – The participant shared that the central groundwater board has skilled officers but they are not showcasing and disseminating their work effectively. However, at the state level, he thinks that the agencies are not adequately staffed, particularly people with expertise in groundwater.

Key points:

- Focus is on monitoring, not evaluation.
- There is practice of monitoring the projects and programs in water sector, not the policies.
- There is inadequacy of data, such as small sample size of monitoring wells and there are mixed views on groundwater estimation methodology.
- The available data is limitedly used to inform policymaking.
- There are capacity issues of staff, particularly at the district and the state level.

3. Post-Implementation

The documentary analysis suggests that there are many provisions of periodic review and revision in the groundwater law/ policy documents. There is evidence of policy revision or update without any specific legal/policy requirement. The interview analysis suggests that there is a need to change the law on groundwater and that the law and policies are not keeping pace with changing times. Further, the policy changes and iterations that are happening are not based on formal policy evaluations.

a. Documentary Analysis

i. Iterative decision-making and Policy adjustment

• Acknowledging change

ABJ schemes' guidelines acknowledge the need of 'learning from implementation experience' and the revising the guidelines from time to time. The Model Groundwater Bill 2016 provides for modifying the bill's provisions to remove any post-implementation difficulty within a specified time period; and revising the groundwater security plans if there are compelling reasons such as significant hydrological changes, drought, etc. On similar lines, the National Water Framework Bill provides for revising the water security plans if there are compelling reasons.

Punjab's draft groundwater guidelines provide flexibility to the regulatory authority in many ways, such as by designing and adopting new water conservations schemes from time to time;³⁹² modifying or amending any condition of permission to extract groundwater;³⁹³ amending quantum of water to be extracted;³⁹⁴ and amending the non-compliance charges.³⁹⁵ The draft guidelines reflect an acknowledgement of the COVID-19's impact on state's economy, and accordingly the authority reduced the groundwater

³⁹¹ See, National Water Framework, supra note 261, Para 17 (2).

³⁸⁸ See, GOI, supra note at 258, Chapter 1. Para 1.3.

³⁸⁹ See, Model Bill, supra note, 260, Para 40(1) and (2).

³⁹⁰ Id.

³⁹² See, PWRDA, supra note 271, Para 2.2.

³⁹³ *Id.* Para 5.2.

³⁹⁴ *Id.* Para 5.3.

³⁹⁵ Id. Note. P-50. (To reflect any changes in its directions, conditions of permission, or otherwise)

charges by 20% till March 2021.³⁹⁶ The Punjab Preservation of sub-soil Act 2009 provides for a specified date prior to which no sowing should happen, however, it also provides that the state government may notify such other date for any area as required.³⁹⁷

• Review

The national water policy 2012 provides for periodically updating the aquifer mapping,³⁹⁸ periodically reviewing the water charges,³⁹⁹ periodically reviewing the declassification of hydrological data which is not in public domain,⁴⁰⁰ and establishing an autonomous center for research in water policy to evaluate the impacts of policy decisions and to evolve policy with changing scenario of water resources.⁴⁰¹

The National Water Framework Bill provides for reviewing and updating the master plan for the river basin every five years, 402 periodically reviewing the domestic water charges meeting considerations of equity and efficiency, 403 revalidating or amending the water security plans every five years, 404 and periodically reviewing the inter-state water sharing agreements, every 25 to 30 years to respond to the changing circumstances. 405

Similarly, the Model Groundwater Bill 2016 provides for revalidating the groundwater security plans every five years, 406 and periodically reviewing (within three to five years) the groundwater protection zones 407 based on the new assessment of the aquifers. 408 The federal groundwater guidelines provide for reviewing and periodically updating the water management plans, 409 periodically reviewing the penalty rates for non-compliance, 410 and modifying the guidelines from time to time. 411

³⁹⁶ *Id.* Para 1.8.

³⁹⁷ See, Punjab Preservation of sub-soil Act, supra note 268, Section 3 (1).

³⁹⁸ See, National Water Policy, supra note 262, Para 5.3.

³⁹⁹ *Id.* Para 7.2.

⁴⁰⁰ Id. Para 14.1. (Such as data classified on national security consideration).

⁴⁰¹ *Id.* Para 15.4.

⁴⁰² See, National Water Framework, supra note 261, Para 12 (11).

⁴⁰³ Id. Para 22 (5).

⁴⁰⁴ *Id.* Para 17 (2).

⁴⁰⁵ Id. Para 29.

⁴⁰⁶ See, Model Bill, supra note, 260, Para 12 (3).

⁴⁰⁷ *Id.* Schedule I. Para 16, 17.

⁴⁰⁸ Id. Para 18.

⁴⁰⁹ See, Notification, supra note, 238, Preamble and Background.

⁴¹⁰ Id. Para 16.0.

⁴¹¹ *Id.* Note: 1.

The ABY scheme's guidelines provide for mid-term reviewing of the scheme;⁴¹² updating village level water budgets on a regular basis (at least once every year);⁴¹³ evaluating and assessing the impact of improvements in groundwater levels (by National Interdepartmental Steering Committee),⁴¹⁴ reviewing district-level water security plans annually;⁴¹⁵ promoting social audit to assess scheme's impact in terms of access, equity, benefit sharing, and accountability;⁴¹⁶ and environmental auditing of the scheme by an external agency twice during the period of scheme (year 2 and 5).⁴¹⁷

The Punjab Water Resources Act provides for reviewing or modifying the state water policies. 418 Further, it provides for modifying the integrated state water plan with a review every three years. 419

• Pilot Programs and Phased-implementation

ABY scheme- It is a federally sponsored pilot scheme of five years duration (2020-21 till 2024-25). Its principle objective is strengthening the institutional framework of participatory groundwater management. The scheme is implemented in select seven states of India.⁴²⁰

"Paani Bachao, Paise Kamao" (Save water, earn money)- The state government of Punjab (Department of Power) launched an incentive-based scheme to encourage water-efficiency in select districts. Farmers are provided a fixed electricity quota and they receive incentive amount through direct benefit transfer, for every unit of electricity saved. The pilot's objective is breaking the nexus between free electricity and water wastage. 421

416 Id. Para 9.2.2.15 (b).

⁴¹² See, GOI, supra note at 258, Para 8.4 (Mid-term review to be completed by December 2022).

⁴¹³ *Id.* Chapter 3. Para 3.1.4.

⁴¹⁴ *Id.* Table 3.4, at 23.

⁴¹⁵ *Id.* Para 3.2.

 $^{^{417}}$ Id. Para 9.1.7.

⁴¹⁸ See, Punjab Water Resources Act, supra note 270, Section 13 (6) (i). (The authority is with the Punjab State Council for Water Management and Development).

⁴¹⁹ *Id.* Section 13 (6) (ii) and Section 14 (4).

⁴²⁰ See, GOI, supra note at 258, Para 1.2. (The seven states are: Gujarat, Haryana, Karnataka, Madhya Pradesh, Maharashtra, Rajasthan and Uttar Pradesh).

⁴²¹ See, NITI, supra note 15 at 11. Also see, The Energy and Resources Institute (TERI) (2018). Around 200 farmers enrolled in Paani Bachao, Paise Kamao scheme, 10 felicitated in Bambiwal village. December 4, 2018. Available at https://www.teriin.org/press-release/around-200-farmers-enrolled-paani-bachao-paise-kamao-scheme-10-felicitated-bambiwal.

• Revising laws, policies, and guidelines

There are examples where despite no specific provision in the policy to revise the policy/guidelines, the same have been revised and modified over time. For example, the federal government's model groundwater bill has been revised at least 6 times since 1970; the national water policy has been revised three times since 1987; the groundwater resources estimation methodology has been revised twice based on evolving science; the groundwater resources assessment that has been taking place intermittently since 1980 has become periodic since 2015; and the federal guidelines on regulating groundwater have been revised several times.

Key points:

- Analyzed documents have several provisions of periodic review and there are examples of both, reviews with and without specified time period.
- There are examples where the provisions recognize the need of change in the future, such as revising groundwater security plans based on significant hydrological changes, recognizing importance of 'learning from implementation' etc.
- There is evidence of revising policies/guidelines from time to time without any legal requirement for such revisions.
- There are very limited examples of pilot programs.

b. Interview Analysis

i. Iterative Decision-making and Policy adjustment

The interview analysis suggests that iterations and changes in the groundwater policy are inadequate. Policy revisions are taking place but largely without evaluation of the earlier ones.

latest in 2020. For detail, see http://cgwb.gov.in/documents/Dynamic-GW-Resources-2011.pdf

⁴²² The Model Bill 1970 has been revised in 1972, 1996, 2005, 2011, and 2016.

⁴²³ The national water policy was adopted in 1987. Thereafter, it was revised in 2002 and 2012. In November 2019, a drafting committee has been constituted to revise the same. For details, *see*, Ministry of Jal Shakti. Draft National Water Policy. Press Release. (March 2020). Available at https://pib.gov.in/PressReleasePage.aspx?PRID=1607166

⁴²⁴ Methodology of 1984 was revised in 1997, which was further revised in 2015. For details, see, Ministry of Water Resources. Government of India. Report of the Ground Water Resource Estimation Committee. 2009. Available at http://cgwb.gov.in/Documents/GEC97.pdf and see, Ministry of Water Resources, River Development & Ganga Rejuvenation. Government of India. Report of the Ground Water Resource Estimation Committee (GEC-2015). (2017). Available at http://cgwb.gov.in/Documents/GEC2015 Report Final%2030.10.2017.pdf.

⁴²⁵ Using this methodology, the central and the state groundwater authorities jointly carry out groundwater resources assessment at periodical intervals such as in 1980, 1995, 2004, 2009, 2011, 2013, 2017, and the

• Review

Participant C – The participant shared that generally in the water policies there is a review clause.

Participant I - Review provisions are not explicitly mentioned in the policy text. Sometimes, it is mentioned that the policy is applicable till new policy is made. But the document is generally silent on the time frame, the process, stakeholder engagement, etc.

Participant E – The participant while giving example of the federal guidelines on groundwater regulation shared that there is no explicit mention of the time period of review. Over time, the guidelines were revised such as to address the implementation issues.

Participant A and C- The participants shared examples such as the review of water tribunal awards after 25-30 years; review of water tariff policy generally after a specified time period; and in Punjab's draft guidelines, the directions to extract groundwater are valid for 3 years, after which these would be revisited.

• Pilot programs and Phased-implementation

Participant E -The participant shared about the national aquifer mapping program, which started on a pilot basis in six select areas depicting different hydrogeological environs.

Participant A and B - The participants shared about the incentive-based scheme piloted in a few districts of Punjab, called 'Save Water and Earn Money' scheme. In this scheme, the government gives a lumpsum cash amount to the user based on his/her prior electricity bill and then charges the actual usage. This gives an incentive to the user to be efficient and save electricity, which in effect saves water. Another example is the research study and demonstration program on soil moisture sensors by the state government of Punjab in collaboration with the state agriculture university.⁴²⁶

 $^{^{426}}$ These sensors are put in the field and based on soil moisture, they trigger when the next irrigation is needed. Thus, it enables in water conservation. (Note from the interview).

Participant C - The participant shared that experiential learning in a formal way or by explicitly conducting a pilot does not happen much. However, civil society activities and action research, as well as international best practices, do inform policy formulation.

• Policy response to change

Participant G -

["Presently, iterative law-making is more situational than experiential"].

For example, every iteration of the Groundwater Act at the state level or the Model Bill is drawn more from the changes in the groundwater situation, rather than due to the experience in law making and implementation. Therefore, the participant shared that it is important to bring in the experience of implementing the law to improve the law, such as based on community experience.

Participant C -A variety of factors influence changes in the water laws and policies. For example, changing objective or the biophysical condition of the resource; increasing concern about environmental issues- climate change; the change in political regime; demand and supply concerns-increasing urban water requirement due to rapid urbanization in India; international developments – shifting from millennium development goals to sustainable development goals; and sometimes due to radical change in the existing situations, the pressure to change the law builds from the civil society or the people.

• Gaps

Participant A - Despite change in the groundwater situation, the policy of providing free electricity to the farmers has not been revised. He shared that the concerned department of the state is willing to make changes based on new data, however, the government or the state legislature is not ready due to deep rooted stakeholder interests.

["the moment government would really introduce regulations, it is going to become unpopular"].

In 1965, the food policy of providing a floor price to grow food was relevant as the country needed to achieve food security. But now the situation has changed, however, the policy remains as it was.

With the impact of climate change, the seasonal patterns have changed. The point of time when the farmers need water in the state of Punjab does not coincide with the time when the dam receives bulk water. Thus, the water needs to be stored for a much longer period for which the storage of dam is not designed. If one does not increase the storage, one needs to reduce the agricultural water consumption.

Participant D and I -Both participants echo similar perspective that the policy takes too long a time to respond to changed circumstances. One gave specific example of British era's Irrigation and Drainage Act. The participant shared that this Act is not relevant to Rajasthan but it is still on the book because it vests powers in the officials who are reluctant to let it go. According to this participant, till the time public awareness is not there or the public does not build pressure, the change in law/policy does not come. And equally important is the political will, without which nothing happens.

Participant F - The policies are made and revised but there is no focus on evaluating the policy accomplishments.

["The water policies in India have been revised so many times but no is questioning what has been the impact of all these policies and why do we still need another one"].

Key points:

- Policies of multiple departments are inter-linked and have bearing on the water situation. Changes therein are equally important to effect meaningful water policies.
- Policies are made or revised over time but without evaluating the impact of the earlier ones.

4. India's laws and policies and Adaptive governance structures

In addition to the presence of adaptive regulatory processes, there are several examples of adaptive governance structures in groundwater management. These governance structures reflect polycentric governance and inter-agency coordination. However, the interview analysis suggests limited inter-agency coordination in the water sector.

a. Documentary Analysis

i. Polycentric governance

The Constitution of India recognizes a three tier local self-government institutions in rural and urban areas. The 73rd Constitutional Amendment Act 1992 established three tiers of Panchayati Raj Institutions (PRIs) in rural areas- the lowest tier is the Gram panchayat (at the village level), followed by the panchayat samitis (at the block level), and district or zilla panchayats (at the district level). Similarly, the 74th Constitutional Amendment Act 1992 established three tiers of urban local bodies (ULBs)- the lowest tier is the Town panchayat (an area in transition from rural to urban), followed by the Municipal Council (smaller urban area), and Municipal Corporation (large urban area). These Constitutional bodies have functions related to water. Therefore, in this context, the general institutional framework in both states is highly decentralized.

The national water policy 2012 provides for granting statutory powers on the water user associations to fix, collect, and retain a portion of water charges;⁴²⁹ requiring community participation in managing water resource projects; and partnering with private sector for improved service delivery in urban projects.⁴³⁰

The National Water Framework Bill emphasizes on people-centred water management including evolving relationships between community institutions and local governance institutions;⁴³¹ undertaking public-private partnership or public-public partnership in urban water management;⁴³² adopting participatory approach in irrigation management including statutory powers for the water user associations;⁴³³ involving users in planning and implementing water projects;⁴³⁴ and promoting land-soil-water management by taking inputs from local academic and research institutions.⁴³⁵

⁴²⁷ Department of Rural Development and Panchayats (DRDP). Government of Punjab. Panchayati Raj System in Independent India (undated). Available at

https://www.pbrdp.gov.in/documents/6205745/98348119/Panchayati%20Raj%20System%20in%20Independent%20India.pdf.

⁴²⁸ *Id*.

⁴²⁹ See, National Water Policy, supra note 262, Para 7.5.

⁴³⁰ *Id.* Para 12.3.

⁴³¹ See, National Water Framework, supra note 261, Para 7.

⁴³² *Id.* Para 23.

⁴³³ Id. Para 24 (1) and (2).

⁴³⁴ *Id.* Para 24 (3).

⁴³⁵ Id. Para 28 (3).

The Model Groundwater Bill 2016 acknowledges the principles of subsidiarity and decentralization of powers in rural and urban areas in regulating groundwater. It provides an institutional framework for groundwater management at four tiers- (i) the village level for rural areas (ward level for urban areas), (ii) block level for rural areas (Municipality/ Municipal Corporation for urban areas), (iii) district level, and (iv) state level. The state groundwater advisory council has members including representatives from groundwater committees at the village/ward level, municipal and district level along with experts having experience in hydrogeology, ecology, or social science. Other examples include the Groundwater Sub-Committee constituted as part of the Village Water and Sanitation Committee by gram panchayat; the local agencies given the power to make byelaws to implement provisions of the Act; and an expert group including non-official scientists, an independent expert on groundwater and an independent environmental expert to examine the social and environment impact assessment report.

The ABY scheme authorizes the water management committees and the village water and sanitation committees to function as the water user associations with key functions in groundwater management. To strengthen institutional arrangements and capacity in the states, it provides for engaging the district implementation partners such as community-based organizations (CBOs)/nongovernmental organizations in preparing the water security plans. 443

For groundwater law in Punjab, there are no comparable decentralized structures for groundwater management. However, it is important to note that the Constitution of India recognizes a three-tier local self-government institutions in rural and urban areas.⁴⁴⁴ Further, the Punjab Water Resources Act requires integrated state water plans to be based

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⁴³⁶ See, Model Bill, supra note, 260, Para 6.

⁴³⁷ *Id. See*, Para 13, 14, 15, and 16. (Chapter VI- Institutional Framework).

⁴³⁸ *Id.* Para 16.

⁴³⁹ *Id.* Para 13 (5) (1).

⁴⁴⁰ Id. Para 38 (1).

⁴⁴¹ *Id.* Schedule -III Para 1 (6). (The expert group to give its recommendation to the appropriate government).

⁴⁴² See, GOI, supra note at 258, Para 4.4.1.

⁴⁴³ *Id.* Para 2.3.1.

⁴⁴⁴ 73rd Constitutional Amendment Act 1992 established three tiers of Panchayati Raj Institutions (PRIs) in rural areas- the lowest tier is the Gram panchayat (at the village level), followed by the panchayat samitis (at the block level), and district or zilla panchayats (at the district level). Similarly, the 74th Constitutional Amendment Act 1992 established three tiers of urban local bodies (ULBs)- the lowest tier is the Town panchayat (an area in transition from rural to urban), followed by the Municipal Council (smaller urban area), and Municipal Corporation (large urban area).

on the block level water plans. It provides for an advisory committee on water resources with experts in the field of environment, hydrogeology, water resources, agriculture, management or economics. The committee must be consulted on all major questions of policy and regulations.⁴⁴⁵

ii. Inter-agency coordination

More examples in the analyzed documents are of vertical coordination i.e. between different levels of government (i.e. federal, state, local) and relatively few of horizontal coordination.

• Horizontal coordination

The ABY scheme provides for National Inter-Departmental Steering Committee (NISC)⁴⁴⁶ and State Inter-departmental Steering Committee (SISC).⁴⁴⁷ These are interagency bodies at the federal and state level respectively, and are responsible for overall management and coordination of ABJ scheme in the states.⁴⁴⁸ Further, it provides for establishing necessary linkages with agencies dealing with the Jal Jeevan Mission at the village panchayat level⁴⁴⁹ and encouraging inter-agency coordination as the scheme necessarily converges the other programs and schemes on water conservation.⁴⁵⁰

The Model Groundwater Bill 2016 requires the Municipal Water Management Committee to work in close coordination with other water-related institutions within the municipality;

In 2019, at the federal level, the two major water related Ministries have been merged under one umbrella Ministry called the Ministry of Water (Ministry of Jal Shakti).⁴⁵¹ However, at the state level, these are still working as two separate departments and Ministries.⁴⁵²

⁴⁴⁹ Para 3.1 (5)

⁴⁴⁵ See, Punjab Water Resources Act, supra note 270, Section 12 (1).

⁴⁴⁶ See, GOI, supra note at 258, Para 4.1.1.

⁴⁴⁷ *Id.* Para 4.2.1.

⁴⁴⁸ *Id*.

⁴⁵⁰ *Id.* Para 2.2. Also, see, Para 4.6.

⁴⁵¹ This Ministry has two departments- (i) Water Resources, River Development & Ganga Rejuvenation and (ii) Drinking Water & Sanitation.

⁴⁵² In Rajasthan, Groundwater department is a part of Public Health and Engineering Department (PHED), whereas the Water Resources Department (earlier called the Irrigation Department) is separate. Similarly, in Punjab, Groundwater is a separate Mission in the Department of Water Resources (earlier called the Irrigation Department) and the Drinking Water and sanitation is a separate department.

• Vertical coordination

The Model Groundwater Bill 2016 requires the state government to consult appropriate government levels while demarcating the groundwater protection zones;⁴⁵³ the district groundwater council to coordinate the preparation of groundwater security plans between panchayats and wards sharing aquifers; 454 the authorities at different government levels to coordinate while preparing the groundwater security plans;⁴⁵⁵ the national level forum to coordinate with the states on water issues; and a similar forum in the state to resolve demands of different parts of the state. 456 Similarly, the federal groundwater guidelines' implementation is monitored by the district level officers authorized in consultation with the state governments.⁴⁵⁷ The ABY scheme provides for a bottom-up participatory approach in groundwater management, thus, requiring coordination between all levels of government involved in scheme implementation- village, district, state, and federal. For example, the district level implementation partners aiding the village panchayat and the village level committees in preparing the water budgets;⁴⁵⁸ the agencies hired by the state program implementing agency guiding and assisting the village panchayats in preparing water budgets and water security plans (WSPs);⁴⁵⁹ the village panchayat coordinating with block and district level administration for monitoring, implementation, community communication and behavior change initiatives;⁴⁶⁰ the state program management unit consolidating the WSPs aggregated at the district level 461 and sending them to National Inter-ministerial Steering Committee for ratification. 462

Punjab's Water Resources Act provides for Punjab State Council for Water Management and Development which has members from different agencies/departments at the state level.⁴⁶³

⁴⁵³ See, Model Bill, supra note, 260, Para 11.

⁴⁵⁴ Id. Para 15 (3) (c).

⁴⁵⁵ *Id.* Para 12 (3). Also, see Para 13, 14, and 15.

⁴⁵⁶ Id. Para 12.1.

⁴⁵⁷ See, Notification, supra note, 238, Para 13.0.

⁴⁵⁸ See, GOI, supra note at 258, Chapter 3, Para 3.1 (4)

⁴⁵⁹ Id. Para 3.1 (6)

⁴⁶⁰ *Id.* Table 3.1, Implementation stage, Activity (e).

⁴⁶¹ *Id.* Para 3.3 (10)

⁴⁶² Id. Para 3.4 (13)

⁴⁶³ Id. Section 13 (1).

Another example is NITI's development of the Composite Water Management Index. In this process, agencies across different levels of government contributed, including multiple agencies and departments at the federal, state, and local governments.⁴⁶⁴

b. Interview Analysis

The interview analysis suggests that there is hardly any agency coordination in the water sector. Regarding the scale of governance, a few participants shared that groundwater management is best if implemented at the state level or the local level.⁴⁶⁵

i. Inter-agency coordination

Regarding inter-agency coordination, some of the participants think there is inter-agency coordination such as through inter-ministerial consultation in law/policymaking. However, some of the participants think that such coordination is lacking and one participant thinks there is absolutely no coordination.

Participant H - There are many departments that deal with water and each looks at water from its own limited prism. There is no semblance of policy between these departments, thus, the water narrative is mostly skewed, disconnected, and incomplete.

Participant G- The participant shared a recent example of hike in the minimum support price (MSP) for rice. He shared that considering rice cultivation is water-intensive, such a policy is not what the water department would want. However, such a policy is what the agriculture department would want. This shows how two policies are working cross-purpose. The participant added that the existing governance structures are adequate for coordination, but the strategy and communication is missing. Over time, the governance structures are becoming more adaptive, though there's still a long way to go.

Participant C - There is a huge scope to improve coordination between departments whose policies impact water. For example, there is a lot of discussion on the electricity policies having bearing on the water policies. However, there is still a need to reorient policies of

⁴⁶⁴ See, NITI, supra note 15 at 1 and 2.

⁴⁶⁵ Only two participants gave response to a sub-question in the interview guide that relates to the most appropriate scale of governance in groundwater management.

other departments for saving water, such as Agriculture departments' cropping choice and subsidy policies, the Food department's public distribution system, and the Education department's mid-day meal scheme, all are interlinked. He shared, if the Agriculture department promotes cultivating millets (which are less water intensive), it could provide a good and nutritious option to the other two departments - for the public distribution system as well as the mid-day meal.

Participant F – The participant thinks that inter-departmental coordination is lacking both at the national and the state level. Further, he shared that even within the department, there is a significant gap between the surface water and groundwater.

Participant A - Another dimension of inter-departmental coordination is in the law and policymaking process. The participant shared that generally, the department which proposes the law, has the sole responsibility to steer the direction of law. Other departments give inputs but it is consultation, not necessarily consensus. Therefore, other departments contribute only marginally, whether positive or negative.

Participant D - The participant shared an interesting 'picture portrait' of inter-departmental dynamics based on the budget of the department. According to him, the three big players in the water sector are based on the size of their budgets- the most important being the irrigation department, followed by the public health and drinking water, and the least is the groundwater.

["The inter-departmental budget dynamics reflects in who leads the key discussions in the joint-meetings, including where the department representatives sit on the table"].

He shared that to overcome such departmental silos, the 12th finance commission recommended creation of water resources department as an umbrella department. The states agreed in principle but in practice, most water resources departments are still fragmented and siloed as none of the big budget department wants to become secondary to the umbrella department.

ii. Scale of governance

Regarding the scale of governance, two participants shared a preference for decentralization.

Participant A - The lowest scale such as between a district and a block is good for groundwater management.

Participant I - Instead of a federal agency, groundwater regulation should be at the state level.

5. Need of Adaptive Regulations

The interview participants were also specifically asked about their views on the need of adaptive regulation in general as well as in groundwater. Most of the participants acknowledged the importance of adaptive regulations, however, they also shared the potential challenges for implementing such regulations.

a. For

Participant-A- ["The roots of a tree need to be firm and deep- just like the Constitution. But one does not want to break the tree with inflexible branches"].

Therefore, the policies and regulations like the branches, need to be flexible. Thus, factors such as technology, climate change, and faster social dynamics are the drivers of more adaptive systems in the policies. The participant shared an insightful perspective on the importance of 'adapting in time.' Because if one does not adapt the policies in time, the decision-maker's attention is diverted towards conflict management, thus, reducing his/her degree of freedom to adapt the policy.

["And as a policymaker, your objective in settling the conflict is to get back your freedom of decision making. Now that to me, doesn't happen because you settle a conflict at one stage. But there are unintended social consequences of any such decision. And you set in motion a new social dynamic, which comes back to you, in a year or two. And unless you're able to move at very quick speed, you don't get anything done. You just slide from one social issue to another"].

Participant G -Review of the laws is one of the most important parts of institutional changes that should happen. He added that we need to bring strong incentives into the regulatory framework than merely disincentives in the form of penalties and fines.

["Instead the law being black and white, there needs to be various shades of grey, making it more adaptive and flexible"].

Also there is a need to make it more participatory. One can build experience from the past to inform future regulation, through more participation in the law making process.

b. Challenges

Participant F –

["The concept of adaptive policy is very good but it is very important to know why are we adapting?"]

To have a vision, the time frame to achieve the vision and goals, would need not one but a series of adaptive policies. However, if the larger vision is not clear, adaptive policies would be meaningless. He gave the example of rainfall, sharing that he analyzed rainfall data of 150 years (of a state) which indicates that total rainfall has not declined but the number of rainy days have come down. Therefore, he suggested that the policy must adapt to this change such as by ensuring that the rainwater is accounted, stored, and not wasted.

Participant G – ["We might end up calling a law adaptive but being far from adaptive"].

Participant C – The participant considers that water is a wicked problem and does not have straightforward solutions. For adaptive regulations, there is a need of systemic efforts to build capacities of people and the institutions. He emphasized the need of decision-support systems at different scales so that the agencies can take decision in the light of new data and information.

Participant H – The challenge is 'how' to be adaptive. To implement adaptive regulations, one needs a lot of restructuring of the institutions and the ways in which the water systems are managed. And according to him, not much discussion is happening on such lines.

Participant B – There is a need to build capacities of people in government agencies to enable implementation of such regulations.

Participant E – To make changes in the policies is not an easy task. The policymaker needs to consider the re-creation of the entire support infrastructure and change management, which is not easy.

Punjab and Rajasthan's Regulatory cycle in groundwater- Summary analysis

In the pre-implementation stage, the adaptive features of assessing risks and assessing impacts of proposed law/policies are not built-in the regulatory process and are limitedly followed in practice. Public participation though increased over time is not a mandatory requirement. In the implementation stage, the analyzed documents have provisions on data collection and monitoring. However, in practice, there are many gaps including data inadequacy, data quality, and data use along with capacity issues of government functionaries. Lastly, in the post-implementation stage, there are provisions of review. Also, there are examples where the policy/ guidelines have been revised over time without any legal/policy requirement for the same. However, these iterations are not based on formal evaluation of the policies. In addition to the adaptive processes, documents indicate several examples of cross agency coordination and polycentric governance. However, in practice, agency coordination is limited.

IV. Comparative Analysis of Groundwater Laws of four states

The following section describes the comparative assessment of the groundwater laws of the US and India by comparing the four states on each of the six broad features of adaptive regulation.

1. Assessing risks and uncertainties

California and Texas Administrative Procedure Acts (APA) require the agencies to assess the potential adverse economic impact of proposed regulation such as on small businesses. However, there is no explicit requirement to assess the risks of the proposed regulation. Similarly, in Punjab and Rajasthan, the law and policy-making process does not mandate the agencies to assess the risks of the proposed law/policy. Therefore, risk assessment is not a mandatory requirement of general law/policymaking process in all four states.

In groundwater law, the documentary analysis suggests several direct and indirect references on risk assessment for both California and Texas. For example, addressing 'undesirable results' through groundwater sustainability plans (California) and designating 'priority' groundwater management areas based on current/ expected critical groundwater problems (Texas). Most of these provisions require the government agency to assess or address the projected negative impacts on groundwater, its quality, aquifer level, etc. Comparatively, in Punjab and Rajasthan, there are limited though direct references on risk assessment. For example, environmental screening of the proposed works and assessment of substantial environmental risks (Rajasthan) and risk assessment by any entity interested in extracting brackish/saline groundwater (Punjab). However, most of the provisions require the permit holder/ applicant/ industry to conduct risk assessment. The provisions are generally silent on the agency's conduct of risk assessment. However, in general, the Central Ground Water Board (CGWB) assess the groundwater resources across the country. And based on the assessment, it categorizes the water blocks as safe, semi-critical,

Table 11. Comparative assessment of four states on Assessing Risks and Uncertainties

| State | In General Law/policymaking | In Groundwater Law/policy |
|------------|---|--|
| California | No explicit requirement to conduct risk | Most identified examples require the |
| | assessment | government agency to assess the risks |
| Texas | No explicit requirement to conduct risk | Most identified examples require the |
| | assessment | government agency to assess the risks |
| Punjab | No explicit requirement to conduct risk | Provisions are generally silent on the |
| | assessment | agency's conduct of risk assessment |
| | | Most identified examples require the |
| | | permit holder/ applicant/ industry to |
| | | conduct risk assessment |
| Rajasthan | No explicit requirement to conduct risk | As above |
| | assessment | |

2. Broader and fuller impact assessment

critical, and over-exploited.466

In general law making, both California and Texas have legislative committees which review the proposed legislative actions. Thus, these could be considered mechanisms of broader impact assessment. On the regulatory side, California APA and Texas APA require agencies to conduct regulatory impact assessment when making new rules/regulations.

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⁴⁶⁶ For details, see, supra Section-III, Table-10.

Similarly, in general law making, both Punjab and Rajasthan have legislative committees which scrutinize the proposed legislations. However, not every bill is referred to these committees. On the regulatory/ policy side, there is no mandate to conduct formal impact assessments. However, there is a legal requirement of inter-ministerial consultation which requires all departments/agencies to give their written comments/views on a proposed law/policy. Thus, this consultation could be considered an important mechanism of broader impact assessment of the proposed law/policy.

In groundwater law, the documentary analysis suggests that both California and Texas have provisions indicating the broader impact assessment. For example, requiring comprehensive analysis of multiple elements while preparing the groundwater sustainability plans (California) and considering a variety of factors including environmental impacts and socio-economic impacts, before voting on the desired future conditions of aquifers (Texas). Similarly, for Rajasthan, the documentary analysis suggests that the federal guidelines (applicable to Rajasthan) and the Model bill (potentially applicable) have many examples requiring the environmental and social impact assessment. Whereas, in Punjab's draft guidelines, there is very limited and indirect reference to broader impact assessment such as while determining water tariffs, the regulatory authority to consider principles of economy, efficiency, equity, and sustainability. The primary difference between the provisions of Rajasthan when compared to California and Texas is the emphasis on equity and rights in the former and its relative absence in the latter. For example, groundwater regulations of Rajasthan provide for social and environment impact assessment which includes assessment of the short-term and cumulative impacts on the right to water for life (the fundamental right to water); equity in terms of users as well as across water uses; prioritization of groundwater use with first priority to meet the right to water for life, followed by water for achieving food security, for supporting sustenance agriculture, for sustainable livelihoods and eco-system needs. In California and Texas, the rights perspective particular the fundamental right to water and equity dimension is less pronounced. This could be attributed to the differences in socio-economic realities of India and the US.

Overall, in the lawmaking process, all four states have the mechanism of legislative committees. In California and Texas, all proposed laws are referred to these committees but its discretionary in Punjab and Rajasthan. Lastly, India's Supreme Court had recognized the right to water as a fundamental right even before this right was recognized

internationally. This right is a part of the proposed legislative framework in the Model Bill. However, the US has not recognized the human right to water yet.

Table 12. Comparative assessment of four states on Broader and Fuller Impact Assessment

| State | In General Law/policymaking | | | In Groundwater Law/policy | | |
|------------|-----------------------------|---|----|--|--|--|
| California | 1. | Proposed legislations referred to the | 1. | Several examples | | |
| | | legislative committees for review; | 2. | Limited emphasis on equity and | | |
| | 2. | Requirement of regulatory impact analysis | | absence of the rights perspective | | |
| | | | | (human right to water) | | |
| Texas | 1. | Proposed legislations referred to the | 1. | Several examples | | |
| | | legislative committees for review; | 2. | Limited emphasis on equity and | | |
| | 2. | Requirement of regulatory impact analysis | | absence of the rights perspective | | |
| | | | | (human right to water) | | |
| Punjab | 1. | Not all proposed legislations referred to | 1. | Limited examples | | |
| | | the legislative committees for review; | 2. | Limited emphasis on equity and absence of the rights perspective | | |
| | 2. | No formal requirement of regulatory | | | | |
| | | impact analysis; | | | | |
| | 3. | Presence of inter-ministerial consultations | | | | |
| Rajasthan | 1. | Not all proposed legislations referred to | 1. | Several examples | | |
| | | the legislative committees for review; | 2. | Emphasis on equity and the rights | | |
| | 2. | No formal requirement of regulatory | | perspective (human right to | | |
| | | impact analysis; | | water) | | |
| | 3. | Presence of inter-ministerial consultations | | | | |

3. Monitoring and Evaluation

For California and Texas, the documentary analysis suggests that there are elaborate provisions of monitoring and evaluation for implementing groundwater sustainability plans (California) and the groundwater management plans (Texas). These include measurable objectives, interim milestones, and specified timelines for groundwater management. Additionally, there are provisions of reporting, auditing, and compliance. For Punjab, the documentary analysis suggests that the monitoring provisions relate to reporting and compliance processes as well as on monitoring groundwater management. For Rajasthan, the applicable federal guidelines' monitoring provisions weigh more on the reporting and compliance processes, however, the Model Bill and the ABY scheme's monitoring provisions are primarily focusing on conservation and sustainable groundwater management. Overall, in this feature, all states have comparable provisions in their law/policy documents.

Additionally, in analyzing Rajasthan's system, two distinct M&E processes are identified. First is an example of linking the incentives with monitoring through 'disbursement linked

indicators' (DLIs). Of the five DLIs, the first four incentivize the state for the activities leading to sustainable management of groundwater while the fifth DLI is related to the outcome of the four DLIs (i.e. Improvement in the rate of decline of groundwater levels). Second is the social audit reflecting the social dimension of evaluation. The Model bill provides for mandatory social audits of various activities performed under the bill/Act by the voter assemblies at the village and ward levels. Similarly, the ABY promotes social audit to assess the scheme's impact in terms of access, equity, benefit sharing, and accountability. This dimension of direct public participation in evaluation activities is not present in Punjab's guidelines as well as in the groundwater laws of both California and Texas.

Table 13. Comparative assessment of four states on Monitoring & Evaluation

| State | In Genera | In Groundwater Law/policy | | |
|------------|------------------|--|--|--|
| | Law/policymaking | | | |
| California | - | Identified several examples of monitoring linked to groundwater management | | |
| | | 2. Identified several reporting and compliance provisions | | |
| Texas | - | Identified several examples of monitoring linked to groundwater management | | |
| | | 2. Identified several reporting and compliance provisions | | |
| Punjab | - | Identified several examples of monitoring linked to groundwater management | | |
| | | 2. Identified several examples of reporting and compliance provisions | | |
| Rajasthan | - | Identified several examples of monitoring linked to groundwater management | | |
| | | 2. Identified several reporting and compliance provisions | | |
| | | 3. Social dimension of evaluation- through social audits | | |
| | | 4. Linking performance indicators with incentives | | |

4. Iterative decision-making and policy adjustment

General statutes of California and Texas contain provisions for reviewing the existing rules and regulations. California's APA provides for reviewing a regulation if the legislative committee considers that the regulation does not meet specified statutory standards while Texas state law requires the agencies to review and consider re-adoption of all rules every

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⁴⁶⁷ Five DLIs are: (i) Public disclosure of groundwater data/information and reports; (ii) Preparation of community-led water security plan; (iii) Public financing of approved water security plans through convergence of ongoing schemes; (iv) Adoption of practices for efficient water use, and (v) Improvement in the rate of decline of groundwater levels.

 $^{^{468}}$ Social audit is an accountability measure of government performance with active involvement of people

four years. In Punjab and Rajasthan, there are no general statute provisions requiring review of existing laws/policies.

In groundwater law, the documentary analysis suggests that both California and Texas have provisions acknowledging change such as updating groundwater sustainability plans based on best available science (California) and altering the boundaries of designated management areas as required by future conditions and data (Texas). Both states have provisions of review as well.

Similarly, Punjab and Rajasthan's groundwater regulations have provisions acknowledging change such as modifying or amending any condition of permission to extract groundwater (Punjab) and revising the groundwater security plans if there are compelling reasons such as significant hydrological changes, drought (Rajasthan). Both states have provisions of review as well.

Most of the provisions in California and Texas documents mention (though briefly) about the purpose of review/evaluation or the basis of evaluation such as to evaluate if the regulations are achieving the objectives, or establishing baselines and identifying methodologies for evaluation. Whereas, most of the provisions in India's documents, particularly Punjab give a high-level mention of review. However, in Rajasthan, there are provisions specifying the basis of evaluation such as review to be based on the new assessment of aquifers.

Table 14. Comparative assessment of four states on Iterative decision-making

| State | In General Law/policymaking | In Groundwater Law/policy | | |
|------------|---|--|--|--|
| California | General statutory provision to review | Most identified examples mention | | |
| | regulations based on legislative committee's | (though briefly) the purpose/ basis of | | |
| | consideration | review/evaluation | | |
| Texas | General statutory provision mandating review | Most identified examples mention | | |
| | of rules every four years | (though briefly) the purpose/ basis of | | |
| | | review/evaluation | | |
| Punjab | No general statute provision requiring review | None of the identified examples | | |
| | | mentions the purpose/ basis of | | |
| | review/evaluation | | | |
| Rajasthan | No general statute provision requiring review | A few of the identified examples | | |
| | | mentions the purpose/ basis of | | |
| | | review/evaluation | | |

5. Public participation

Generally, the legislative committee hearings in California and Texas are public in nature. The rulemaking process of both states is participatory with a mandatory requirement of public notice and comment. In California's groundwater law, most examples are of public notice and public hearing such as notifying public while developing the groundwater sustainability plans. There are limited examples are of public participation in decisionmaking, such as to include advisory committee of interested parties in developing and implementing GSP. On the other hand, Texas general statute provides for 'negotiated rulemaking' where the initial rule is developed by a committee of representatives of interested persons who will be affected by the rule, followed by the agency adopting the rulemaking process including public notice and comment. Though not a part of Texan groundwater law provisions, the Texas State Soil and Water Conservation Board may engage in negotiated rulemaking. In Texas groundwater law, there are provisions of public notice and public hearing such as while designating and delineating the priority groundwater management areas. Additionally, there are provisions indicating the higher level of public participation. For example, before an area is included in a Groundwater Conservation District, a majority of voters of that area must approve the district creation.

In Punjab and Rajasthan, the proceedings and reports of the state legislative committees are confidential. The state law and policymaking process does not mandate public notice and comment. For Punjab, the groundwater guidelines provide for public hearing and publishing the summary of key objections. For Rajasthan, the applicable groundwater law has provisions requiring public notice, public hearings as well as higher levels of public participation. For example, mandating the role of community water groups/committees and vulnerable population in decision-making such as in preparing water security plans and water budgets at the village level. There is a mandatory participation of at least 33 % women in the village level water user associations (WUAs). These WUAs have many key functions such as conducting water budgeting exercises and identifying supply-side and demand-side activities for groundwater management. Further, the Model Bill requires the village level groundwater security plans to be approved by the assembly of voters called Gram Sabha.⁴⁶⁹ Social audits by Gram Sabha and Ward Sabha are another example of direct

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⁴⁶⁹ Gram sabha is provided under the Constitution of India (Article 243 (b)). (The decisions taken by the Gram Sabha cannot be annulled by any other body except itself).

public participation in evaluating the groundwater management activities undertaken in the village/ ward. The bill provides for independent audits by the civil society or citizen groups. Such strong community involvement in key decision-making is not present in the analyzed documents of the other three states.

Table 15. Comparative assessment of four states on Public Participation

| State | In General Law/policymaking | In Groundwater Law/policy |
|------------|---|--|
| California | Legislative committee hearing are public | s 1. Identified examples of public notice, public hearings, public meetings' provisions |
| | Legal requirement of public participation in rulemaking (notice and comment) | c 2. Identified examples of public involvement- |
| Texas | Legislative committee hearing are public | s 1. Identified examples of public notice, public hearings, public meetings' provisions |
| | Legal requirement of public participation in rulemaking (notice and comment) | 1 1 |
| | 3. Negotiated Rulemaking | 3. Identified example of public empowerment- Approval of majority voters for including an area in GCD |
| Punjab | Legislative committee hearing are not public | s 1. Identified examples of public notice and comment provisions |
| | No legal requirement of public participation in rulemaking (notice and comment) | c 2. No identified example of public |
| Rajasthan | Legislative committee hearing are not public | s 1. Identified examples of public notice and public hearings' provisions |
| | No legal requirement of publi participation in rulemaking (notice and comment) | * * |
| | | 3. Identified example of public empowerment- Assembly of voters approve the village water security plans |

6. Adaptive Governance Structures

The US Constitution does directly address the powers or roles of local governments, focusing instead on federalism issues between state and federal governments as well as individual rights. Therefore, different states vary in the level of authority delegated to the local governments broadly categorized as Home Rule states and the Dillon Rule states.⁴⁷⁰ California's Constitution provides for Home Rule as a self-executing power and the Dillon Rule applies to certain local governments. Whereas the Texas Constitution recognizes the

⁴⁷⁰ See, Moore, supra note, 180.

Home Rule but requires an enabling legislation, therefore, Texas is an example of Dillon Home-Rule combination.

For California and Texas, the documentary analysis suggests that both states have examples of polycentric governance as well as inter-agency coordination. California's groundwater law provides authority to the local governments to manage groundwater by establishing the Groundwater Sustainability Agencies (GSAs) at the local level. Additionally, there is the role of counties, the Department of Water Resources, and the State Water Resources Control Board in groundwater management. Similarly, in Texas, the law establishes the Groundwater Conservation Districts (GCDs) for groundwater management. Additionally, there is role of the Texas Water Development Board and the Texas Commission on Environmental Quality in groundwater conservation and management.

The Constitution of India recognizes a three tier local self-government institutions in rural and urban areas. These Constitutional bodies have functions related to water. Therefore, in this context, the general institutional framework in Punjab is decentralized. However, in Punjab's groundwater law does not recognize such decentralized structures though its Water Resources Act requires integrated state water plans to be based on water plans made for the administrative blocks. Further, there are limited examples of inter-agency coordination in Punjab's groundwater guidelines. However, in general, the agencies/departments at the state level adopt a process of inter-ministerial/ inter-agency consultation and seek comments/feedback on the proposed law/policy.

For Rajasthan, the applicable groundwater law has examples of polycentric governance structures. For example, the Model Bill recognizes the principles of subsidiarity and decentralization. It provides an institutional framework for groundwater management at four tiers- (i) the village level for rural areas (ward level for urban areas), (ii) block level for rural areas (Municipality/ Municipal Corporation for urban areas), (iii) district level, and (iv) state level. Further, there are many examples of inter-agency coordination in the applicable groundwater guidelines. Additionally, the agencies/departments at the state

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⁴⁷¹ See, DRDP, supra note, 427.

level adopt a process of inter-ministerial/ inter-agency consultation and seek comments/feedback on the proposed law/policy.

Table 16. Comparative assessment of four states on Polycentric governance and Inter-Agency Coordination

| State | In General Law/policymaking | In Groundwater Law/policy | |
|------------|--|---|--|
| California | Constitution recognizes the Home Rule as a self-executing power | Sustainability Agencies (GSAs) at the | |
| | Dillon Rule applies to certain local governments. | local level 2. Identified several examples of interagency coordination | |
| Texas | Dillon Home- Rule combination Constitution recognizes the Home Rule but requires an enabling legislation/statute. | 1. Polycentric structures- Groundwater Conservation Districts (GCDs) at the | |
| Punjab | Three-tier structure of directly elected Constitutional local bodies in rural areas | agency coordination 1. Polycentric structures- advisory | |
| | Three-tier structure of directly elected Constitutional local bodies in urban areas Inter-ministerial consultation | 1 0 , | |
| Rajasthan | As above | 1. Polycentric structures- institutional framework for groundwater management at four tiers (village/block/district, and state) | |
| D 1 1 | | 2. Identified several examples of interagency coordination | |

Based on the comparative analysis, following lessons could be potentially relevant for the states in these two countries.

Table 17. Comparative Analysis of four states- Summary of Potential lessons

| Lesson | Presently | Potentially | Adaptive feature |
|--|---|-------------------------|--------------------------------------|
| | applicable | applicable | |
| Introduce formal risk assessment in law/policymaking | None | All four states | Assessing risks and uncertainties |
| Introduce regulatory impact assessment in law/policymaking | California and Texas | Punjab, Rajasthan | Broader and fuller impact assessment |
| Refer every bill to the State legislative committees | California and Texas | Punjab, Rajasthan | Broader and fuller impact assessment |
| Recognize the fundamental right to water | India (Model Groundwater Bill and National Water Framework Bill) | California and Texas | Broader and fuller impact assessment |

| Disbursement linked indicators to monitor state performance | Rajasthan | Punjab, California and Texas | Monitoring, Evaluation, and feedback |
|--|-----------------------------------|--------------------------------------|--|
| Social audits of groundwater management activities | Rajasthan | Punjab, California and Texas | Monitoring, Evaluation, and feedback |
| Periodic review of rules | Texas | California, Punjab, and Rajasthan | Iterative decision- making and policy adjustment |
| Public notice and comment in law/policymaking | California and Texas | Punjab and Rajasthan | Public Participation |
| Negotiated rulemaking | Texas | California, Punjab, and Rajasthan | Public Participation |
| Community involvement in groundwater decision-making (village level groundwater security plans approved by assembly of village voters/Social audits) | India (Model Groundwater Bill) | Punjab, California and Texas | Public Participation |

V. Whether the groundwater laws/policies work

The SGMA, California is in the initial stages of implementation. In a phased manner, the statute mandates creating Groundwater Sustainability Agencies (GSAs) by 2017, followed by adopting and starting to implement the groundwater sustainability plans (GSPs) in critical overdraft basins (Jan 2020) and basins not in critical overdraft (Jan 2022). The GSAs have twenty years to implement and achieve the groundwater sustainability. Thus, it is too early to know if the law is effective or not. However, a few studies have evaluated the law since its enactment in 2014 and noted implementation issues. These issues are mostly limited to the establishment of GSAs and preparation of GSPs such as institutional fragmentation, lack of trust among stakeholders, under-representation of disadvantaged communities, and lack of financial resources.⁴⁷² Further, studies have expressed concerns on the overall capacity of GSAs to implement GSPs in the long run and the state capacity to meet the legal requirements where basins fail to meet the same.⁴⁷³

⁴⁷² Leach, William D. et al., (2021). Evaluating California's Sustainable Groundwater Management Act: The First Five Years of Governance and Planning. Paper No. JAWR-20-0120-P of the Journal of the American Water Resources Association. Also, *see*, Lubell, Mark, et al., (2020). Sustainable Groundwater Management in California: A Grand Experiment in Environmental Governance, Society & Natural Resources, 33:12, 1447-1467.

⁴⁷³ *Id*.

In Texas, one of the latest reports of Texas Water Development Board (TWDB) highlights that between 1995 and 2015, there has been a decline in the median water levels state-wide (less than 2 feet per year) whereas the localized declines in some areas are significantly higher.⁴⁷⁴ Though evaluation studies of a particular groundwater law/policy are not available, there are a few studies on Groundwater Conservation Districts. One of the latest studies evaluates the 'desired future conditions' (DFCs) in Texas.⁴⁷⁵ Texas law requires the conservation districts to define the DFCs which are aquifer-specific management goals allowing sustainable groundwater pumping over time. The study suggests that 95% of the state-wide DFCs allow for water-level decline and aquifer depletion.⁴⁷⁶ Another study states that the conservation districts lack local data needed to set sustainable DFCs and management goals in the first place. Further, the TWDB's groundwater availability models are too regional to provide any meaningful data on localized impact of various levels of drawdown.⁴⁷⁷ Thus, the studies' suggest a potential review of the DFCs as well as refining local data and strengthening decision-support tools.

In India, the Comptroller and Auditor General of India (CAG) released its audit report⁴⁷⁸ evaluating the ground water management and regulation for the period 2013-18. The report states an increase in the stage of groundwater extraction in the country from 58% in 2004 to 63% in 2017. It found serious gaps in implementation of the federal guidelines, such as 78% of packaged drinking water units in 15 states were found operating since 2013 based on licensing from the Bureau of Indian Standards but without the no-objection certificate (NOC) from Central Groundwater Authority (CGWA);⁴⁷⁹ 474 cases where industrial entities are continuing to extract groundwater without applying for renewal of

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⁴⁷⁴ Texas Water Development Board. (2016). Texas Aquifers Study: Groundwater Quantity, Quality, Flow, and Contributions to Surface Water. P-13.

 $^{^{475}}$ Mace, Robert. (2021). Groundwater Sustainability in Texas, The Meadows Center for Water and the Environment, Texas State University.

⁴⁷⁶ Mace, Robert. (2021). Five Gallons of Water in a Ten Gallon Hat: Groundwater Sustainability in Texas, The Meadows Center for Water and the Environment, Texas State University at 32. ("Overall, the maximum sustainable production for the major and minor aquifers of the state amounts to about 4.0 million acre-feet per year while production (current use) is about 7.01 million acre-feet per year and modeled available groundwater (allowable maximum use) is 8.9 million acre-feet. That means that Texas is currently producing its aquifers 1.8 times the sustainable rate and makes available 2.4 times the maximum sustainable production rate.")

⁴⁷⁷ Williams, Vanessa P. et al., (2021). Advancing Groundwater Sustainability in Texas: A Guide to Existing Authorities and Management Tools for Groundwater Conservation Districts and Communities. Environmental Defense Fund, at 21.

⁴⁷⁸ See, CAG Report, supra note, 210.

⁴⁷⁹ *Id.* Para 3.3.2

their NOCs;⁴⁸⁰ and several cases where the CGWA has not taken any action despite the violations of NOC conditions. However, in case of Rajasthan, impact evaluation of the state government's scheme on groundwater conservation shows that in 21 non-desert districts, there is an average rise in groundwater table by 4.66 feet, 56% reduction of water supply through tankers, and rejuvenation of 64% installed hand-pumps.⁴⁸¹ These reports provide relevant information on the policy and regulatory performance and identify implementation gaps.

The regulatory impact assessments and rule reviews are more structured in California and Texas than Rajasthan and Punjab. Based on this dissertation study, it is difficult to say how different regulatory processes of the states actually result in meeting the larger groundwater policy goals or whether more adaptive regulatory processes result in groundwater policy success than less adaptive processes. In evaluating the groundwater policies and laws, it would be important to understand what has been their impact post-implementation. How well they achieved the goals and objectives? How effectively they worked and how could they be improved? Though beyond the scope of this research, one of the ways to answer such questions is to evaluate their impact by comparing the ex-ante regulatory analysis with the ex-post regulatory analysis. 482 Further, the agencies in all four states may focus on improving the regulatory learning by introducing multi-rule reviews. 483 Mostly, the agencies focus on reviewing one rule/policy at time thus they miss out on the learnings that could be gained from reviewing multiple past rules/policies within an agency as well as from the interactive effect of multiple rules/policies across agencies. Such collective analysis could provide lessons to improve future policies through better choice of policy designs, better methodologies, and better overall assessments. 484

VI. Conclusion and Recommendations for India

Based on the documentary and interview analysis, the analyzed groundwater policies/regulations in India indicate presence of all adaptive features though in varying

⁴⁸⁰ Id. Para 3.5

⁴⁸¹ See, Mukhya Mantri Jal Swavlamban Abhiyan, supra note, 281.

⁴⁸² Bennear, Lori S. and Wiener, Jonathan B. (2021). Institutional Roles and Goals for Retrospective Regulatory Analysis. Journal of Benefit-Cost Analysis, 12 (3), 466-493. Also *see* Cropper et al., (2017). Looking Backward to Move Regulations Forward. Science, 355 (6332): 1375–1376, and Dudley et al., (2019). Crossing the Aisle to Streamline Regulation. Wall Street Journal, May 13, 2019, available at https://www.wsj.com/articles/crossing-the-aisle-tostreamline-regulation-11557788679.

⁴⁸³ See, Bennear & Wiener, supra note, 482.

⁴⁸⁴ *Id*.

degrees. The law/policymaking processes could be improved, institutionalized, and made more adaptive. India's groundwater space is very challenging to regulate due to deep socio-cultural, economic, and political interests. In this context, following are the recommendations for India:

1. Update the groundwater legal framework

The current groundwater framework is largely based on the English cases and has not changed since the 19th century. It allows permissive use of groundwater resulting in its exploitative consumption by private individuals. With increasing reliance on groundwater as a major source of drinking and irrigation and its dwindling water levels, the existing framework poses several challenges from equity and sustainability perspectives. Further, the Supreme Court of India has given rulings on public trust and the right to water as a fundamental right which are not incorporated in the formal legislative framework on groundwater. Therefore, there is a need to update the groundwater laws to reflect the changed circumstances based on evidence and science as well as reflect the major legal developments.

2. Introduce structured decision-making processes

Another area for improvement is to introduce structured decision-making in government agencies, such as the practice of regulatory analysis. However, this may be introduced in a phased manner and may not be required for all the proposed laws/policies such as limiting to the major impact laws/policies (e.g. the laws/regulations which have immense economic, social, or environmental impact). Further, these processes may encourage the use of simpler and flexible methodologies. Examples of simplified assessments are available with the Data Monitoring and Evaluation Office of NITI in the government of India. Further, DMEO could handhold the agencies and provide the required capacity building support.

3. Plan relevant data collection and use

In groundwater monitoring, there is a need to strengthen data collection by prospective planning. Identifying in advance the relevant data and outcomes could improve the quality of monitoring and evaluation. Such provisions could be built-in the policy/ regulation. Additionally, there should be emphasis on building a culture of using the available data to

inform law and policy making. For this, institutional reforms may be needed, including improving data quality, data sharing, and capacity building of personnel in public agencies.

4. Introduce post-implementation evaluation

In India, the water policies and the federal guidelines have been revised several times, which indicates that the policies are not static and are changing over time. However, these revisions are not based on any formal impact assessment of the policy. Therefore, it is recommended to introduce post-implementation evaluations/ reviews to understand if the policy/regulation is meeting the objectives for which it was created. Such retrospective reviews, could be built-in the policy/regulation and preferably with a specified time period. The time period to conduct such reviews could vary depending on the value of new information that a review could generate and the expected cost of conducting such a review. Further, instead of reviewing one rule/policy at a time, the review of earlier multiple policies on the subject could be reviewed to improve regulatory learning. 486

5. Introduce pre-legislative consultation

Pre-legislative consultation increases the legitimacy of the proposed law/policy by providing the scope to deliberate the proposal with public and interested stakeholders. The groundwater Model Bills as well as the ABY scheme are participatory in nature and provide for community involvement in key groundwater management activities such as in developing the water security plans and the water budgets. However, public participation in law and policymaking process is not mandatory, and remains agency discretionary. Therefore, it is recommended to mandate public consultation at the pre-legislative or the policy formulation stage.

6. Strengthen Inter-agency coordination through multi-policy reviews

Interview analysis suggests that inter-agency coordination is inadequate, particularly at the state level. The agencies hold inter-ministerial consultations and get feedback on the proposed law/policy by all departments/ agencies. However, the consultations seem to miss out the larger picture which is evidenced by the existence of policies that sometimes work at cross-purpose. This highlights the need to strengthen the existing inter-ministerial consultation process. One way to strengthen is by introducing multi agency, multi policy

⁴⁸⁶ *Id*.

⁴⁸⁵ *Id*.

reviews.⁴⁸⁷ For example, the water policies/laws which impact more than one department/agency should be reviewed by the relevant departments/agencies together such as through inter-agency working group. The collective impact analysis could maximize the benefits of review process, potentially reduce the cost of review, and provide lessons which are relevant across agencies.

7. Experiment with negotiated law/ policymaking

Federal government of India has made different versions of Model Groundwater Bills since 1970s and sent to the state governments for framing legislation. However, as of 2021, only 19 of 36 states/union territories in India have passed groundwater legislation. Therefore, it is important to understand why the states are reluctant in passing the legislations. Are the Model Bills feasible and practical? Is the ground reality very different than reflected in the Model Bills? In groundwater context, merely legislating in a traditional way (top down approach) may not be the answer. Therefore, the states in India may experiment with negotiated law/ policymaking⁴⁸⁸ in which the stakeholders and the rightsholders play a key role in drafting the proposed law/policy. Such a consultative process could enable to address the major concerns of the stakeholders, reduce resistance, and result in effective and implementable law/policies.

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⁴⁸⁸ See, supra note, at 105 and 106.

Chapter-4

Electric Vehicle (EV) regulations in India- An analysis

Summary: This chapter's analysis is anchored on the adaptive regulatory cycle which has six adaptive features embedded in three stages of the cycle. Based on the relative presence or absence of the adaptive features, stage-wise adaptiveness is inferred for EV sector. For India, this inference is based on the review of EV law and policy documents and interviews while for the US, this inference is based only on the review of EV law and policy documents. In the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments), India's regulatory cycle indicates low to moderate adaptiveness on the books whereas moderate to high adaptiveness in practice. In the implementation stage (monitoring and evaluation), India's regulatory cycle indicates high adaptiveness on the books and moderate adaptiveness in practice. And in the postimplementation stage (iterative decision-making), India's regulatory cycle indicates high adaptiveness both on the books as well as in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the inference is mixed. Public participation shows moderate presence on the books but high prevalence in practice. And interagency coordination shows low presence on the books but moderate prevalence in practice. The high level comparative analysis of the US and India EV law/policies suggests that in the preimplementation and implementation stages, the US regulatory cycle indicates more adaptiveness on the books than India. Whereas, in the post-implementation stage, both US and India's regulatory cycles indicate similar adaptiveness on the books. Based on this study, it is difficult to say how different regulatory processes of the two countries actually result in meeting the larger policy goals or whether more adaptive regulatory processes result in policy success than less adaptive processes. However, this study recommends that the agencies in both countries should emphasize on conducting retrospective reviews and introduce multi-rule reviews to assess the effectiveness of the laws/policies and to improve regulatory learning. The chapter concludes with specific recommendations for India.

EVs and Adaptive Regulation

Transport sector is the second largest emitter of global GHG emissions after industry. In 2019, this sector accounted for 27% of global emissions. To limit global warming to 1.5°C, it is imperative to reduce emissions in the transport sector. In this context, EVs could play a significant role by reducing the fossil fuel usage, increasing the energy efficiency, and reducing the local pollution.

Globally, sales of EVs is experiencing fast growth. In 2020, despite the pandemic, the sale of electric cars⁴ showed a record increase of 40% from 2019, whereas the sale of other cars dropped by 16%.⁵ These sale trends vary in different parts of the world with the largest increase in Europe, followed by China, and the US. Other segments of EVs such as the two-wheelers and three-wheelers also show significant increase - 25% of all 2W in the world are electric. China accounts for 95% of global electric 2W and 3W, followed by India, and other ASEAN countries.⁶ In heavy transportation, e-buses show an increase of 10% from 2019 with maximum share of China (98%). However, Europe, India, and Latin America are also increasingly procuring the e-buses. Similar trends are for the e-truck registrations, which show an increase of 10% from 2019 with China leading, followed by Europe and the US.⁷

The regulatory and policy choices of many countries are also promoting these trends. By the end of 2020, more than 20 countries announced targets to phase out internal combustion engine vehicles in the next 10 -30 years.⁸ As of April 2021, 70 subnational governments announced the phase out of internal combustion engine vehicles or 100%

⁸ *Id*.

¹ International Energy Agency (IEA). (2021). Greenhouse Gas Emissions from Energy: Overview. An essential tool for analysts and policy makers. Statistics report. (August 2021).

² Intergovernmental Panel on Climate Change (IPCC). (2018). Special Report on Global Warming of 1.5°C.

³ Parajuly, K et al., (2020). The Future of Electric Vehicles and Material Resources: A Foresight Brief. UNU/UNITAR - SCYCLE (Bonn) & UNEP-IETC (Osaka). Available at https://wedocs.unep.org/bitstream/handle/20.500.11822/34225/ElecVe.pdf?sequence=1&isAllowed=y

⁴ Electric cars include passenger light-duty battery electric vehicles, plug-in hybrid electric vehicles and fuel cell electric vehicles.

⁵ Paoli, Leonardo. (2022). Electric Vehicles, IEA. Available at https://www.iea.org/reports/electric-vehicles.

⁶ *Id*.

⁷ *Id.* Also, *see*, International Energy Agency (IEA). (2021). Global EV Outlook 2021. Accelerating ambitions despite the pandemic at 5. Available at https://iea.blob.core.windows.net/assets/ed5f4484-f556-4110-8c5c-4ede8bcba637/GlobalEVOutlook2021.pdf.

zero-emission vehicle targets by 2050.9 Also, 18 of the world's top 20 vehicle manufacturers committed to expand their portfolio of EV models and increase EV production. Thus, the global trends indicate that the EVs are here to stay and may bring a 'revolution in propulsion.'

However, EV adoption is a rapidly evolving area with its own share of uncertainties such as surrounding concerns with price sensitivity, range limitation, lack of charging infrastructure, and consumer preferences. ¹² Similarly, there are associated risks such as the total lifecycle environmental impact of EVs, ¹³ the supply risks linked with the material resources of EV batteries (due to geopolitical issues), ¹⁴ the health and environmental impact of lithium-ion batteries (disposal and battery management), ¹⁵ and other unintended consequences of the EV supply chain such as the social and ethical issues linked with extraction of some metals, use of child labor, and maintenance of poor working conditions. ¹⁶ Therefore, it is important to explore if the EV laws and policies are keeping pace with the evolving policy concerns. Are there built-in provisions to accommodate future changes? Is there any consideration and assessment of the anticipated risks while designing the laws and policies? Are there provisions to monitor the ongoing developments in such emerging sectors? Is regulatory experimentation taking place in the EV space? To investigate such questions, this chapter analyses the EV laws and policies of the US and India using the framework of adaptive regulatory cycle.

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⁹ See, Paoli, supra note 5.

¹⁰ Id. Also, see IEA Global EV Outlook 2021, supra note 7 at 25.

¹¹ We may be standing on the precipice of a revolution in propulsion not seen since the horse and buggy.' For details, *see*, Graham, John D. The Global Rise of the Modern Plug-In Electric Vehicle. Chapter 1- Rise of the modern electric vehicle. 2021.

¹² See, Parajuly, K. et al., supra note 3, at 16,17.

¹³ Id

¹⁴ Olivetti, E. A. et al., (2017). Lithium-Ion Battery Supply Chain Considerations: Analysis of Potential Bottlenecks in Critical Metals. Joule 1, 229-243.

¹⁵ See, Parajuly et al, supra note 3 at 28.

¹⁶ World Economic Forum. (2019). A Vision for a Sustainable Battery Value Chain in 2030: Unlocking the Full Potential to Power Sustainable Development and Climate Change Mitigation at 19. September 2019. Available at

https://www3.weforum.org/docs/WEF A Vision for a Sustainable Battery Value Chain in 2030 Report.pdf.

I. Adaptive Regulatory Cycle

Typically, a policy or regulatory cycle has three basic stages i.e. pre-implementation, implementation, and post-implementation.¹⁷ In the adaptive regulatory cycle, each stage has adaptive features which enable learning and improvement over the lifecycle of a policy or regulation. The adaptive regulatory cycle is informed by the six features of adaptive regulation (based on the literature review). ¹⁸ These features are (i) Assessing the risks and uncertainties, (ii) Broader and fuller impact assessment, (iii) Monitoring, evaluation, and feedback, and (iv) Iterative decision-making and Policy adjustment. These features are shown in different stages of the regulatory cycle. Additionally, there are two overarching features: (v) Public participation and (vi) Adaptive governance structures, which play an important role in all stages of the cycle.

1. Pre-Implementation

Adaptive regulations acknowledge the importance of assessing the risks and uncertainties and responding to them directly. In adaptive regulatory cycle, this implies that while formulating the regulations/policies, the agencies undertake risk assessment. Another feature is the fuller impact assessment of the policy/ regulatory alternatives. The objective is to avoid the perils of narrow decision-making. This implies that the decision-makers assess the full portfolio of impacts such as the costs, benefits, and distributional effects, including the co-benefits and the countervailing risks. Lastly, adaptive regulations acknowledge the importance of planning relevant data collection. This implies there is adequate planning to identify the relevant information to be collected so that it could result in meaningful monitoring and reviews.

¹⁷ For details, see, Section VIII 'Adaptive Regulatory Cycle' in Chapter 1.

¹⁸ For details, see Chapter 1.

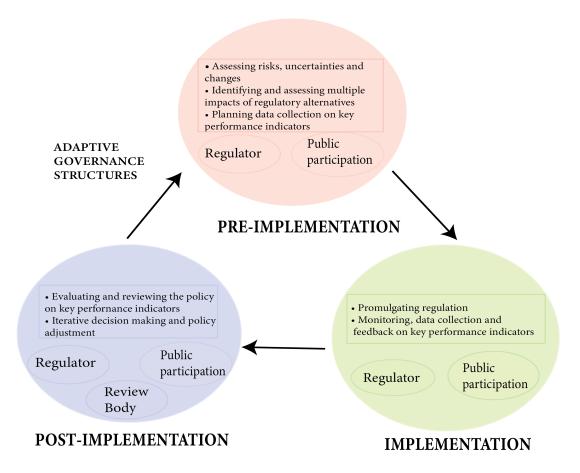


Figure 1. Adaptive Regulatory Cycle

2. Implementation

In this stage, the regulation/ policy is implemented. Adaptive regulations have built-in mechanisms of monitoring and feedback that enable policy adjustments. This implies relevant data collection and analysis take place; policy outcomes and key performance indicators are monitored, and the outcomes of monitoring and feedback are fed back into the regulatory process i.e. inform future policies and regulations.

3. Post-Implementation

In adaptive regulations, the decision-making is not a one-time binary yes/no but a continuous process where new information and post-implementation experience inform the future decisions. This implies there are built-in provisions of policy learning and iterative decision-making, such as periodic review, retrospective review, and sunset clause. In this stage, the regulations are reviewed/ evaluated such as by comparing the ex-post assessments with the ex-ante assessments. Thus, the policy changes or improvements are based on the evaluation of policies.

4. Overarching features

Public participation and adaptive governance structures are the overarching features which play an important role in all stages of the regulatory cycle.

Public Participation- Public participation has a very broad meaning. Often the terms community participation, public participation, community involvement, community engagement, citizen participation, etc., are used interchangeably.¹⁹ In adaptive regulatory cycle, the term public participation implies the right of the affected public to participate in the decision-making processes (regulatory/ policy-making). The word public includes both general public and the stakeholders/ right holders.

Adaptive Governance Structures- Adaptive governance structures represent the larger ecosystem that enables the implementation of adaptive regulations. A decentralized and polycentric approach facilitates adaptive approaches and allows for risk diversification, policy experimentation, and innovation across jurisdictions. In the adaptive regulatory cycle, these include the presence of polycentric structures and the inter-agency coordination both vertical (across different levels of government) and horizontal (at the same level of government).

The analysis of the law and policy documents and the interviews in the following sections builds on the adaptive regulatory cycle and its three stages.²⁰

II. Summary Analysis of US EV federal laws and incentives

U.S. is currently the third-largest electric vehicle market in the world with approximately 1.7 million EVs.²¹ However, as a percentage of the total new car sales, EV share in the US is 2% whereas the world average is 4.6% (2020).²² Over the last few years, EV sales in the

¹⁹ National Environmental Justice Advisory Council (NEJAC), Model Guidelines for Public Participation (2013), at 1

²⁰ For details, see, Chapter 1.

²¹ Of the total stock of 10.2 million EVs in the world, US has approximately 17 % (1.7 million), China has the largest share of 44% (more than 4.5 million), and Europe accounts for 31% (3.2 million). For details, see IEA Global EV Outlook 2021, supra note 7 at 7. Also, see, Desilver, Drew. (2021) Today's electric vehicle market: Slow growth in US, faster in China, Europe. Pew Research Center. Available at https://www.pewresearch.org/fact-tank/2021/06/07/todays-electric-vehicle-market-slow-growth-in-u-s-faster-in-china-europe/.

²² Id.

US have slowed. In 2020, 64,300 plug-in hybrids were sold which is half of the numbers in 2018. Similarly, in 2020, about 231,000 all-electric vehicles were sold which is 3.2% less than 2018.²³ Various factors could be attributed to this change including the pandemic, the phase out of the federal tax credits on popular EV models, and the receding popularity of the plug-in hybrids.²⁴

However, the US federal government has recently taken several policy measures to encourage EVs for advancing the economic opportunities and jobs for the Americans, reducing pollution, protecting public health, and addressing the issues of climate change and environmental justice.²⁵ President Biden announced the aspirational target of 50% of all new vehicles sales to be zero-emission vehicles in 2030. These include battery electric, plug-in hybrid electric, or fuel cell electric vehicles.²⁶ The Presidential Executive Order 14057 mandates the federal fleet to become comprised of 100% zero-emission vehicles by 2035.²⁷

A. Federal Regulations on EVs

The U.S. has several federal laws and incentives to encourage EVs such as the tax incentives on EV purchase and on constructing EV charging infrastructure. The federal government also invests in the research and development of batteries to reduce the production costs, increase the range of EVs, and reduce the charging times.²⁸ Beyond these federal laws and incentives, many states and electric utilities promote vehicle electrification through incentives and programs.

²³ Id.

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²⁵ Executive Order 14057 (December 8, 2021). Sec 101.70935 Federal Register / Vol. 86, No. 236 / Monday, December 13, 2021 / Presidential Documents. Available at https://www.govinfo.gov/content/pkg/FR-2021-12-13/pdf/2021-27114.pdf.

²⁶ The White House. Factsheet: President Biden Announces Steps to Drive American Leadership Forward on Clean Cars and Trucks. Statements and Releases. (Aug 2021). Available at https://www.whitehouse.gov/briefing-room/statements-releases/2021/08/05/fact-sheet-president-biden-announces-steps-to-drive-american-leadership-forward-on-clean-cars-and-trucks/

²⁷ Sec 102 (ii). See, supra note 25.

²⁸ Cattaneo, Lia. (2018) Plug-in Electric Vehicle Policy- Evaluating the Effectiveness of State Policies for Increasing Deployment. Energy and Environment. Center for American Progress. Also *see* Congressional Research Service (CRS). (2019) Vehicle Electrification: Federal and State Issues Affecting Deployment at 3.

The focus of this dissertation is to analyze the federal laws on EVs. Accordingly, based on the systematic search of the website of Alternative Fuels Data Center (AFDC),²⁹ 26 EV laws and incentives of the federal government are selected.³⁰

B. Analysis of select US EV Laws and Incentives

To explore if the regulatory cycle in the US EV sector is adaptive or not, the analysis of select federal EV laws and incentives along with the federal law and policy making process is as follows.

1. Pre-Implementation

Under US law and related administrative rulemaking processes there are many mechanisms enabling broader impact assessments of the proposed law or regulation. Several Presidential Executive Orders emphasize on such impact assessments including assessing the risks and countervailing risks of the proposed rule. In the pre-implementation stage, the agencies encourage public participation by inviting comments, conducting public hearings, webinars, etc.

a. Assessing risks and uncertainty

Presidential Executive Orders as well as the OMB circulars currently in effect emphasise the agencies to acknowledge and address the risks in their regulatory analyses. For example, the Executive Order 12866 requires the agencies to consider the degree and nature of the relevant risks while setting the agency regulatory priorities.³¹ Also, it requires agencies to assess the adverse effects of the proposed regulatory action on health, safety, and the natural environment among others.³² Supplementing this requirement, Circular A-4 requires the agencies to identify the undesirable side-effects (countervailing risks) and ancillary benefits of the proposed regulatory action as well as of the alternatives.³³

²⁹ AFDC is a resource of the Vehicle Technologies Office (U.S. Department of Energy). I searched the website for key words "laws and incentives" on "EVs" at the "federal jurisdiction" (the words in quotes are the relevant filters). The search generated a list of 26 such laws and incentives. The search was done on 11th March 2021.

³⁰ For details, see Chapter 2.

³¹ Sec 1 (b) (4). Executive Order 12866 of September 30, 1993.

³² Sec 6 (a) 3 (C) (ii). Executive Order 12866 of September 30, 1993.

³³ Office of Management and Budget (OMB) Circular A-4 (September 2003). Available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/.

b. Broader and fuller impact assessment

Congress uses the legislative committees to investigate any proposed law or amendments to existing law in-depth. When a bill is introduced in the House/ Senate, it is assigned to a legislative committee for study. The committee examines and intensively considers the proposed measure along with its strengths and limitations.³⁴ Similarly, from time to time, the President's Executive Orders have emphasized the federal agencies to conduct good regulatory analysis. These EOs require the agencies to estimate the costs and benefits of the proposed regulatory action and determine if the benefits of the regulation justify the costs. The agencies must examine the alternative approaches, assess the potential risks, ancillary benefits, as well as the distributional effects of the proposed regulatory action.³⁵ Additionally, laws such as the Unfunded Mandates Reform Act and the Regulatory Flexibility Act require the agencies to evaluate the costs and benefits of specified rulemakings, while the Administrative Procedures Act (APA)³⁶ governs aspect of process and judicial review of rulemakings in general.

In the Notice of Proposed Rulemaking, the agency discusses various alternatives, the merits of the proposed solution, and explains why the agency did not choose the other alternatives. After analyzing the public comments, the Notice of Final Rulemaking also has all these details along with the agency response to public comments and the rationale of choosing one alternative over the others. Additionally, the Office of Information & Regulatory Affairs (OIRA)³⁷ reviews the draft proposed rules which are significant in nature.³⁸ OIRA is responsible for ensuring agency compliance of the Executive Order 12866.

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³⁴ The White House. Our Government- The Legislative Branch. (Undated). (There are 17 Senate committees, with 70 subcommittees, and 23 House committees, with 104 subcommittees.) Available at https://www.whitehouse.gov/about-the-white-house/our-government/the-legislative-branch/. Also *see*, United States House of Representatives. (Undated). The Legislative Process. Available at https://www.house.gov/the-house-explained/the-legislative-process.

³⁵ Executive Orders such as 12866, 13563, and 13579 establish principles and guidance for the rulemaking process.

³⁶ APA is a federal statute enacted in 1946. It governs the process by which federal agencies make regulations. The statute establishes (i) classification for different types of agency decision-making and (ii) a set of procedural rules to govern agency decision-making. For details, *see*, Elias, Roni A. (2016). The Legislative History of the Administrative Procedure Act. Fordham Environmental Law Review, 27: 207. ³⁷ OIRA is part of the Office of Management and Budget (OMB), an agency within the Executive Office of the President.

³⁸ "Significant" due to economic effects or because they raise important policy issues. For details, *see* FAQs on Regulations and Rulemaking Process. Available at https://www.reginfo.gov/public/jsp/Utilities/faq.myjsp.

There are a few examples where the law supporting a regulation specifies an agency to consider a variety of factors before finalizing a standard such as the average fuel economy standards³⁹ and the GHG emission standards.⁴⁰

c. Public participation

Public participation is encouraged in the law-making as well as in the regulatory process. For example, the legislative committees typically provide a public hearing while examining the bill.⁴¹ The committee may invite experts, advocates, as well as opponents to appear before the committee and provide testimony.⁴² Any member of the public could petition the agency for rulemaking- to issue, amend or repeal any rule.⁴³ Based on this, the agency may decide to start the process of rulemaking. There is provision of public notice and comment in all stages of rulemaking- the advanced notice of proposed rulemaking, the proposed rulemaking, and the final rulemaking.⁴⁴

Key points:

- The US Presidential Executive Orders require agencies to consider and address relevant risks, and conduct regulatory impact analysis of economically significant regulations.
- Each legislative proposal/bill is assigned to the concerned legislative committee(s) for review.
- Public hearing is an integral part of the legislative committees' functions but not a mandatory requirement. However, the legislative committee meetings are typically open to the public.
- In the analyzed documents, there are limited examples of provisions related to risk assessment, though there are provisions indicating impact assessment.

⁴³ 5 U.S.C. § 553(e).

cortez-homelessness.

³⁹ 49 U.S.C. 32902(f). (The Department of Transportation must consider the following factors while deciding the maximum feasible average fuel economy standards: technological feasibility, economic practicability, the effect of other standards of the Government on fuel economy, and the need of the United States to conserve energy).

⁴⁰ 40 CFR § 86.1818-12 (h). (The EPA is required to consider several factors in setting the GHG emission standards. These include technology, cost, feasibility and practicality, impact on energy security and fuel savings, impact on industry, impact on vehicle safety as well as impact on CAFÉ standards).

⁴¹ See, supra note 57. However, in practice, there are professional line sitters whose presence prevents public to be there, due to limited space. For details, see, Cliff, Sarah. (2019). Paid line-standing: the bizarre congressional practice that shocked Ocasio-Cortez, explained. Vox. Available at https://www.vox.com/policy-and-politics/2019/2/13/18223836/paid-line-standing-congress-ocasio-

⁴² Id.

⁴⁴ 5 U.S.C. § 553 (c) and (d). ANPR is a preliminary notice announcing that an agency is considering regulatory action. Also, *see*, Regulations.gov. Learn about the Regulatory Process, Available at https://www.regulations.gov/learn.

2. Implementation

The US EV laws and incentives have elaborate provisions of data collection and monitoring. Most of the provisions lay out the reporting requirements for the agencies. Public participation is reflected in the form of community engagement by the agencies. A few examples are as follows:

a. Monitoring, Evaluation, and Feedback

The selected federal laws and incentives examined here have detailed provisions on setting goals and objectives, collecting data, and specifying reporting mechanisms to monitor the performance of regulation. For example, under the minimum federal fleet requirement, each federal agency is required to submit an annual compliance report to the Congress. Among other details, the annual report must include a plan of compliance with specific dates and information on any failure to meet the statutory requirements.⁴⁵ Similarly, the Secretary of Energy is required to monitor the use of alternative fuel by the federal agencies and report annually to the Congress. In addition to the extent of achievement, the report must include annual reduction in the use of petroleum-based fuels as well as the problems encountered in acquiring alternative fuels.⁴⁶ Another example is of the Administrator of General Services, who is required to submit an annual report to the Congress on operating battery charging stations in the parking areas used by the federal employees. The law specifies parameters to be monitored such as the number of battery recharging stations installed, requests received from other federal agencies, and the status and disposition of such requests.⁴⁷ Similar examples include the President submitting annual report to the Congress on installation of alternative fuel infrastructure by the federal agencies, 48 the states submitting annual reports in the mandatory state fleet program, ⁴⁹ and the alternative fuel providers submitting annual reports on their annual light-duty vehicle acquisitions.⁵⁰

b. Public Participation

Many examples demonstrate that agencies are encouraging community engagement through EV programs and consumer awareness. For example, under the Clean Cities program, the Department of Energy funds projects across the country to reduce petroleum

⁴⁸ 42 U.S.C. § 17053(a) and(b).

⁴⁵ 42 U.S. Code § 13218 (b). Also see, 42 U.S. Code § 13212.

⁴⁶ 42 U.S.C. § 6374(a)(3)(E) (ii).

⁴⁷ 42 USC 6364 (5).

 $^{^{49}}$ \S 490.205 (§ 490.201 AFV acquisition mandate schedule).

 $^{^{50}}$ % 490.308. (% 490.302 Vehicle acquisition mandate schedule).

use in transportation. The program increases consumer awareness of PEVs by supporting non-profits and academic institutions, and funding the pilot programs.⁵¹ In EV Community Readiness initiative, the department announced awards for EV projects that helped communities in 24 states and the District of Columbia by preparing for EV deployment and charging infrastructure. 52 Another example is the National Parks initiative, a joint initiative of the Department of Energy and the National Park Service (NPS). It supports transportation projects to educate park visitors on the benefits of shifting to alternative fuels, advanced vehicles, and fuel-saving technologies. Since 2010, these agencies have collaborated on 35 projects on putting alternative fuel vehicles on road, reducing vehicle idling, and improving vehicle efficiency.⁵³

Key points:

- The US EV laws and incentives have elaborate provisions of data collection and monitoring.
- Most of the statutory provisions lay out reporting requirements for the agencies along with parameters to be monitored and evaluated.
- There are a few examples of provisions specifying the role of stakeholders in decision-making.

3. Post-Implementation

The US law and rulemaking processes have a few examples of post-implementation review. However, there are many provisions of post-implementation review and evaluation in the statutes. Regarding public participation, the agency must follow the notice-and-comment process to make any change/ revision in the regulation. Few key examples are shared as follows:

a. Iterative Decision-making and Policy Adjustment

The legislative standing committees evaluate the implementation and effectiveness of laws on the subject matters of their jurisdiction. They review the conditions and circumstances necessitating the need of a new or additional law. These committees also have the function of undertaking future research on the subject matter of their jurisdiction along with

https://cleancities.energy.gov/partnerships/projects#electric-vehicle-projects.

⁵¹ United States Department of Energy (DOE), Office of Energy Efficiency & Renewable Energy, "About Clean Cities," available at https://cleancities.energy.gov/about/ (last accessed March 2021).

⁵² Id. at Partnerships & Projects, "Funded Projects," available at

⁵³ US DOE, Office of EERE, Clean Cities Coalition Network, "National Parks Initiative," available at https://cleancities.energy.gov/national-parks.

studying the impact or potential impact of tax policies on such matters.⁵⁴ Similarly, an agency could review and revise the rule in several ways, including based on agency experience of implementing a rule; requirement by law or Presidential directive; petition from the public; and review by experts. In all these situations, the agency must follow the notice-and-comment process to make the changes.⁵⁵

In the selected federal EV laws and incentives, there are examples of pilot programs such as Zero-emission airport vehicles and infrastructure pilot program. These programs focus on purchasing, leasing, or operating zero-emission vehicles along with constructing or modifying the infrastructure to facilitate fuel delivery for such vehicles at the airport.⁵⁶ Another example is demonstration projects for advancing innovation in public transportation. The eligible projects include deployment of low or no emission vehicles, zero emission vehicles, and/ or associated advanced technology.⁵⁷

Laws require the EPA Administrator to conduct mid-term evaluation of GHG emission standards and revise them making them more or less stringent.⁵⁸ Similarly, as a part of reporting and evaluation, the EPA administrator is required to evaluate the implementation of diesel emissions reduction programs and submit biennial report to the Congress. ⁵⁹ In congestion mitigation and air quality improvement program, the Secretary of Transportation is required to evaluate and assess the projects including impact on the cost and cost-effectiveness based on reductions in congestion and emissions.⁶⁰ Also, there is periodic review of the projects' cost-effectiveness and assessment of measures over a variety of timeframes.⁶¹

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⁵⁴ Congress.Gov. How our Laws are Made. VIII. Legislative Oversight by Standing Committees. Available at https://www.congress.gov/help/learn-about-the-legislative-process/how-our-laws-are-made.

⁵⁵ The Office of Federal Register. (Undated). A Guide to the Rulemaking Process. Available at https://www.federalregister.gov/uploads/2011/01/the-rulemaking-process.pdf.

⁵⁶ 49 U.S. Code § 47136 (a).

⁵⁷ 49 U.S. Code § 5312 (e).

⁵⁸ 40 CFR § 86.1818-12 (h). Also see, 40 CFR § 86.1818-12 (a) (The EPA sets greenhouse gas emission standards for light-duty vehicles, light-duty trucks, and medium-duty passenger vehicles. These standards are applicable to the electric vehicles).

⁵⁹ 42 U.S. Code § 16134. (In addition to the information on the grant applications that are received and approved, the law requires to include the description of "actual and estimated air quality and diesel fuel conservation benefits, cost-effectiveness, and cost-benefits of the grant, rebate, and loan programs under this part").

^{60 23} U.S. Code § 149 (i) (1) (A) and (B).

^{61 23} U.S. Code § 149 (i) (2) (A) (B) and (C).

Other review examples include annually reviewing the values of average fuel economy calculation for electric vehicles, 62 periodic review and modification of replacement fuel goals, 63 and updating and re-designating the National EV charging corridors every five years.64

Lastly, the examples of sunset clause include the vehicle tax credit for qualified twowheeled plug-in electric drive motor vehicle that is available for vehicles acquired before January 1, 2022;65 and the High Occupancy Vehicle (HOV) exemption for alternative fuel vehicles (AFVs) and plug-in electric vehicles (PEVs) which expires on September 30, 2025.66

Key points:

- The legislative standing committees evaluate the implementation of laws on subject matters of their jurisdiction.
- Agencies may also review the regulations provided they follow the notice and comment process.
- In addition, the EV laws and incentives have several examples allowing iterative decision-making, such as pilot programs, sunset clauses, as well as postimplementation review and evaluation.

4. US law and incentives and Adaptive governance structures

In addition to the presence of adaptive regulatory processes, there are examples of adaptive governance structures in the US EV space. These governance structures reflect polycentrism as well as inter-agency coordination.

a. Polycentric governance

Examples include the Secretary of Transportation involving stakeholders in designating the alternative fuel corridors; 67 the Diesel Emissions Reduction Act providing for agency-

^{62 49} U.S. Code § 32904. (The statute further provides the Secretary of Energy to review these values every year and also propose required revisions based on multiple factors listed such as the electrical energy efficiency of the vehicle, it's kind, mission, and weight).

^{63 42} U.S. Code § 13254. (If upon the review, the Secretary determines that the goals including percentage requirements or dates are not achievable, the Secretary in consultation with appropriate federal agencies could modify the goals).

^{64 23} U.S. Code § 151. (National electric vehicle charging and hydrogen, propane, and natural gas fueling corridors)

^{65 26} U.S. Code § 30D (g).

⁶⁶ The low-emission and energy-efficient vehicle toll-access to HOV lanes expired on September 30, 2019. For details, see, 23 U.S. Code § 166.

⁶⁷ 23 U.S. Code § 151 (c). The stakeholders include the representatives of energy utilities; electric vehicle industries; the freight and shipping industry; clean technology firms; the hospitality industry; the restaurant industry; highway rest stop vendors; industrial gas and hydrogen manufacturers.

industry coordination to tap international markets for the US developed technologies in emission reductions;⁶⁸ the EPA's Ports initiative promoting collaboration with port industry, communities, and other port stakeholders;⁶⁹ the DOE's Clean Cities program providing for public- and private-sector matching funds and in-kind contributions;⁷⁰ the Public Transportation Research, Demonstration, and Deployment Funding being open to the public transportation systems, universities, state department of transport, non-profit, and for-profit organizations among others;⁷¹ and the congestion mitigation and air quality improvement program providing program implementation through agreements with any public, private, or nonprofit entity.⁷²

b. Inter-agency coordination

There are examples of agency coordination both horizontally (between agency at the same level of government) and vertically (between agencies at different levels of government).

Examples of horizontal coordination include the Secretary of Transportation setting the average fuel economy standards after consulting the Secretary of Energy and the Administrator of the Environmental Protection Agency.⁷³ Similarly, the EPA Administrator must consult the Secretary of Transportation, while issuing guidance on the emission credits for air quality projects.⁷⁴

Examples of vertical coordination include the federal government funding the municipal transit bus electrification through Federal Transit Administration grants.⁷⁵ Similarly, the federal law provides for qualified energy conservation bonds for the state, tribal, and local governments. These bonds can be issued by the governments at competitive rates for funding capital expenditures on qualified energy conservation projects. Eligible projects include research and demonstration projects on non-fossil fuels as well as advanced battery

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⁶⁸ 42 U.S. Code § 16135 (d).

⁶⁹ It is an incentive-based program to reduce emissions by the port authorities and terminal operators by retrofitting and replacing older diesel engines with new technologies and using cleaner fuels. EPA, "About EPA Ports Initiative," available at https://www.epa.gov/ports-initiative/about-epa-ports-initiative
70 U.S. DOE, Office of EERE, Clean Cities Coalitions: Advancing Affordable, Domestic Transportation

Fuels and Technologies Across the Country, DOE/GO-102020-5515, January 2021, at https://www.afdc.energy.gov/uploads/publication/clean_cities_overview.pdf.

^{71 49} U.S.C. 5312.

⁷² 23 U.S. Code § 149 (f).

⁷³ 49 U.S. Code § 32902 (b).

⁷⁴ 49 U.S. Code § 47139.

⁷⁵ 49 U.S.C. 5339 (c). Also, *see* Federal Transit Administration, "Low or No Emission Vehicle Program-5339 (c)," available at https://cms7.fta.dot.gov/funding/grants/lowno.

manufacturing technologies.⁷⁶ Other examples of vertical coordination are in the state energy program⁷⁷ and the congestion mitigation and air quality improvement program.⁷⁸

The above analysis suggests that the US federal EV laws and incentives have many adaptive features. Most of these features are built-in the regulatory process and are mandatory for the agencies. In addition to the adaptive processes, there are also examples of adaptive governance structures indicating polycentrism and cross agency coordination. Therefore, on the books, the US laws and regulations appear adaptive in all the three stages of regulatory cycle. To understand how the laws and regulations are in practice, it is important to interview key stakeholders to understand their perspectives on agency implementation as well as to analyze other documents such as agency reports on impact assessment, postimplementation review, evaluation, etc. However, due to the limitation of time, this dissertation's focus is only on the EV law and policy documents and the government sources on the law and rulemaking process.

III. Detailed Analysis of India's EV federal laws and policies

A. EVs and Road Transport in India

Electric vehicle production in India dates back to 1996 when Scooters India Ltd, developed the first electric three-wheeler - Vikram SAFA, followed by Mahindra & Mahindra's electric three-wheeler in 1999. In 2000, Bharat Heavy Electricals Limited (BHEL) developed an 18-seater electric bus and in 2001, the Reva company developed the electric cars. Thereafter, many manufacturers such as TATA motors, General Motors, Maruti Suzuki India, Hero Motocorp, and TVS have launched electric vehicles. However, over the years, the high cost of electric vehicles and inadequate charging infrastructure have posed major concerns for mass adoption.⁷⁹

⁷⁶ 26 U.S.C. § 54D.

⁷⁷ Office of Energy Efficiency & Renewable Energy, "About the State Energy Program," available at https://www.energy.gov/eere/wipo/about-state-energy-program (It provides funding and technical assistance to states, territories, and the District of Columbia for enhancing energy security, increasing energy affordability, and advancing state and local government led clean energy initiatives. It includes funding and supporting transportation programs that accelerate use of alternative fuels). ⁷⁸ 23 U.S. Code § 149 (h). (The Secretary of Transportation is required to encourage states and metropolitan planning organizations to have inter-agency consultation at the state and local level on the estimated emission reductions from the proposed air quality improvement programs and projects). ⁷⁹ National Electric Mobility Mission Plan (NEMMP) 2020. (2012). Department of Heavy Industry, Ministry of Heavy Industries & Public Enterprises, Government of India, at 10,11.

India has the second-largest road network in the world⁸⁰ and the road transport caters to 90% of India's total passenger traffic and 64.5% of the country's goods movement.⁸¹ India is the fifth largest automobile market in the world⁸² and increasing urbanization is impacting the growth of road transportation industry as well as the automobile sector. Between 2015-2019, India's rate of urbanization increased from 32.78% to 34.47% leading to the growth of road transport industry at a CAGR of 9.40% and commensurate growth of the automobile sector.⁸³

When compared to the western automobile market, Indian market has many unique features,⁸⁴ such as the low vehicle ownership ratio (22 cars per 1,000 individuals),⁸⁵ two-wheelers dominance (80.8% market share),⁸⁶ price-sensitive customers,⁸⁷ preference for public transportation,⁸⁸ high traffic density on the roads,⁸⁹ and short average commuting distances (upto 5 km per day).⁹⁰ Considering the uniqueness of consumer preferences and market realities, the products and policies of other geographies may not be replicated in India. India's EV solutions need to be designed based on India's contextual realities.

The present EV scenario of India reflects these unique features. The three-wheeler EV segment is leading the electrification of automobiles and includes e-rickshaws and e-carts. This segment contributes to 79% of overall EV presence in India. Several factors are resulting in a high uptake of this segment. The three-wheelers (3 W) are the providers of affordable shared mobility and last mile connectivity. These vehicles generally ply on short routes which takes care of the range anxiety. Further, compared to the ICE 3W, the electric

⁸⁰ Gesellschaft für Internationale Zusammenarbeit (GIZ) (On behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Federal Republic of Germany). Status quo analysis of various segments of electric mobility and low carbon passenger road transport in India. (July 2021) at 1. (India's road network's total length is 5.89 million Kilometers).

 ⁸² India Brand Equity Foundation (IBEF). (November 2021). Indian Automobile Industry Report. Ministry of Commerce & Industry, Government of India. https://www.ibef.org/industry/india-automobiles.aspx.
 83 See GIZ, supra note 80.

⁸⁴ Id. at 16. (Adapted from Figure 30-Overview of Indian mobility landscape.)

⁸⁵ The western countries, such as US and UK had 980 and 850 cars per 1,000 individuals.

⁸⁶ The passenger cars' market share is 12.9%. IBEF. Automobile Industry in India. https://www.ibef.org/industry/india-automobiles.aspx. Last updated on Dec, 17 2021

 $^{^{87}}$ Affordability drive the ownership of vehicles in India. The average income in India is less when compared to the western counterparts.

⁸⁸ Public transport including trains, buses, trains, cabs, shared autos etc.

⁸⁹ Due to limited infrastructure, there is high traffic density on Indian roads (particularly in the cities)

⁹⁰ In the US the average commuting distance for work is 26 km per day. See GIZ, supra note 80.

⁹¹ "E-cart" means a special purpose battery operated vehicle having three wheels and intended to provide last mile connectivity for carrying goods for hire or reward. "E-rickshaw" means a special purpose battery operated vehicle having three wheels and intended to provide last mile connectivity for transport of passengers. For details, *see*, MoRTH GSR notification dated 8.10.2014.

3 W have low maintenance cost and high efficiency. The two-wheeler EV segment contributes to 17% of EV presence in India. The two-wheeler (2 W) segment is picking up with multiple companies offering a variety of EV models at competitive prices. However, the high cost of EV 2 W when compared to a conventional ICE 2 W is still preventing the high uptake. The Four-wheeler segment contributes to only 3% of EVs in India. Several factors resulting in the low uptake include the availability of limited models, high cost, range anxiety, and the lack of charging infrastructure. In addition to the battery cost, the import of auto-parts of EVs adds to the high costs. The Electric bus segment contributes the least (~1%) to the EV population in India. However, this segment is witnessing changes with the manufacturers offering new e-bus models and the government of India committing substantial resources to electrify public transportation in the country.

B. India's policy shift towards EVs

Several factors are influencing India's policy shift towards the EVs- the energy security and environmental factors, being the major drivers.

Energy security- India has very high dependency on the oil and gas imports. The import trends of 2013 to 2019 show a further increasing import dependency. The crude oil import increased from 84% in 2013 to 88% in 2019 and the natural gas import increased from 23% to 36% for the same period. Further, India has very limited share in the global crude oil and natural gas reserves (0.3% and 0.7% respectively). Therefore, it is imperative for India to reduce the usage of conventional fossil fuels and consider the non-conventional vehicle technologies.

Air pollution- In 2019, India was ranked fifth most polluted country of the world in air contamination. Ambient air pollution causes a staggering 670,000 deaths in India each year⁹⁷ and transportation sources account for one- third of Particulate Matter (PM) pollution and a higher percentage of nitrogen oxides (NOX).⁹⁸ Further, India is the fifth

94 Id. at 12,13.

⁹² See GIZ, supra note 80 at 10,11.

⁹³ Id. at 8,9.

⁹⁵ *Id.* at 15.

⁹⁶ Id. at 4,5.

⁹⁷ Balakrishnan, K. et al., (2018). The impact of air pollution on deaths, disease burden, and life expectancy across the states of India: The Global Burden of Disease Study 2017. The Lancet Planetary Health.

⁹⁸ International Council on Clean Transportation. Publications on India, available at

largest automobile market in the world. In 2020, it sold ~3.49 million units in the passenger and commercial vehicles categories.⁹⁹ Therefore, cleaner fuel vehicles would help in improving the air quality in India.

Climate change and International commitments- Transport sector is the third highest contributor of India's overall GHG emissions after power industry and industrial combustion. In 2019, transport sector accounted for 14% of India's carbon emissions, of which more than 90% were from the road transport. Further, the majority of Indian vehicles are powered by the conventional fuel technologies- petrol (84%), diesel (13%), and other (3%). As a signatory to the Paris Agreement, India's target is to reduce 33-35% emissions intensity of GDP by 2030. Also, India has endorsed the IEA's EV30@30 Campaign which sets an aspirational goal of reaching 30% EV sales share (excluding two/three-wheelers) by 2030 by all the signatory countries.

C. Key federal agencies and EV law and policymaking

India's EV space has multiple agencies and departments, each having defined roles. The key agencies include the (i) Department of Heavy Industries (DHI)- It frames the policies/schemes on demand incentives for consumers and EV manufacturing; (ii) Ministry of Power- It frames regulations and guidelines on the charging infrastructure and related safety standards; (iii) Ministry of Road Transport and Highways (MoRTH)- It frames regulations and policies on electric vehicles along with non- financial incentives; and (iv) NITI Aayog- It plays the role of coordinating as well as leading the research impacting EV policies and regulations

In 2005, the term 'Battery operated vehicle' was added in the Central Motor Vehicle Rules. 104 However, policymaking in the EV space started 2011 onwards when the

100 See GIZ, supra note 82 at v.

https://theicct.org/india#publications.

⁹⁹ See, IBEF supra note 80.

¹⁰¹ International Energy Agency (IEA). (2021). Air quality and climate policy integration in India. Frameworks to deliver co-benefits. Country report — May 2021. https://www.iea.org/reports/air-quality-and-climate-policy-integration-in-india.

¹⁰² See GIZ, supra note 80 at 3.

¹⁰³ See, IEA Global EV Outlook 2021, *supra* note 7 at 13. (Fourteen countries endorsed the campaign: Canada; Chile; China; Finland; France; Germany; India; Japan; Mexico; Netherlands; Norway; Portugal; Sweden and United Kingdom). Also *see*, Clean Energy Ministerial. EV 30@30 Campaign. Factsheet. ¹⁰⁴ Inserted by G.S.R. 589(E), dated 16-9-2005 (w.e.f. 16-9-2005).

government of India approved the National Mission on Electric Mobility. Subsequently in 2012, the government launched the National Electric Mobility Mission Plan (NEMMP) 2020. The NEMMP had the EV penetration target of 14%-16% by 2020. Despite considerable measures, the target remained grossly under-achieved with less than 1% EV penetration in India by 2020. However, NEMMP played the crucial role of increasing EV awareness among the consumers and providing the initial fillip to electric mobility in the country. ¹⁰⁶

In 2015, the Department of Heavy Industry notified the Faster Adoption and Manufacturing of (Hybrid and) Electric Vehicles in India (FAME-I) scheme, with four focus areas: developing technology (R&D), providing demand incentives, developing public charging infrastructure, and carrying out pilot projects.¹⁰⁷ However, FAME I was a limited success as it could utilize only 41% of the allocated funds in four years of the scheme implementation.¹⁰⁸

Based on the learnings of FAME-I, the government notified the second phase called FAME-II in 2019 with allocation of 1.4 billion USD for 3 years. It has provisions allowing modification in the coverage as well as the limit of fund allocation based on 'emerging requirements.' The maximum share of the incentives is for e-buses (41%), followed by e- 3W (29%) and e-2 W (23%). Till December 2021, 1.85 lakh Electric Vehicles have been incentivized under FAME II. 110

In 2019, the government of India started the Phased Manufacturing Programme (PMP) to promote domestic manufacturing of electric vehicles. The programme's objective is to increase value addition and capacity building of indigenous manufacturing through graded customs duty on EVs and components.¹¹¹ However, due to low target achievement by

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¹⁰⁵ See NEMMP, supra note 79.

¹⁰⁶ See GIZ, supra note 80 at 88.

¹⁰⁷ FAME-I. (2015). Ministry of Heavy Industries and Public Enterprises, Department of Heavy Industry, Notification S.O. 830 (E), 13th March, 2015.

¹⁰⁸ See GIZ, supra note 80 at 89.

¹⁰⁹ FAME-II. (2019). Ministry of Heavy Industries and Public Enterprises, Department of Heavy Industry, Notification S.O. 1300 E, 8th March, 2019.

¹¹⁰ Ministry of Heavy Industries. Year-end-Review of the Ministry of Heavy Industries-2021. Available at https://pib.gov.in/PressReleasePage.aspx?PRID=1784161#:~:text=1%20million%20Electric%202%20W <a href="https://peaserge.aspx?PRID=1784161#:~:text=1%20million%20Electric%202%20W <a href="https://peaserge.aspx?PRID=1784161#:~:text=18841

¹¹¹ Phased Manufacturing Programme (PMP). (2019). Ministry of Heavy Industries and Public Enterprises, Department of Heavy Industry, Notification. Phased Manufacturing Programme (PMP) to promote indigenous manufacturing of Electric Vehicle, its assemblies and parts/sub-parts/inputs of the sub-assemblies thereof.

September 2020, the Government extended the effective date of indigenization of EV parts.¹¹²

In 2021, the government of India started two major Production Linked Incentive schemes related to EVs: (i) National Programme on Advanced Chemistry Cell (ACC) Battery Storage- The scheme incentivizes setting up of manufacturing facilities in India for 50 Giga Watt Hour of ACC and 5 GWh of "Niche" ACC¹¹³ and (ii) Automobile and Auto Components Industry- The scheme incentivizes manufacturing capabilities for advanced automotive products in India and attracting investments in the automotive manufacturing value chain. ¹¹⁴

In addition to the above major policies/ schemes by the DHI, several other agencies/ ministries have amended regulations and formulated policies to improve EV adoption. For example, the Ministry of Road Transport and Highways has amended the Central Motor Vehicle Rules to include various provisions regarding EVs.¹¹⁵ The Ministry of Housing and Urban Development has required 20 percent of the parking space in the residential and commercial complexes to be allotted for EV charging facilities.¹¹⁶ The Ministry has made necessary amendments to include the norms and standards for EV charging infrastructure in the city infrastructure planning.¹¹⁷ The Ministry of Power has issued guidelines and standards for the EV charging infrastructure.¹¹⁸ The Central Electricity Agency has notified amendments to existing regulations to facilitate grid connectivity for charging infrastructure.¹²⁰

¹¹² See GIZ, supra note 80 at 39.

¹¹³ Production-Linked Incentive (PLI) scheme, 'National Programme on Advanced Chemistry Cell (ACC) Battery Storage.' (2021). Ministry of Heavy Industries and Public Enterprises, Department of Heavy Industry, Notification, 9th June 2021.

¹¹⁴ Production-Linked Incentive (PLI) scheme for Automobile and Auto Components Industry in India. (2021). Ministry of Heavy Industries. Notification. 23rd September 2021.

¹¹⁵ The Central Motor Vehicle Rules have been amended at least 14 times since 2014.

 $^{^{116}}$ Ministry of Housing and Urban Affairs has notified Amendments in Model Building Bye-Laws (MBBL) -2016.

¹¹⁷ Handbook of Electric Vehicle Charging Infrastructure Implementation. Version-1. at 28. (The Urban and Regional Development Plans Formulation and Implementation Guidelines – 2014. However, the states have the jurisdiction to adopt and enforce amendments in the building byelaws, through the local development authorities or municipal corporations).

¹¹⁸ The "Charging Infrastructure for Electric Vehicles - Guidelines and Standards" were issued by the Ministry of Power on 14.12.2018 which were subsequently revised on 01.10.2019, June 2020, and January 2022.

¹¹⁹ Central Electricity Authority (CEA). Technical Standards for Connectivity of the Distributed Generation Resources (Amendment) Regulations, 2019. Notification. 6th February, 2019.

¹²⁰ Central Electricity Authority (CEA). Measures Relating to Safety and Electric Supply (Amendment) Regulations, 2019. Notification. 28th June, 2019.

D. Analysis of select India's EV laws and policies

To explore if India's regulatory cycle in EV space is adaptive or not, I have analyzed 23 EV law/policy documents along with 8 interviews of key stakeholders. Additionally, government sources on the law and policy making process are analyzed.

1. Pre-Implementation

The documentary analysis suggests that the law and policy making process of India does not mandate the departments/ Ministries to conduct risk and uncertainty assessment. The interview analysis suggests that the concerned department/ Ministry, sometimes conduct risk assessments which are qualitative and less formal. Regarding the broader impact assessments of the proposed laws and policies, the documentary analysis suggests that there are a few mechanisms enabling the same. However, the interviews suggest that such assessments are largely unstructured with mixed views on being broader or skewed in their scope. Lastly, the documentary analysis suggests that public participation in the law and policy making process is limited as there is no legal mandate to consult public. The interviews however suggest that general public participation is low whereas the stakeholder participation is high. Further, the public platforms for publishing the draft laws and policies have increased though transparency and accessibility issues remain.

a. Documentary analysis

i. Acknowledging risks and uncertainties

The agencies have no legal mandate to consider and address the risks of proposed law/policy. In the analyzed EV documents, there are very limited provisions indicating risk assessment. Except the NEMMP, none of the analysed documents mention risk or risk assessment. For example, the NEMMP provides a few indirect references, such as while mentioning the factors necessitating the shift towards electronic mobility, it included fast depletion of fossil fuels, rising energy costs, and adverse environmental impacts like climate change.¹²¹

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¹²¹ See, NEMMP, supra note, 79 at 7-10.

ii. Broader and fuller impact assessment

Most of the identified examples are from the NEMMP. Other documents have limited provisions or they briefly state the objectives in the background section. The NEMMP includes detailed information on the cost benefit analysis of EVs in different segment (2W,3W,4W, buses, etc.); ¹²² international best practices and global trends on R&D efforts in EVs; ¹²³ comparative assessment of e-mobility strategies of several countries including US, China, France, and Japan; ¹²⁴ scenario analysis of vehicle demand projection in India ¹²⁵ and of infrastructure requirement for different EV segments; ¹²⁶ and assessment of policy options on the scope of demand incentives ¹²⁷ and for channelizing demand incentives. ¹²⁸

The federal government's pre-legislative consultation policy of 2014 has provisions regarding the broader impact assessments. It requires the concerned department/Ministry to publish the proposed legislation's financial implications, its impact on environment, and on the fundamental rights of the affected people, and their livelihoods. However, this policy is not binding on the departments/Ministries.

The inter-ministerial consultation is another avenue of assessing various aspects of the law/policy under consideration. In government, the concerned department/ Ministry initiates the legislative proposal and considers its implications from various aspects such as economic, political, social, administrative, and financial. It consults other departments and experts, and prepares a self-contained memorandum which is cleared by the Ministry of Law before it reaches the Cabinet. The Cabinet generally discusses the broad aspects of policy underlying the proposal and gives its decision. It may refer the proposal to a standing committee or an ad-hoc committee for in-depth appraisal.

Similarly, the legislative committees play an important role in assessing different aspects of the legislative proposal in the form of bill. Once the Cabinet approves the memorandum,

¹²² Id. Para 8.5 at 135,136.

¹²³ Id. Para 5.1.3 at 76,77.

¹²⁴ *Id.* Para 8.6 at 138, 139 and Para 7.1.4 at 109,110.

¹²⁵ Id. Para 4.3 at 39,40.

¹²⁶ Id. Para 7.2 at 112 -115.

¹²⁷ Id. Para 4.6.3 at 64,65. (weighing 3 options on types of vehicle segments and technologies)

¹²⁸ *Id.* Para 4.9.5 at 72. (weighing 4 options such as cash incentive to OEM, tax incentive to OEM, cash incentive to consumer, claimed by OEM, and tax incentive to the consumer).

¹²⁹ Pre-Legislative Consultation Policy (PLCP). Para 2. (February 2014). Ministry of Law & Justice, Government of India.

¹³⁰ Parliament of India. Rajya Sabha. (July 2020). The Law Making Process at 5.

¹³¹ Cabinet is a key body within the council of Ministers at the federal level.

it is drafted as a bill and introduced in either of the two houses of the Parliament- Rajya Sabha (Council of States) and Lok Sabha (House of People). The Chairperson/ Speaker of the house may refer the bill to the standing committees such as the department-related Parliamentary standing committees (DRSCs). In addition, there are ad-hoc committees which are constituted for a specific purpose, such as the select committees and the joint committees. These committees examine the bill clause by clause and submit a detailed report. In addition, the select committees and the joint committees. These committees examine the bill clause by clause and submit a detailed report.

In the government, there is a practice of creating committees or task groups to study key technical and policy issues. These committees and task groups are generally interdepartmental in nature with members from academia as well as industry. Their reports are in-depth including consideration of a variety of policy options.¹³⁴ Another example relates to the Production-linked Incentive (PLI) scheme on Advanced Chemistry Cell battery storage. The scheme does not mention the cost-benefit analysis; however, the official press release of the government gives a summary of cost-benefits associated with the scheme.¹³⁵ This indicates that the department conducted cost- benefit analysis, but such details are not available in the policy documents.

iii. Public Participation

The official notifications are published in the Gazette of India and generally mention a period of thirty days for inviting objections and suggestions from the public. However, in two documents the period was as short as 10 days. ¹³⁶ In terms of reaching out to the public and soliciting their feedback in law and policymaking process, the NEMMP is the only document describing such an endeavour by the government in EV space. It describes the joint government -industry study, which informed the development of scenarios for EV

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¹³² See, supra note 130 at 10. Also see, Rule 270 (b) and 273. (There are 24 DRSCs, of which 8 are under Rajya Sabha and 16 are under Lok Sabha. These committees generally have 3 months to examine the bill and submit report.)

¹³³ *Id.* at 11.

¹³⁴ Consultative Group on Future Transportation. Status Report. 30th September 2021. For example, the consultative group on future technology created a task group to address the issue of 'high power charging infrastructure for e-buses.' The task group assessed multiple alternate options and worked on each option to prepare draft standards (1.High Power Plug-in DC Charging 2. High Power Automated Connector Charging (also called Opportunistic Charging or Pantograph charging) 3. Swappable Batteries for e-Bus)
¹³⁵ Press Information Bureau, Delhi. Cabinet approves Production Linked Incentive scheme "National Programme on Advanced Chemistry Cell Battery Storage." 12 May 2021.

¹³⁶ Ministry of Road Transport and Highways. Notification. 8th October 2014. The Central Motor Vehicles (Sixteenth Amendment) Rules 2014.

penetration as well as demand projections of India.¹³⁷ As a part of this study, consumer surveys were conducted to understand consumer preferences, ¹³⁸ along with focus group discussions and interviews of potential consumers and key stakeholders.¹³⁹

In addition to the objective of informed decision-making, several provisions of the prelegislative consultation policy aim to increase transparency of legislative proposals and improve public participation. For example, it requires the department/ Ministry to publish draft legislation for at least 30 days,¹⁴⁰ publish an explanatory note with details of the key legal provisions in a simple language,¹⁴¹ publish the summary of public feedback and comments on its official website,¹⁴² and hold additional stakeholder consultations when required.¹⁴³ However, these provisions are not binding on the departments/ Ministries.

Also, for the legislative committees, it is not mandatory to consult members of the public. For example, the department related Parliamentary standing committees may circulate the bill for eliciting the public opinion.¹⁴⁴ Similarly, the select committees and the joint committees also may hold stakeholder consultations and take evidence of the public bodies, experts, and relevant associations.¹⁴⁵

Key points:

- In India, the law/ policymaking process does not formally acknowledge the need to consider and assess the risks.
- The federal government's pre-legislative consultation policy requires impact assessment
 of proposed regulations, but this policy does not have a legal backing, hence not
 mandatory.
- The legislative committees play an important role in assessing different aspects of the legislative proposal (bill), however, not every bill is referred to them.
- Public consultation in law and policymaking is not a mandatory legal requirement- This
 is based on the assumption that people's interests are voiced by their chosen elected
 representatives.

¹³⁷ See, NEMMP, supra note 79. Para 4.4 at 40-48. Also, see Para 3.2.8 at 23.

¹³⁸ *Id.* The consumer survey covered 7000 respondents across 16 cities, including the tier 1, tier II and tier III & IV cities and 12 focus groups across the nation covering all vehicle segments.

¹³⁹ *Id.* [200 interviews were conducted covering all automotive stakeholders including the Government (Central Ministries & Departments, State Governments etc.), Industry (both OEMs and suppliers), Research Institutes and Associations etc.]. For details, *see* Para 3.2 at 22,23.

¹⁴⁰ See, PLCP, supra note 129, Para 2.

¹⁴¹ *Id.* Para 5.

¹⁴² *Id.* Para 6.

 $^{^{143}}$ Id. Para 7.

¹⁴⁴ See, Parliament of India, supra note 130 at 11. Also, see Rule 69.

¹⁴⁵ *Id*.

b. Interview Analysis

i. Acknowledging risks and uncertainties

The interview analysis suggests that generally, the law and policy making processes do not include formal assessment of risks and uncertainties. Such processes are more informal or at best qualitative.

• Ad hoc risk assessment

Two participants think that the risk assessment is done in a very ad-hoc manner and the domain experts are not given sufficient autonomy. They think that policymaking in India is risk-averse where risk means the possibility of a bad outcome.

Participant- A ["The tendency of decision-makers is to 'minimise the risks' and not necessarily 'to maximize the benefits"].

Further, the policy processes do not incorporate scenario-based thinking, therefore, a policy is not designed to accommodate a range of outcomes, thus, becomes inflexible at times.

• Detailed risk assessment

Two participants consider that policymaking includes risk and uncertainty assessments. Of these, one participant shared that such assessments are mostly qualitative in nature. The participant shared that while creating the advanced chemistry cell battery manufacturing scheme, the decision-makers conducted SWOT analysis. ¹⁴⁶ Other two participants without mentioning the qualitative or quantitative aspect, affirmed that such risk assessments are conducted through institutions such as the NITI Aayog, other policy thinktanks, and non-profit organizations who are providing consultancy services to the government. Further, a participant shared that India is a signatory to UN Working Party 29, a world forum for harmonizing the vehicle regulations, ¹⁴⁷ thus, the policymakers are privy to the best practices and international safety standards which inform policymaking.

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¹⁴⁶ This included discussion on the possibility of raw materials such as cobalt being not available, assessing feasibility from the global supply perspective, sourcing from within the country, etc.

¹⁴⁷ United Nations Economic Commission for Europe. The UNECE World Forum for Harmonization of Vehicle Regulations (WP.29) is a unique worldwide regulatory forum within the institutional framework of the UNECE Inland Transport Committee. For details, *see* https://unece.org/wp29-introduction.

ii. Broader and fuller impact assessment

The interview analysis suggests that more participants think that the impact assessments are less structured than the participants who think such assessments are structured. There are mixed views of the participants on whether the assessments are broad or skewed in their scope.

• Less structured Assessment

The participants sharing this perspective think that in general, the policymakers consider the broader impacts of policy choices and policy outcomes but in an unstructured way. For example, in EV policymaking, the agencies look at what is happening in other countries including international best practices; listen to a variety of perspectives of stakeholders which add to the policy alternatives; and hold in-depth consultations with industry and include their views as potential policy provisions.

Participant- B ["The decision-makers discuss various policy options/ possibilities, however, it is debatable if they necessarily go for the best one. Often, the decisions are bounded by short-term political gains"].

Some participants believe that broader level policy analysis takes place but does not include evaluating the costs and benefits or weighing policy alternatives in a formal manner. The deliberations happen in an amorphous manner with a focus on building consensus and aligning the stakeholders.¹⁴⁸

Participant- A ["Evaluating cost-benefits actually appears to play far less important role in Indian policymaking than issues of, both consensus and stakeholder appearement/ alignment in favor of a particular policy outcome]."

• Structured Assessment

Some participants think that such assessments are structured including detailed analysis of economic and environmental benefits of the policy. For example, a participant shared that for FAME-II, the decision-makers considered assessments of avoided fuel import costs as well as avoided CO2 emissions.

¹⁴⁸ And the 'focus on consensus necessitates a lot of back and forth in the policy design process' that sometimes is detrimental in preventing timely policy decisions.

Participant- D ["In the case of state EV policies, the majority of the incentives that are proposed are designed based on an analysis of total cost of ownership of the vehicles]."

The participants sharing this perspective attribute such structured assessments to the consultancy organizations working for the government.

• Skewed Assessment

The participants who think that the agency assessments are skewed in their scope shared some examples. One participant shared that the government is promoting multiple clean fuels in big ways such as the compressed natural gas (CNG), the EVs, and the ethanol-blended fuel. However, there is no comprehensive document on the government's holistic strategy on clean fuels, which leads to industry confusion.

Participant C- "[I don't see that comprehensive policy. It's like, everything is got a piece, but all the pieces are not falling into place"].

The participant shared another example of skewed assessment where in 2018, under the national e-mobility programme, EESL- a government owned joint venture procured 10,000 EVs for introducing in the government fleet. However, till date only 1514 EVs have been deployed. The participant attributed the failure to the lopsided emphasis on the supply side.

Another participant shared the example of a state policy of rationing vehicles on the roads called the odd-even policy. This policy applied to the non-commercial four wheelers and exempted a variety of vehicles including 2W and 3W.¹⁴⁹ The participant linked this example with the latest scientific study that shows that the petrol 2W, 3W, and the diesel vehicles are the most polluting vehicles in India.¹⁵⁰ Therefore, the state is grossly miscalculating the

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¹⁴⁹ Odd-even is the policy of the state government of Delhi. The vehicles with odd last digit in the registration number are allowed on roads on odd dates and those with even last digit ply on even dates. For details, *see* Government notification 2019, available at

https://transport.delhi.gov.in/sites/default/files/All-PDF/Notification%20odd%20even.pdf ¹⁵⁰ Hakkim et al., (2022). Air pollution scenario analyses of fleet replacement strategies to accomplish reductions in criteria air pollutants and 74 VOCs over India. Atmospheric Environment: X, Volume 13, 100150, ISSN 2590-1621, https://doi.org/10.1016/j.aeaoa.2022.100150. Available at https://www.sciencedirect.com/science/article/pii/S2590162122000041.

policy outcomes by exempting the 2W and 3W, and by targeting the relatively cleaner vehicles.

Participant- B ["You see, this is why it's very important to have the Evidence Based policy intervention"].

The participant shared another example of setting up 'smog towers' in Delhi based on the ruling by the apex court of the country. The participant shared that there are no peer-reviewed studies supporting the claim of the effectiveness of smog towers in cleaning the polluted air, still the government is spending exchaquer's money on such technologies.

Participant- B ["now for the ordinary person on the street, it looks like oh, something has been done for us. This will clean the air. I think this as a false assurance by deflection"].

iii. Public Participation

Interview analysis suggests that over the years, public participation in law and policymaking has increased and so has the transparency. However, there is still a huge scope to improve.

• Low general public participation

In EV space, the participation of general public is very low. One participant noted that genuine public participation where citizens are voicing their concerns and shaping policies does not happen. In this context, the participant remarked that 'the EV space is very elitist.' Another participant echoed this concern but also noted that public engagement in EV sector could be very challenging considering its technical nature. Therefore, there is more engagement with the industry than the end-users.

Participant- D [" in terms of Public Engagement more broadly, on a subject like EVs, it's challenging. I think on one hand, I would say that, I would like to see greater public engagement. And on the other hand, I would say, how effective is public engagement at informing policy for a very technical subject?"].

Also, considering that India's vast majority of population is not vehicle owners and prefer to commute by public transportation, the public in general is not concerned with the 'type of fuel' the public transport runs on.

Participant- D [" So I think they're not as concerned about what fuel the bus runs on. Or what drive, train power train, the auto rickshaw uses, they're more concerned about, do I get from point A to point B?"].

However, the participant emphasized that public engagement is important for non-technical aspects such as deciding the location of charging stations.

One participant however, shared an example of heightened public awareness attributed to the use and availability of the low-cost air pollution sensors. Such sensors are easily affordable for the middle class and upper middle class, and are proving to be the gamechangers. People are becoming aware of the ambient pollution and are demanding action in terms of improving the ambient air quality. However, the participant also cautioned that a large part of India's population is still poor and struggling for their basic survival. Therefore, their participation using such technologies is quite far in the future.

• Accessibility

Participants shared that most of the policy or regulatory notifications are hosted on the concerned Ministry/ department's official website as well as in the official gazette. These drafts are also shared with relevant associations and groups as well as published in the leading newspapers and sometimes on social media platforms.

Participant A- ["I said, general trend towards openness and governance is happening. I do see it is easier now, then maybe 10 years ago"].

Participant E- ["As far as availability of a notification or gazette or a circular, it is available, there is no doubt about it... Unfortunately, in the ministry .. there was no classification and no indexing"].

However, some participants noted that there are gaps in accessibility and usability. For example, the information on official websites is not well-organized, there is no indexing or proper classification. Sometimes, the information is buried in the website, thus making it difficult to retrieve. The public avenues for sharing comments are very limited, in many cases, almost singular, that is an official email address. Considering the inequities in literacy,

economic means, and access to the internet, there is a vast population for which these pieces of policy and legislation are simply not accessible.

• Lack of Transparency

In general, the participants think that the public does not get any reply or even acknowledgement of the comments they share on the draft laws/ policies. Whether the public comments are read or acted upon or not acted upon, remain unclear to the public. Further, a participant shared that many times the policies are designed behind the closed doors for a long period of time and public engagement comes at a much later stage when the key components of the policy are already finalized. However, the participant added that the stakeholder consultations are more effective and meaningful at the state level than the federal level. Also, when the final rule or the policy is published, there is no account of the stakeholder engagement processes or the comments received from people, unlike other countries, such as the US where this practice is followed and required by law.

Participant A- (Regarding agency response to public comments) ["Now that is entirely unnecessary in India, right? I mean, nobody requires it to do it. I mean, why would you do it? If you're not required to do it? I mean, it's so much work"].

• High Stakeholder Participation

Participants shared that considering the automobile sector's contribution to the country's GDP, the government is keen to engage the relevant stakeholders in law/policy making process. Industry is the major participant including the Original Equipment manufacturers (OEMs), the auto component associations, and the trade bodies, that play a major role in shaping the policies. Other stakeholders include the experts, the testing agencies, the non-profit organizations, and the policy thinktanks.

Participant C- ["At certain point of time, it was slightly more push from the government. But the industry is engaged now"].

Participant E- ["The Ministry of Road Transport and Highways has a standing committee called Central Motor Vehicle Technical which meets once every three months and discusses every new regulation with the relevant stakeholders and experts"].

A participant from industry shared two examples showing the dynamics of the stakeholder engagement processes and alluding that the final policy choices are not necessarily driven by the dominant stakeholder (industry). The first example relates to the European Union's request to the government of India for reducing the import tariffs on automobiles and auto components. The industry vehemently opposed this proposal as the move would have been detrimental to the local manufacturers. The government agreed with the industry and did not agree to the EU request. The second example relates to the government of India's decision of leapfrogging the emission standards from BS-IV to BS-VI to meet the CO2 emission targets. The industry opposed this move of the government because the automobile manufacturers were not ready for this change. However, the government did not agree with the industry and went ahead with its decision of tightening the emission norms.

Key points:

- The departments/ministries conduct risk assessments which are largely informal or at best qualitative.
- Similarly, the departments/ Ministries undertake impact assessments which are largely less structured with mixed views that these are broader or skewed in their scope. Also, information of such assessments is seldom available in public domain.
- The departments/ministries consult the stakeholders in law/policymaking and the
 public participation has increased over time. However, public consultation
 processes are discretionary, and the issues of transparency and accessibility
 remain.

2. Implementation

In the implementation stage, the adaptive regulatory cycle emphasizes the need of relevant data collection, effective monitoring and evaluation (M&E) mechanisms, and feedback avenues to gauge policy performance. The documentary analysis suggests that India's laws and policies have several provisions related to monitoring and evaluation. However, the interviews suggest that there are many gaps in practice. The M&E processes are largely informal and subjective, the metric is inadequate, the M&E processes are generally not available in the public domain, and the data is not effectively and optimally used. Regarding public participation, there are examples where the law/policy specifies the role of stakeholders in decision-making.

a. Documentary analysis

i. Monitoring, evaluation, and feedback

The analyzed documents have various provisions related to monitoring and evaluation. The provisions have been categorized as structure-based and process-based. Structure-based M&E implies that the provisions are focusing on setting up bodies and organizations for monitoring, whereas the process-based M&E implies that the provisions are focusing on the activities to be carried out as a part of monitoring.

• Structure-based M&E

The NEMMP provides a three-tier structure for implementing the electric mobility mission plan - the national council at the apex level, followed by the national board, and the national automotive board (NAB) on the last tier. The review at the apex i.e. national council level is required at least once a year, at the national board level 3-4 times in a year, and at NAB once in a month. It also provides for multiple working groups to monitor and review the schemes and mission implementation. Similarly, FAME-I and FAME-II provide for an inter-ministerial body to implement and monitor the schemes. Both the PLI schemes on ACC as well as Auto component provide for the Empowered Group of Secretaries to monitor and ensure that the expenditure is within the prescribed outlay.

• Process-based M&E

The NEMMP describes a dynamic cycle of monitoring based on continuous feedback loop. This cycle has four parts- design, implement, assess outcomes, and modify if required.¹⁵⁵ FAME -I provides for data analysis based on performance parameters and fossil fuel savings.¹⁵⁶

FAME-II guidelines on eligibility assessment provide detailed procedure and criteria for assessing technology functions, and performance and eligibility criteria for the scheme.¹⁵⁷

¹⁵¹ See, NEMMP, supra note 79. Para 4.12.1 and 4.12.2

¹⁵² Id. Para 4.10.2 at 73, Section 5.7 at 93, Para 6.4.1 at 107, Para 7.3.10 at 122,123.

¹⁵³ See, FAME-I, supra note 107, Annexure12. Also, see FAME-II, supra note 109, Para 6.

¹⁵⁴ See, PLI scheme for Automobile and Auto Components, supra note 114, Para 6.3. Also, see, PLI scheme on ACC, supra note 113, Para 7.1

¹⁵⁵ See, NEMMP, supra note 79, at 145.

¹⁵⁶ See, FAME-I, supra note 107, Para 16.

¹⁵⁷ Department of Heavy Industry. Government of India. Guidelines for FAME II Eligibility Assessment Procedure. F.No. 7(02)/2019-NAB—II (Auto). 28th May 2019.

FAME-II operational guidelines on demand incentives have provisions which could enable monitoring of the scheme/its various components. For example, the FAME-II eligibility certificate is valid for one year and all approved vehicle models have to undergo revalidation every year.¹⁵⁸ The dealers are required to maintain record of vehicle sales for five years from the date of sale¹⁵⁹ and daily upload the data on an online platform.¹⁶⁰

The PLI scheme on Auto component mentions using data for transparency and quick disbursement of incentives, ¹⁶¹ and cost auditing by an external auditor. ¹⁶² Similarly, the ACC scheme has detailed provision on monitoring including the parameters to monitor disbursal of incentives. ¹⁶³

The Ministry of Power's guidelines on EV charging infrastructure have provisions that could be linked to the process-based monitoring. For example, the public charging stations are required to share the charging station data with the distribution company, maintain appropriate protocols, and provide database access to the Central Electricity Agency (CEA). Further, the CEA is mandated to create and maintain a national online database of the public charging stations through distribution companies. The CEA's regulations provide for inspection and periodic assessment of the charging stations, and requires the owner of charging station to maintain records regarding inspection, testing, and periodic assessment.

ii. Public Participation

There are a few examples where the law/policy provides for engaging the stakeholders in decision-making, such as, FAME-I encourages active stakeholder participation while preparing the scope of pilot programs. Both FAME-I and II specify active participation and involvement of stakeholders while setting up the public charging infrastructure, ¹⁶⁸ and

¹⁶⁰ *Id.* Para 6.6.

¹⁵⁸ Operational Guidelines for Delivery of Demand Incentives- FAME-II. (22nd March, 2019). Para 2.15 and 2.16. Ministry of Heavy Industries & Public Enterprises, Department of Heavy Industry.

¹⁵⁹ Id. Para 6.1.

¹⁶¹ See, PLI scheme for Automobile and Auto Components, supra note 114, Para 6.4 (V).

¹⁶² *Id.* Para 6.2.

¹⁶³ See, PLI scheme on ACC, supra note 113, Para 8.

¹⁶⁴ See, Ministry of Power Guidelines (2018), supra note 118, Para 3.1 (ix).

¹⁶⁵ *Id.* Para 6.

¹⁶⁶ See, CEA, supra note 120, Sec 121.

¹⁶⁷ Id. Sec 122.

¹⁶⁸ See, FAME-I, supra note 107, Para 33 and 35. Also see, FAME-II, supra note 109, Para 32.

considering stakeholder inputs while reviewing the scheme.¹⁶⁹ FAME-I and FAME-II provide for an extensive IEC program for consumer awareness on EVs including education, publicity, seminars, business meetings, conferences, etc. to be conducted jointly by DHI and voluntary organizations.¹⁷⁰ Another example is the Ministry of Power's revised guidelines & standards for charging infrastructure, which acknowledges that the revision is based on the stakeholder suggestions.¹⁷¹

Key points:

- India's EV laws and policies have several provisions related to monitoring.
- There are a few examples where the law/policy provide for engaging the stakeholders in decision-making processes.

b. Interview Analysis

i. Monitoring, evaluation, and feedback

The interview analysis suggests that more participants think that monitoring, evaluation, and feedback processes in the government are informal than formal. A related observation is about the 'inadequacy of metrics' used for monitoring and evaluation. Regarding data, the participants shared two broad views. Most participants think that the data is not being used effectively and a few participants think that the data is being used effectively in M&E. Similarly, there is mixed opinion on the capacity issues for M&E.

• Less formal and less structured

Most of the participants think that M&E and feedback processes in the government don't have a robust framework; these are informal, fragmented, or subjective.

Participant C- ["But there's no formal mechanism, I can say from an outside perspective. What they're doing internally, I have no clue"].

M&E is not a part of the policymaking process and generally done by the outside actors such as academia, civil society, and research organizations. In the government, monitoring and feedback is mostly through stakeholder consultations and workshops. For example, a

¹⁶⁹ See, FAME-I, supra note 107, Para 11.

¹⁷⁰ See, FAME-I, supra note 107, Para 15. Also see, FAME-II, supra note 109, Para 39.

¹⁷¹ See, Ministry of Power Guidelines (2019), supra note 118.

participant shared that the government of India conducted a series of workshops in more than 30 cities and sought feedback on the new contract structure for e-buses.

Participant E- ["we don't have a kind of like a formal set up where in a team is made to see how a particular policy is being executed formally. To be very frank in the government, we don't have it. But there are other channels"].

Adding to this, one participant shared that there is no established methodology or even intentionality to conduct M&E, which results in many missed learning opportunities for policy improvement. For example, under FAME-II, when the incentives were given for ebus adoption across multiple cities, the department did not undertake any study or review to understand the capacity of cities to ply the e-buses, the need to revisit subsidies, or the need to even fully understand the basic functioning of the scheme.

Participant A- ["Again, I'm not saying that, you know, there isn't outside evaluation. That's going on. But if the government policy itself did that, it would be a lot more helpful"].

The participant shared that the agencies are not adopting even in a semi-structured approach to understand these issues. Further, the decision-makers have no incentives for M&E. They are overworked with limited staff and their performance is not linked to achieving the policy outcomes or implementing the programs cost-effectively. This results in weak and superficial M&E processes.

Inadequacy of metrics

Some participants think that in the EV space, the metric of policy success is highly misplaced. The government agencies are mostly focusing on spending their budgetary allocation, else it reflects poorly on them. In many ways, the monitoring is just limited to the number of EVs and the amount of funds allocated. So, the decision-makers are mostly looking at the numbers and monitoring intuitive trends but the processes of gaining deeper insights are missing.

Participant A- [" (For people in the government), the most important job is to get the money out the door, because you know, they need to be efficient, and that's the efficiency"].

There are no specific targets and time-bound mandates for achieving EV adoption, which makes it difficult to fathom what is working and what is not. However, one participant shared an example of good metric in EV policy space at the state level. In Delhi, the metric of EV policy success is clearly defined i.e. EVs should make up 25% of new registrations by 2024. This metric is relevant because the state government has authority on vehicle registration not on vehicle sales.

Participant D- ["I think one of the most important parts of M&E will be determining what is the actual metric for success for the policy? and I think this is often a challenging metric"].

• Lack of Transparency

A few participants think that the government's M&E processes have transparency issues. One participant shared that the government has informal channels of monitoring and feedback such as industry inputs, market trends, media, research institutions, as well as social media. However, there seems to be no formal monitoring mechanism to gauge the impact of the government schemes and policies. For example, it is difficult to establish a causal relation between the increasing EV adoption in India and the FAME subsidies. The monitoring is happening in a fragmented manner and what is being monitored and how is it being evaluated, such information is not in the public domain.

Participant A- ["looking into these policies to now, it's a lot better, you know, a lot more transparency and openness in the government than previously. But it's nowhere close to where it needs to go"].

The feedback channels are subjective and non-transparent. For example, one can reach out and meet key decision-makers and share feedback on the ongoing scheme/policy but when the revised version comes in the public domain, there is no mechanism to know how and why the revisions happened.

Data- Not used effectively

Most interview participants shared that the data availability could be a barrier sometimes. The existing policy processes do not focus on designing monitoring

processes and collecting the data; it is mostly an after -thought. Further, at the field level (such as for air quality monitoring) when new monitoring stations/ devices are set up, the data quality is good for the initial one or two years. Thereafter, the monitoring quality deteriorates as checks go down, resources become scarce, and many times the staff is over worked and malpractices like data manipulation start happening. In the field monitoring stations, sometimes there are just one or two engineers manning five or six stations, thus, impacting the data quality.

Participant B- ["So, on paper, we started a monitoring. But now the details in terms of how that monitoring, the foresight to ensure that this can be done in a manner that is required, the resources over the long term are not provided or not built in"].

At the Ministry/ department level, every Ministry has a dashboard where basic data is being tracked. But the data is not informing policy/ program evaluation. It is not being linked to the policy objectives and outcomes. The participants think that there are capacity issues in the government to conduct good quality M&E in terms of limited resources, limited technical skills, and chronic understaffing.

• Data - used effectively

The participants holding this view shared that there are huge databases in the country, such as of EV sales with vehicle details as well as of driving license and vehicle registration. All these services are online and this data is being used by a variety of stakeholders' subject to privacy policies. They also think that the government agencies have adequate capacities for effectively carrying out M&E.

Key points:

- The M&E processes are largely less formal and subjective with mixed views on their effectiveness.
- The available data is not optimally utilized to inform policymaking.
- Information on M&E processes is generally not available in public domain.
- There are issues of staff capacities and inadequacy of metrics.

3. Post-Implementation

The documentary analysis suggests that there are many provisions such as the periodic review, revision, phased implementation, and pilot programs that could facilitate the review and revision of the law or policy. The interview analysis suggests that there are

many factors that result in the revision of the laws/policies, particularly when there is no legal/ policy requirement for such revisions or changes. The factors include new developments, post-implementation issues, as well as incomplete policies. Regarding public participation, there are few examples where stakeholder engagement is mandated as a part of such review processes.

a. Documentary Analysis

i. Iterative decision-making and Policy adjustment

The functions of *Parliamentary standing committees* include examining the annual reports of Ministries /departments as well as the long-term policy documents presented to the House.¹⁷² The committees' recommendations are sent to the Ministry/department for action-taken report within 3 months of the report's presentation. ¹⁷³ There are many examples of the standing committees evaluating the performance of laws and policies (in other sectors).¹⁷⁴ However, such evaluations are not done for every law and policy, and the choice of subject of study/examination is the committee's discretion. In general, the committees continue to work on the subjects that are under-examination by the previous committees.

Similarly, the Law Commission of India enables the post-legislative scrutiny by identifying the laws requiring amendment or repeal. Since 1956, the Law Commission has submitted 277 reports, however, after 2018, the government has discontinued constituting new Law Commissions. From time to time, the government of India also sets up commissions focusing on reforms in a particular sector. Such commissions review the relevant laws and engage the stakeholders in preparing their reports. For example, the government of India constituted the Second Administrative Reforms Commissions (2005) which reviewed several laws related to public administration and consulted stakeholders while submitting

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¹⁷² Lok Sabha Secretariat. (2019). An Introductory Guide. Departmentally Related Standing Committees at 7,8. May 2019. Available at

http://loksabhaph.nic.in/Committee/INTRODUCTORY GUIDE(ENGLISH).pdf

¹⁷³ *Id.* at 30.

¹⁷⁴ *Id.* at 12. (The standing committees have scrutinized and presented reports to the Parliament on prominent national long-term policies including the draft Agriculture Policy Resolution (1992), National Agriculture Policy, New Telecom Policy (1999), National Drug Policy, and National Housing Policy.)

15 reports on the key issues.¹⁷⁵ Similarly, in 2011, the Ministry of Finance constituted the Financial Sector Legislative Reforms Commission to review the Indian financial laws.¹⁷⁶

Acknowledging change

The analysed documents contain many provisions acknowledging change. For example, the NEMMP recognizes the importance of 'change management' for the stakeholders including consumers, industry, and the government in an evolving sector of EVs. ¹⁷⁷ It adopts 'technology agnostic approach' for EVs, including the option of working out priorities subject to market feedback, impact assessment, and technological breakthroughs in the future. ¹⁷⁸

Similarly, most of the schemes have provisions enabling change dependent on the evolving conditions. For example, FAME-I provides flexibility of distributing funds by aligning with the actual demand profile in the market.¹⁷⁹ The FAME-II provides for changing funding allocation contingent on issues arising during implementation¹⁸⁰ and revising the demand incentives subject to the market and technology trends on batteries.¹⁸¹ The PLI scheme on Automobile and Auto Components Industry provides for changing the yearly incentive outlays subject to the sales and market scenario.¹⁸² This scheme is also technology agnostic¹⁸³ and provides 'fungibility of funds' both within and across the scheme components.¹⁸⁴ Both PLI schemes authorize the Empowered Group of Secretaries to makes such changes within the overall financial outlay.¹⁸⁵

Some of the guidelines also have provisions for making changes in the future. For example, FAME-II operational guidelines on demand incentives authorize DHI/NAB to alter/

¹⁷⁵ Kalra, Harsimran. (2011). PRS Legislative Research. Public Engagement with the Legislative Process. Also, *see*, Department of Administrative Reforms & Public Grievances, Government of India. Government Decision with regard to Second Administrative Reforms Commission, Reports available at https://darpg.gov.in/en/government-decisions-on-2nd-arc?page=1.

¹⁷⁶ Resolution No. 18/1/2011-RE dated March 24, 2011, Ministry of Finance, Government of India.

¹⁷⁷ See, NEMMP, supra note 79, Para 8.1.1 at 125, 126.

¹⁷⁸ Id. Para 8.5.4 and 8.5.5 at 137, 138.

¹⁷⁹ See, FAME-I, supra note 107, Para 6.

¹⁸⁰ See, FAME-II, supra note 109, Para 7 and 10.

¹⁸¹ *Id.* Para 16.

¹⁸² See, PLI scheme on ACC, supra note 113, Para 4.1 (Note).

¹⁸³ *Id.* Para 2 and 3.3.

¹⁸⁴ *Id.* Para 4.5

¹⁸⁵ See, PLI scheme on Automobile and Auto Components, *supra* note 114, Para 6.3. Also *see*, PLI scheme on ACC, *supra* note 113, Para 7.1.

amend any provision of the scheme and the guidelines.¹⁸⁶ The Ministry of Power's guidelines on charging infrastructure while specifying the norms for setting up the public charging stations, also provides the scope of making any change in these norms.¹⁸⁷ Similarly, it provides for linking the electricity supply tariff of the public charging stations with the extant tariff policy, thus keeping built-in scope of future revisions.¹⁸⁸ Further, it is observed that in the official notifications on vehicles and EVs, there is a general practice of mentioning the applicable vehicle standards (such AIS standards, BIS standards) along with the words "as amended from time to time." This blanket provision in a way acknowledges the future changes in the applicable standards.¹⁸⁹

• Review

The NEMMP specifies that 'continued review, monitoring and mid-course corrections' is an integral part of the mission.¹⁹⁰ It mentions that the schemes and policies as a part of the electric mobility mission should be 'planned to be designed to be adaptive' and to evolve through the design-implement-assess- modify feedback loop.¹⁹¹ Further, the powers and functions of the National Board for Electric Mobility as well as the National Automotive Board (NAB) include monitoring and review of the progress of various schemes including suggesting mid-course corrections.¹⁹²

Similarly, FAME-I provides for review after 2 years¹⁹³ and FAME-II provides for review but without time specificity.¹⁹⁴ It also provides for an annual or earlier review of the rate of demand incentives¹⁹⁵ and an annual review of the cap on incentives.¹⁹⁶ Both the PLI schemes provide for 'periodic review' of the outgo under the schemes without specifying the time period.¹⁹⁷ In addition, the latest reports/documents by the government agencies

¹⁸⁶ See, FAME-II operational guidelines, supra note 158, Para 8.1.

¹⁸⁷ See, Ministry of Power Guidelines (2018), supra note 118, Para 5.5 (Any change to these norms could be approved by the State Nodal Agency in consultation with the Central Nodal Agency).

¹⁸⁸ *Id.* Revised Guidelines 2019, Para 7.1.

¹⁸⁹ For example, Ministry of Road Transport and Highways, Notification. S.O. 411(E). 9th February, 2016.

¹⁹⁰ See, NEMMP, supra note 79, Para 2.2.5 at 19.

¹⁹¹ *Id.* Para 8.8.5 and Figure 11 at p-145.

¹⁹² Ministry of Heavy Industries and Public Enterprises (Department of Heavy industry) (27th May, 2011). Notification. Para 2 (n). Also *see*, NEMMP, *supra* note 79, Annexure-III, 'Roles, Responsibilities and Functions of NATIS/NAB' Para (i).

¹⁹³ See, FAME-I, supra note 107, Para 11 and 38.

¹⁹⁴ See, FAME-II, supra note 109, Para 12.

¹⁹⁵ *Id.* Para 20 and 22.

¹⁹⁶ *Id.* Para 26.

¹⁹⁷ See, PLI scheme on Automobile and Auto Components, *supra* note 114, Para 6.3. Also *see*, PLI scheme on ACC, *supra* note 113, Para 7.1.

are being published in 'versions' and specifying that the report/document would be updated on a periodic basis. 198

There are several examples where the policy/scheme is planned to be implemented in phases or through pilot programs. Such phased roll outs or piloting enable learning opportunities for the agencies.

• Pilot Programs and Phased-implementation

The NEMMP provides for pilot testing and assessing the impact of government investment in public charging stations, and accordingly developing a viable business model for the full-scale implementation. 199 The pilot programs are one of the four focus areas of FAME-I.²⁰⁰ These pilots aim to test new technologies and new business models with a focus on public transportation.²⁰¹ Additionally, there are a few examples of pilot programs which are not a part of any formal policy but such programs have enabled the development of specific EV charging standards.²⁰² For example, a pilot project on 'prototyping & field validation of Light EV AC Charge Point' deployed 100 prototyped devices in the cities of Delhi and Bangalore. The pilot enabled testing and validation of the applicable draft standards. Later, the Bureau of Indian Standards (BIS) notified the charge-point standards, which are the first ever formal standards on AC Charge-point for 2W/3W EVs in the world. Another example is testing the 'dual gun plug-in charging for e-buses' at Ahmedabad (a city in Gujarat state). The project was implemented successfully for over 6 months and informed development of the draft specifications for dual-gun plug-in charging. These are likely the world's first inter-operable dual gun charging specifications. 203

The NEMMP provides for a phased approach to promote EV manufacturing in India²⁰⁴ as well as for the roll out of the EV charging infrastructure.²⁰⁵ Similarly, FAME-I and

²⁰² See, Consultative Group on Future Transportation, supra note, 134.

¹⁹⁸ See, Handbook of EV Charging Infrastructure Implementation, supra note 117, at 9.

¹⁹⁹ See, NEMMP, supra note 79, Para 7.3 at 116,117.

²⁰⁰ See, FAME-I, supra note 107, Para 5.

²⁰¹ *Id.* Para 33

²⁰³ *Id.* This system draws on most of the specifications and standards that have already been developed for the Single-gun charging system and for which standards have been deployed. Wherever, Dual-gun specifications are different or not applicable (compared to the Single-gun system) those specifications have been defined and prepared for drafting as parts of the new standard.

²⁰⁴ See, NEMMP, supra note 79, at 103,104.

²⁰⁵ *Id.* 117 to 121.

FAME-II- the flagship schemes of the government of India have been implemented in phases. The learnings from the first phase have informed the development and improvement of the second phase. The Ministry of Power also provides for a phased roll-out of EV public charging infrastructure²⁰⁶

• Revising laws, policies, and guidelines

There are several examples where despite no specific provision in the policy to revise the policy/ guidelines, the same have been revised and modified many times. These could be considered as examples of unplanned adaptive regulations i.e. changing without a planned process. For example, the Phased Manufacturing Programme (PMP) provides graded basic customs duty for EV parts over a period of time. This scheme was linked with FAME-II and revised three times since March 2019. FAME-II operational guidelines for the delivery of demand incentives have been revised once and FAME-II scheme has been amended twice, and extended once.²⁰⁷ Since 2014, the Ministry of Road Transport and Highways, has amended the Central Motor Vehicle Rules more than 14 times to include various provisions related to EVs.²⁰⁸ The Ministry of Power has revised guidelines and standards for the EV charging infrastructure three times since 2018. The Central Electricity Authority has amended the regulations and added provisions related to safety and electric supply for EV charging infrastructure.²⁰⁹ The Ministry of Housing and Urban Development has amended the model building bye-laws for EV charging infrastructure in building premises and core urban areas.²¹⁰

Key points:

- In general, there are examples of Parliamentary standing committees evaluating the laws and policies, however, such evaluations are not done for every law and policy.
- The EV policies have flexible provisions enabling change in the policy or any part thereof.
- There are several examples of provisions of review, pilot programs, and phased implementation.

²⁰⁶ See, Ministry of Power Guidelines (2018), supra note 118, Para 9. (Phase-I to cover all mega cities with 4 million plus population, and the expressways and highways connecting these cities and Phase-II to cover state capitals and union territories headquarters.)

²⁰⁷ Ministry of Heavy Industries & Public Enterprises, Department of Heavy Industry. Notification. S.O. 2526(E). June 2021. (FAME India Phase II scheme is extended for a period of two (2) years i.e. up to 31st March 2024).

²⁰⁸ The Central Motor Vehicle Rules have been amended at least 14 times since 2014.

²⁰⁹ See, CEA, supra note 120.

²¹⁰ See, Ministry of Housing and Urban Affairs, supra note 116. Chapter 10: Sustainability and Green Provisions.

b. Interview Analysis

i. Iterative Decision-making and Policy adjustment

The interview analysis suggests that decision making in policy and regulatory space is iterative in nature. However, these iterations are mostly less planned and the reasons/rationale of policy revisions are seldom available in public domain. Some examples are shared as follows:

• Review

The participants shared a few examples of planned reviews, such as the fuel efficiency regulations provide for revising the average weight of vehicles, but these are not periodic in nature. Most participants shared the example of FAME-I which had a specific review provision and based on its review, FAME-II was developed. It had improvements such as the incentives were changed to per kilo watt hour basis (instead the earlier based on vehicle) and the different vehicle segments were prioritized. Another example is of the vehicle emission norms called Bharat Stage (BS) which are India's emission standards in line with the European standards. Since, 2000 these standards are being revised though not periodically. Further, a participant shared that many state EV policies have a provision of mid-term review or interim review.

• Pilot programs and Phased-implementation

A few participants shared the example of India's emission standards. Since 2000, India has been implementing the BS standards first by piloting in major cities, followed by the nationwide implementation. Another example is of a pilot being conducted in the national capital (New Delhi) to reduce air pollution through smart mitigation. This pilot is a decision support system based on real-time monitoring of chemical traces in the ambient air.

The participants shared a few examples of phased implementation such as the ethanolblended fuel program of India. It was initially piloted in 3 locations in a state and gradually, other states implemented.²¹¹ Another example is of a city municipal corporation (Surat) which adopted a phased approach for fleet replacement by EVs.

One participant acknowledged that in India, the practice of conducting pilot programs is very much prevalent. However, the focus on monitoring and evaluation as well as adapting learnings from the initial phases are less structured and much less effective.

Policy response to change

The participants shared several reasons that they think result in policy changes. These include responding to the new developments, ironing out the post-implementation issues, and rolling out of incomplete policies.

New developments- The participants think that generally, the laws and policies are amended from time to time due to new circumstances, new developments such as technology improvements or even due to change in leadership. One participant shared that the government extended the timeline of the phased manufacturing programme (PMP) due to pandemic's impact on the global procurement of EV parts. Some participants think that the new developments could stem from the stakeholders' feedback. For example, based on the stakeholder feedback, the Ministry of Road Transport and Highways delinked the battery cost from EV cost and allowed the sale and registration of 2 and 3 W EVs without batteries.

Participant E- ["And even if it (rule) is published, then also one can take a corrective measure .. which is quite obvious because down the time, the technology also keeps on improving, the society also keeps on improving"].

Another factor driving policy-making could be the change in the ecosystem. For example, a participant shared that new emission standards are generally rolled out after the Original Equipment Manufacturers (OEMs) demonstrate to have sufficiently met the previous emission norms through technology improvements.

²¹¹ In 2019, it was implemented across India with 10% blending to be achieved by 2022 and 20% by 2030. For details, see, Ministry of Petroleum and Natural Gas, Government of India. Ethanol Blended-Petrol Programme. Available at https://mopng.gov.in/en/refining/ethanol-blended-petrol.

Post-implementation issues- Some participants think that the policy changes also happen to address post- implementation issues. However, they shared that the government agency does not have established processes or formal evaluations for making such revisions. For example, in FAME-II, after facing implementation challenges related to procurement and subsidy withdrawal for e-buses, the government revised the policy and shifted the focus from initially planned 64 cities/ state transport undertakings to the top 10 financially most solvent transit agencies in the country.

Participant F- ["In terms of FAME-II, the government very recently revised or updated the subsidies to promote and make two-wheeler at par with some of the ICE petrol version of EV"].

Similarly, Maharashtra's 2018 state EV policy earlier focused on the supply side incentives. However, after two-three years of implementation, the state realized that the EV adoption was not increasing. Therefore, it revised the policy to shift focus on the demand incentives for the consumers.

Participant A- ["I don't see that many such examples in regulations that I've seen, and they are much more driven by complaints from stakeholder, that something's not working, or something's broken. And then rules get changed, as opposed to sort of anticipating that the situation is going to change"].

Adding to the same view, another participant shared that considering the size of vehicle population as well as country's one billion plus human population, there are bound to be post-implementation issues, often raised by the stakeholder groups. Further, post-implementation, sometimes the policy assumptions play out very differently. For example, the policy assumes a certain number of years for technology development or for achieving cost competitiveness and keeps a provision. But in the real world, the technology could evolve earlier than projected or even later, both ways resulting in policy revisions.

Incomplete policies- One participant shared that incompleteness or ambiguity of policies is sometimes the reason to revisit the policies. Thus, it has to change by 'necessity' or add elements to clarify. For example, in FAME-II, initially, the e-buses were allocated to 64 cities and state transport undertakings without doing the preparatory work to understand

if each of these cities have the capacity to deploy these buses. And later, the government had to revise the allocation. Further, the participant added that changing a policy is not always viewed positively. The policymakers are often afraid of criticism for changing their original decisions, such as revisiting the goals set earlier could reflect poorly on them as they were not able to meet them. Therefore, they tend to set a low enough bar which is easy to reach.

Static laws- One participant shared an example where the law has not changed despite new developments. The provisions of Motor Vehicle Rules of 1980s are still governing the digital ride hailing companies such as Ola and Uber in India. Similarly, these rules do not allow new business models such as two-wheeler taxis.

Key points:

- Decision making in EV policy and regulatory space is iterative in nature.
- Policy change could be in response to new developments, to iron out postimplementation issues, or to fix issues due to roll-out of incomplete policies.
- Most policy iterations are not based on formal evaluations.
- Reasons/ rationale of policy revisions in the form of a comprehensive document are seldom available in public domain.

4. India's laws and policies and Adaptive governance structures

In addition to the presence of adaptive regulatory processes, there are many examples of adaptive governance structures in India's EV space. These governance structures reflect polycentric governance and inter-agency coordination both horizontally and vertically.

a. Documentary Analysis

i. Polycentric governance

The analysed documents have few examples emphasizing the engagement of diverse organizations in decision-making, including industry, academia, and non-profits. For example, the NEMMP provides the two apex bodies for implementing the national electric mobility mission to have representation from industry and academia. ²¹² Further, it provides the government and OEMs, universities, and national labs to collaborate on the R&D on EV technologies. ²¹³

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²¹² See, NEMMP, supra note 79, Para 2.1.2 at 17.

²¹³ *Id.* Para 5.3.4 at p-81.

Similarly, FAME-I provides for a collaborative approach for technology development with industry and academia, and to undertake public-private partnership projects.²¹⁴ It provides for the 'Technology Advisory Group' with representation from the industry and academia.²¹⁵ This group envisages to establish the centers of excellence for developing niche technologies and acting as bridge between the academia and the industry.²¹⁶ FAME-I and II provide for the 'Project Implementation and Sanctioning Committee,' to implement and monitor the schemes. This committee has participation of the members of industry.²¹⁷ Another example is the DST-PSAO Group which is established for guiding the development of Indian Standards for EV charging infrastructure. The Group has broader participation from the automakers, suppliers from the auto industry and electronics industry, members of the committee of Bureau of Indian Standards (BIS), and the homologation and certification agencies.²¹⁸

ii. Inter-agency coordination

There are examples of 'Horizontal coordination' i.e. between agencies at the same level of government as well as 'Vertical coordination' i.e. between different levels of government (i.e. federal, state, local).

• Horizontal coordination

The two apex bodies for implementing the national electric mobility mission have members from different ministries/ departments at the federal level. National Council for Electric Mobility (NCEM) is an inter-ministerial body²¹⁹ and the National Board for Electric Mobility (NBEM) comprises of the secretaries of the concerned central ministries/ departments (at the federal level).²²⁰ FAME-I's 'Technology Advisory Group' on electric mobility is jointly supervised by two departments of the federal government-DHI and Department of Science and Technology.²²¹ Further, FAME-I and II's 'Project Implementation and Sanctioning Committee,' is an inter-ministerial body with members

²¹⁴ See, FAME-I, supra note 107, Para 18.

²¹⁵ *Id.* Para 20.

²¹⁶ Id. Para 21. (These COEs to focus on R&D, developing prototype components, and testing their validity and commercial applicability)

²¹⁷ Id. Annexure 12. Also, see FAME-II, supra note 109, Para 6.

²¹⁸ See, Consultative Group on Future Transportation, supra note, 134.

²¹⁹ See, NEMMP, supra note 79, Para 2.1.2 at 17.

²²⁰ Id.

²²¹ See, FAME-I, supra note 107, Para 20.

from different ministries of the federal government. ²²² The Department of Science and Technology and the Office of Principal Scientific Advisor of the federal government jointly established a group to guide the development of Indian Standards for EV Charging Infrastructure. ²²³

• Vertical coordination

The NEMMP recognizes the important role of the state governments and the local municipal bodies in facilitating EV adoption. ²²⁴ Similarly, FAME-II acknowledges the need of support from the state governments to promote e-mobility and encourages the states to offer additional fiscal and non-fiscal incentives. ²²⁵ The Ministry of Power authorizes the State Nodal agency to approve any changes in the prescribed norms of establishing the public charging infrastructure in consultation with the Central Nodal Agency. ²²⁶ In the phased roll-out of EV public charging infrastructure, the guidelines require agencies of the centre and the state governments to consult and coordinate including the urban local bodies. ²²⁷ The Energy Efficiency Services Limited (EESL), a federal government organization is developing EV charging infrastructure through MoUs with the municipalities and distribution companies. ²²⁸

b. Interview Analysis

The interview analysis suggests that there are multiple agencies functioning in the EV regulatory space, however, there is no nodal agency per se. There are mixed views on agency coordination. Also, most participants think the existing federal-state governance is the best scale of EV governance though certain improvements could be made.

i. Inter-agency coordination

Regarding inter-agency coordination, many participants think that the agencies lack a coordinated approach. In general, the policy and law proposals, pass through an inter-

²²² See, FAME-I, supra note 107, Annexure 12. Also see, FAME-II, supra note 109, Para 6.

²²³ See, Consultative Group on Future Transportation, supra note, 134.

²²⁴ See, NEMMP, supra note 79, Para 3.8.6 at 33. (such as by providing road tax incentives, amending the building byelaws to include charging infrastructure, enabling private parties to sell electricity, and providing non-fiscal incentives such as reserving certain spaces for EVs only)

²²⁵ See, FAME-II, supra note 109, Para 11.

²²⁶ See, Ministry of Power Guidelines (2018), supra note 118, Para 5.5.

²²⁷ Id. Para 9.3 and 10.

²²⁸ Energy Efficiency Services Limited (EESL). Electric Vehicles & EV Charging Infrastructure. National E-Mobility Programme. Available at https://eeslindia.org/en/electric-vehicles/.

ministerial process where the concerned departments and ministries provide their feedback. Despite this general non-siloed approach, every agency takes care of the tasks assigned on EVs but no single agency takes the overall role of monitoring the EV adoption in the country. In this context, the concerned agencies lack a coordinated approach for achieving the larger policy goals and effectively monitoring the policy outcomes. Those who think that inter-agency coordination is happening well, attribute this to the clear task differentiation among various agencies and the NITI Aayog providing the high-level perspective to other agencies.

Participant E- ["when you're talking about challenges between the inter-ministry coordination, are sometimes there but generally I think technology and consultation makes it easier"].

ii. Scale of governance

Regarding the scale of governance for the EVs, most of the participants echo the existing federal- state model in which the federal government lays out the major EV policies and the states implement the same. However, one participant thinks that the governance scale should be the local level i.e. municipal bodies in the cities should be the main drivers of EV policies.

A few participants supporting the existing federal- state model, pitched for a greater role of the federal government. They think there is a need for improving coordination between the two levels of government, building capacities of the states, providing greater direction by the federal government, and providing detailed frameworks for implementation by the states (by keeping adequate scope for state differences).

Participant D- ["I think sometimes there's need for greater direction from the central government on how to actually accomplish the policy guidelines and visions that they're putting out"].

Further, they note that in an evolving and cutting-edge technology sector like EV, there is a need of ample resources and expertise. Considering the federal government has more resources and easy access to experts including the international best practices, such as vehicle safety standards, than the states, the federal government should lead the EV policy and regulations.

5. Need of Adaptive Regulations

The interview participants were also specifically asked about their views on the need of adaptive regulation in general as well as in the EV space. While most of the participants acknowledged the importance of adaptive regulations particularly in dynamic sectors such as EVs, a few participants also shared the potential risks and challenges associated with such regulations.

Most of the participants endorsed the need of adaptive regulation in general as well in the EV sector.

Participant B- ["Learning from what works better and what can work better and what does not work at all on ground is important as this is an experiment where unanticipated feedbacks can only be discovered and taken cognizance of after experiential learning"].

Considering the evolving technology and uncertainty about a lot of features of EVs, it is important that regulations are adaptive so these could be updated and revised in the light of new developments including technological breakthroughs. For example, a participant shared that if in the near future, the feasibility and cost-competitiveness of hydrogen fuel cell vehicles is proven to be better than EVs or any other vehicle technology emerges, then we should have policies which account for these changes and make necessary revisions. The participant further shared that considering the fast-paced changes in technology, the interval of review should be kept shorter. Another participant noted that adaptive regulations also make regulations relevant by enabling to keep pace with global developments such as the best international vehicle standards. This could increase the export potential of vehicles.

A few participants think that India's regulations are already adaptive as the laws are amended and the policies revised based on changes from time to time.

Participant D- ["I'm already seeing it (adaptive regulation) in practice in the EV sector through the FAME scheme, through state EV policies. So, I think it's, it's alive. It's real, it's important"].

Particularly in the EV sector, several aspects of adaptive regulation such as reviews, pilot programs, policy adjustments are already happening though in a less structured way. Thus, it could be better if a clear structure is adopted.

A few participants also shared the risks and challenges associated with implementing adaptive regulations. Firstly, they think that all things need not be adaptable and the period of adapting could be more or less dependent on the regulated sector. Further, such regulations pose tremendous political risks by providing an option to revisit a law/ policy which could be misused and in the absence of such mandatory reviews, the political risks get automatically reduced.

Participant A- ["If you are reasonably sure that a sound policymaking process will be followed, then an adaptive regulatory approach will likely help you rather than harm you. But again, that's easier to set at a theoretical level than at a practical level. And how do you actually get it done? is very tricky. And I would say, process is only one part of it.. But I mean, personalities are equally important. And the same process under the hands of a different regulator will get you a different outcome"].

Further, the adaptive regulations may increase the chances of creating sub-optimal policies/ laws because the policymakers may start viewing that due to review/ revision provisions, any corrective action could be always be taken later in time. Another participant shared that without effective monitoring and evaluation and without involvement of stakeholders and the monitoring agencies, the adaptive regulations may not be implemented well.

The above analysis suggests that India's regulatory cycle reflects various shades of adaptiveness. In the pre-implementation stage, the adaptive features are not built-in the regulatory process and are not mandatory for the departments/ Ministries. However, in practice, these adaptive features are implemented though in less structured ways. In the implementation stage, the laws/policies have monitoring and evaluation provisions. In

practice, most of the monitoring and evaluation mechanisms are informal and less structured and limitedly inform the future laws and policies. Lastly, in the post-implementation stage, there are provisions that enable iterative decision-making and there is evidence of implementing these provisions in practice. Many EV related laws/policies have been amended and revised over time without any specific mandate for such revisions. In addition to the adaptive processes, there are examples of adaptive governance structures indicating inter agency coordination and polycentric governance. However, in practice, there is a need of better inter agency coordination.

IV. US and India- Comparison and Effectiveness of EV laws/policies

A. High-level comparison of US and India

Based on the documentary analysis of the Health data law/policies of the US and India, following are the stage-wise summary findings:

- i. In pre-implementation stage, of the three adaptive features (i.e. assessing risks, broader and fuller impact assessment, and public participation), the US law in general requires federal agencies to adopt all three features in the regulatory process, whereas, India's law does not require the same. However, the select EV law/policy documents indicate a comparable picture for both countries i.e. very limited provisions identified for risk assessment and comparable provisions of broader impact assessment and public participation.
- i. In implementation stage, the two adaptive features (i.e. monitoring & evaluation and public participation) show high presence in the select EV documents of the US and relatively moderate presence in the select EV documents of India.
- ii. In post-implementation stage, there is one adaptive feature i.e. iterative decision-making and the identified provisions in select EV law/policy documents are comparable for both countries. Additionally, the US law in general requires the agencies to conduct ex-post reviews, though it has been limitedly implemented by the agencies. In India, though there is no general legal requirement for ex-post reviews, agencies revise the policies/laws from time to time. However, such reviews are not based on the formal evaluation of the laws/ policies.

Combining the general regulatory requirements with the provisions identified in the select EV law/policy documents suggests that in the pre-implementation and implementation

stages, the US regulatory cycle is more adaptive than India's regulatory cycle. Whereas, in the post-implementation stage, both US and India's regulatory cycles are similarly adaptive.

The regulatory risk assessment, impact assessment, and monitoring and evaluation are more structured, elaborate, and rigorous in the US than in India. However, it is important to understand whether such different regulatory processes actually result in meeting the larger policy goals and objectives and whether more adaptive regulatory processes result in policy success than the less adaptive processes.

B. Whether EV laws/policies are effective

In the US, the year 1992 could be considered the beginning of law making related to EVs. In this year, the Energy Policy Act was passed which had provisions related to alternative fuel vehicles including EVs. Over the years, the US federal policies and regulations have not specified targets for EVs in particular, though there have been targets regarding the percentage of alternative fuel vehicles, such as in the federal and the state fleets. Recently, the Presidential Executive Order 14037 called for an aspirational target of 50% of all new passenger cars and light trucks sales to be zero-emission vehicles in 2030, though in 2020, the EVs comprise 2% (approx.) of the total new car sales in the US.

In India, the year 2005 could be considered the beginning of law making related to EVs. In this year, the Central Motor Vehicle Rules were amended to add the term 'Battery operated vehicle.' However, policymaking in the EV space started 2011 onwards when the government of India approved the National Mission on Electric Mobility and subsequently in 2012, launched the National Electric Mobility Mission Plan (NEMMP). This plan estimated to achieve 6 to 7 million electric vehicles on the road by 2020. However, in 2020, the number of registered EVs in India is 0.52 million.²³³

²²⁹ Recently, the Presidential Executive Order 14057 mandates the federal fleet to comprise of 100% zeroemission vehicles by 2035 including 100% light-duty ZEV acquisitions by 2027; and net-zero emissions from overall federal operations by 2050, including 65% emissions reduction by 2030. Sec 102 (ii). *See, supra* note, 25.

²³⁰ Executive Order 14037. Federal Register Vol. 86, No. 151 Tuesday, August 10, 2021. Available at https://www.federalregister.gov/documents/2021/08/10/2021-17121/strengthening-american-leadership-in-clean-cars-and-trucks.

²³¹ See, Desilver, *supra* note, 21. Also *see*, IEA Global EV Outlook 2021, *supra* note 7.

²³² Inserted by G.S.R. 589(E), dated 16-9-2005 (w.e.f. 16-9-2005).

²³³ See GIZ, supra note 80, at 6.

The EV policies of both the countries have many similar policy goals such as achieving energy security, creating jobs, and improving economic growth. However, the US policies seem to focus more on improving air quality and reducing emissions, ²³⁴ whereas, India's policies seem to focus more on promoting indigenous manufacturing of EVs and reducing import dependence on fossil fuels. The policy goals of the US EV policies include voluntary programs to reduce emissions, ²³⁵ grant programs to reduce mobile source emissions, target compliance to reduce petroleum consumption, ²³⁶ tax credits to incentivise the purchase of qualified EVs and alternative fuel infrastructure, and loan programs for manufacturing advanced technology vehicles. On the other hand, India's EV policies include the schemes to promote demand by incentivizing consumers, ²³⁷ and the schemes to promote supply by incentivizing the manufacturers through production-linked incentives to create indigenous EV ecosystem and reduce import burden of both, EV components and oil.

A few studies in the US context have analysed EV related policies and programs. For example, a recent study analyzed US policies, incentives, laws, programs on Electric Vehicle Supply Equipment (EVSE), implemented from 2016 to 2020, to evaluate the effectiveness of policies and evaluate the relationship between these policies and EVSE market development. ²³⁸ The study found that the policies are impacting EVSE market development in many ways. In particular, it found that the policies categorized as both, 'incentives' and 'laws and regulations' have significant positive associations with EVSE market development. ²³⁹ Another study analysed if various state EV incentives are influencing EV adoption rates. It compared the total monetary benefits of the consumers (provided through state incentives) to the EV sales in a given year (2013). The study found a significant positive correlation between the two. Further, certain incentives were found more effective in increasing EV sales than others, such as subsidies, carpool lane access,

²³⁴ This could be due to a larger number of the analyzed US policies relate to 'alternative fuel vehicles' of which EVs are a part. In case of India, the analyzed policies/ regulations are only on EVs. For other alternate fuels, such as Bio-fuels, Compressed Natural Gas (CNG), etc., India has separate policies/ regulations.

²³⁵ Such as to reduce diesel exhaust emissions and to reduce ground level emissions in commercial airports located in designated ozone and carbon monoxide air quality non-attainment areas.

²³⁶ By acquiring alternative fuel vehicles.

²³⁷ Such as FAME-II's 86% outlay is reserved for demand incentives.

²³⁸ Fuels Institute. (2022). Evaluation of Policies for Electric Vehicle Charging Infrastructure Deployment. Electric Vehicle Council.

²³⁹ *Id.* ('Incentives include grants, rebates, tax incentives, loans and leases, and utility incentive programs. Laws and regulations include air quality and emissions reduction programs, concerted efforts to increase charger deployments, legislation clarifying that EV charger owners and operators are not to be regulated as public utilities, and requirements related to alternative vehicle procurement and fuel use").

and emissions testing exemptions, were found to be most effective. Based on the benefit-cost analysis comparing a consumer's incentive benefits to state spending, the study found carpool lane access and public charger availability are particularly cost-effective measures. Such studies are important in understanding how different policies are performing and in particular what policy 'types' are more effective than others. However, there is limited analysis to understand the impact of a particular policy/ regulation in terms of its effectiveness in achieving what it aimed to achieve when it was proposed.

Whether the EV policies of the US and India are achieving their objectives needs to be assessed. At a very high level, if we compare the EV penetration in both countries, it is evident that the EV adoption is not picking up as was anticipated when the policies were made. In case of the US, the target of 50 % EV penetration is a recent policy decision and the timeline is 2030, therefore, it is to be seen if the country accomplishes the same or not. In case of India, it is evident that the country did not achieve the EV adoption target it planned to achieve by 2020. Interestingly, there was a planned review of FAME-I (major federal EV scheme) of 2015 and based on its implementation for two years, ex-post review was done and a revised scheme FAME-II was implemented in 2019.

Based on this dissertation study, it is difficult to say how different regulatory processes of the two countries actually result in meeting the larger EV policy goals or whether more adaptive regulatory processes result in EV policy success than less adaptive processes. However, in India's context, the interview participants shared that the planned review of FAME-I improved FAME-II in many ways. Therefore, it could be said that the ex-post reviews add to regulatory learning and policy improvement. But whether the policy succeeds in achieving its objectives could only be seen with time.

To assess if the EV law/policies are effective and achieving their objectives, one of the best approaches is to evaluate their impact by comparing the ex-ante regulatory analysis with the ex-post regulatory analysis.²⁴¹ Though beyond the scope of this research study,

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²⁴⁰ Jin, Lingzhi et al., (2014). White paper- Evaluation of State-level US Electric Vehicle Incentives. The International Council on Clean Transportation (ICCT).

²⁴¹ Bennear, Lori S. and Wiener, Jonathan B. (2021). Institutional Roles and Goals for Retrospective Regulatory Analysis. Journal of Benefit-Cost Analysis, 12 (3), 466-493. Also *see* Cropper et al., (2017). Looking Backward to Move Regulations Forward. Science, 355 (6332): 1375–1376, and Dudley et al., (2019). Crossing the Aisle to Streamline Regulation. Wall Street Journal, May 13, 2019, available at https://www.wsj.com/articles/crossing-the-aisle-tostreamline- regulation-11557788679.

the impact assessment could be in terms of the costs, benefits, and unintended consequences of the law/policy as proposed (ex-ante) and as implemented (ex-post). Further, the agencies in both countries may focus on improving the regulatory learning by introducing multi-rule reviews.²⁴² Mostly, the agencies focus on reviewing one rule at time thus they miss out on the learnings that could be gained from reviewing multiple past rules within an agency as well as from the interactive effect of multiple rules across agencies. Such collective analyses could provide lessons to improve future rules through better choice of policy designs, better methodologies, and better overall assessments.²⁴³

V. Conclusion and Recommendations for India

Based on the documentary and interview analysis, it could be concluded that India's EV laws and policies are not static. These are revised and amended over time based on various factors including new developments. However, the policies are not necessarily achieving their goals and objectives. Additionally, there is tremendous scope to improve the law/policymaking processes to improve regulatory learning. Following are the recommendations based on the documentary and interview analysis of the EV sector.

1. Introduce structured decision-making processes

Structured decision-making processes are excellent ways to optimize learning based on planned processes to collect, assess, and use information, such as the practice of regulatory impact assessment. However, this may be introduced in a phased manner and may not be required for all the proposed laws/policies e.g. limiting to the major impact laws/policies (such as the laws/regulations which have immense economic, social, or environmental impact). Further, simple and flexible methodologies are recommended for conducting impact assessments. Examples of simplified assessments are available with the Data Monitoring and Evaluation Office of NITI in the government of India. Similar approach could be adopted by the agencies in law/policymaking. Further, DMEO could handhold the agencies and provide the required capacity building support.

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²⁴² See, Bennear & Wiener, supra note, 241.

²⁴³ Id.

2. Introduce planned Monitoring and Evaluation

The monitoring mechanisms need a complete facelift in practice. The existing mechanisms are less structured, less formal, and mostly an afterthought process. It is recommended that relevant data collection and clear metric of monitoring are deliberated in advance and incorporated in the design of the proposed law/policy. Further, there should be emphasis on using the M&E information to inform the law/policymaking and policy adjustments.

3. Introduce planned retrospective reviews and multi-rule reviews

It is good that in the EV sector, India's laws and regulations are not static and are changing over time. However, the reviews are less planned and not based on the evaluation of the policy performance. Retrospective review of the policies is one such mechanism to compare the ex-ante assessments of the costs and benefits with the actual costs and benefits, post-implementation. Such retrospective reviews, could be built-in the policy/regulation and preferably with a specified period. The time period to conduct such reviews could vary depending on the value of new information that a review could generate and the expected cost of conducting such a review.²⁴⁴ Further, India should consider introducing multi-rule reviews i.e. learning from the multiple past rules/policies and using their analyses to improve future rules/policies and assessments. A review of policies impacting one another could be planned together for the maximum benefit of the evaluation process and to potentially reduce the cost.²⁴⁵

4. Improve inter-agency coordination

India's federal structure provides a robust foundation for the flourishing adaptive governance structures. However, interview analysis suggests mixed views on agency coordination. This highlights the need to strengthen the existing inter-ministerial consultation process. One way to strengthen is by introducing multi agency, multi rule reviews.²⁴⁶ In this process, policies of multiple EV related departments/ agencies which impact one another could be collectively reviewed. The collective impact analysis could maximize the benefits of review process, potentially reduce the cost of review, and provide lessons which are relevant across agencies.

²⁴⁵ *Id*.

 $^{^{244}}Id$.

²⁴⁶ Id.

5. Mandate pre-legislative consultation

Pre-legislative consultation increases the legitimacy of the proposed law/policy. It provides the scope of deliberating the proposal with the public and interested stakeholders. In India, pre-legislative consultation is not mandatory. Further, each bill in the Parliament may not be examined by the legislative committees. This effectively could result in laws and policies that never undergo any consultation process. Though the interview analysis suggests that stakeholder participation is happening in policymaking in the EV sector, there is a need to end agency discretion and make pre-legislative consultation a statutory requirement.

Chapter-5

Health Data Regulations in India- An analysis

Summary: This chapter's analysis is anchored on the adaptive regulatory cycle which has six adaptive features embedded in three stages of the cycle. Based on the relative presence or absence of the adaptive features, stage-wise adaptiveness is inferred for the health data sector. For India, this inference is based on the review of federal health data law and policy documents and nine interviews. For the US, this inference is based only on the review of federal health data law and policy documents. In the pre-implementation stage (assessing risks and uncertainties, and broader impact assessments), India's regulatory cycle indicates low adaptiveness on the books and moderate adaptiveness in practice. In the implementation stage (monitoring and evaluation), India's regulatory cycle indicates high adaptiveness on the books and moderate adaptiveness in practice. And in the post-implementation stage (iterative decision-making), India's regulatory cycle indicates high adaptiveness both on the books as well as in practice. Regarding the two overarching adaptive features of public participation and adaptive governance structures, the inference is quite stark. Public participation shows high presence both on the books and in practice. Whereas, the interagency coordination shows low presence both on the books and in practice. The high level comparative analysis of the US and India health data laws suggests that in the pre-implementation and implementation stages, the US regulatory cycle indicates more adaptiveness on the books than India. Whereas, in the post-implementation stage, both US and India's regulatory cycles indicate similar adaptiveness on the books. Based on this study, it is difficult to say how different regulatory processes of the two countries actually result in meeting the larger policy goals or whether more adaptive regulatory processes result in policy success than less adaptive processes. However, this study recommends that to assess the effectiveness of the laws/policies and to improve regulatory learning, the agencies in both countries should emphasize on conducting retrospective regulatory reviews and introduce multi-rule reviews. The chapter concludes with specific recommendations for India.

Health Data and Adaptive Regulation

Health data could be both, in paper or electronic form. In healthcare practice, health data is collected for both primary and secondary uses.¹ However, with the increasing use of technology in the health sector, the transition towards collecting and sharing electronic health data is witnessing a meteoric rise.² The entities that handle and use health data have expanded from the traditional health care providers to the web portals for patients and social media sites.³

With the advent of big data, exponential amount of data is being generated, collected, and analyzed using new computing capabilities. These emerging technologies are raising concerns about the changing nature of privacy and how individual privacy could be compromised or protected.⁴ In addition to the health data, there is enormous amount of non-health data which could be used to make inferences about health. For example, an individual's data on income, race/ethnicity, physical activity, and neighborhood could predict his/her risk of cardiovascular disease. Such data is increasingly being collected and traded online and could be a better predictor of health than an individual's health records.⁵

Similarly, health IT products have pervaded people's lives in myriad ways including mobile health applications and wearables. These products make it easier to access and share one's health data, save time, and improve the overall service delivery. However, they also expose health information to several risks such as data privacy violations and security breaches. Over the years, the reported cases of health care data breaches in the US have significantly

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¹ Office for State, Tribal, Local and Territorial Support (OSTLTS). (2015). Federal Public Health Law Supporting Data Use and Sharing, Centers for Disease Control and Prevention at p-1. (Collecting patient data to provide direct healthcare services is called 'primary use.' On the other hand, sharing data for research and analysis to support disease prevention and promote health is called 'secondary use').

² Id. Also see. Blumenthal, David and Tavenner, Marilyn, (2010), The "Meaningful Use" Regulation for

² Id. Also see, Blumenthal, David and Tavenner, Marilyn. (2010), The "Meaningful Use" Regulation for Electronic Health Records, 363 The New England Journal of Medicine. 6, 501; Hoffman, Sharona and Podgurski, Andy. (2013). Big Bad Data: Law, Public Health, and Biomedical Databases, Journal of Law, Medicine and Ethics. Suppl. 56. Also See, e.g., Safran, Charles, et al., (2007). Toward a National Framework for the Secondary Use of Health Data: An American Medical Informatics Association White Paper, Journal of American Medical Informatics Association, 14, 1–9.

³ National Committee on Vital and Health Statistics (NCVHS). (2018). Health information privacy beyond HIPAA: a 2018 environmental scan of major trends and challenges. https://www.ncvhs.hhs.gov/wpcontent/uploads/2018/02/NCVHS-Beyond-HIPAA_Report-Final-02-08-18.pdf.

⁴ President's Council of Advisors on Science and Technology. (2014). Big Data and Privacy: A Technological Perspective at page ix. Available at

https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/PCAST/pcast_big_data_and_privacy_-_may_2014.pdf.

⁵ Cohen, Glenn and Mello, Michelle M. (2018). HIPAA and Protecting Health Information in the 21st Century. Journal of American Medical Association, July 17, 2018, Volume 320, Number 3.

increased such as hacking, ransomware attacks, malware, exposure of protected health information over the internet, and data exfiltration attacks.⁷

In this context, the law could play an important role in regulating health data such as in terms of setting standards for collecting, storing, using, or protecting the generated health information. However, in such dynamic problem contexts, static laws and regulations may not be adequate. Therefore, it is relevant to understand how the health data laws in the US and India are responding to these new technological realities? Do the legal/policy provisions acknowledge the risks and uncertainties surrounding health data? Do health data laws and policies have built-in mechanisms for monitoring such risks and monitoring law/policy performance? Do laws and policies have provisions to look back and assess the impact post-facto? Are there examples of such impact assessments? Are agencies focusing on a broader public participation process while framing the health data laws/policies? This chapter is an attempt to find answers to similar questions.

I. Adaptive Regulatory Cycle

Typically, a policy or regulatory cycle has three basic stages i.e. pre-implementation, implementation, and post-implementation.⁸ In the adaptive regulatory cycle, each stage has adaptive features which enable learning and improvement over the lifecycle of a policy or regulation. The adaptive regulatory cycle is informed by the six features of adaptive regulation (based on the literature review). ⁹ These features are (i) Assessing the risks and uncertainties, (ii) Broader and fuller impact assessment, (iii) Monitoring, evaluation, and feedback, and (iv) Iterative decision-making and Policy adjustment. These features are shown in different stages of the regulatory cycle. Additionally, there are two overarching features: (v) Public participation and (vi) Adaptive governance structures, which play an important role in all stages of the cycle.

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⁷ (As 2018 and 2019, hacking/IT incidents remain the largest category of breaches occurring in year 2020 affecting 500 or more individuals, and also affecting the most individuals, constituting 68% of the reported breaches. For the under 500 breaches, unauthorized access or disclosures was the largest category of type of breach report). For details, *see*, U.S. Department of Health and Human Services, Office for Civil Rights. (2020). Annual Report to Congress on Breaches of Unsecured Protected Health Information For Calendar Year 2020. Available at https://www.hhs.gov/sites/default/files/breach-report-to-congress-2020.pdf

⁸ For details, see, Section VIII 'Adaptive Regulatory Cycle' in Chapter 1.

⁹ For details, see Chapter 1.

1. Pre-Implementation

Adaptive regulations acknowledge the importance of assessing the risks and uncertainties and responding to them directly. In adaptive regulatory cycle, this implies that while formulating the regulations/policies, the agencies undertake risk assessment. Another feature is the fuller impact assessment of the policy/ regulatory alternatives. The objective is to avoid the perils of narrow decision-making. This implies that the decision-makers assess the full portfolio of impacts such as the costs, benefits, and distributional effects, including the co-benefits and the countervailing risks. Lastly, adaptive regulations acknowledge the importance of planning relevant data collection. This implies there is adequate planning to identify the relevant information to be collected so that it could result in meaningful monitoring and reviews.

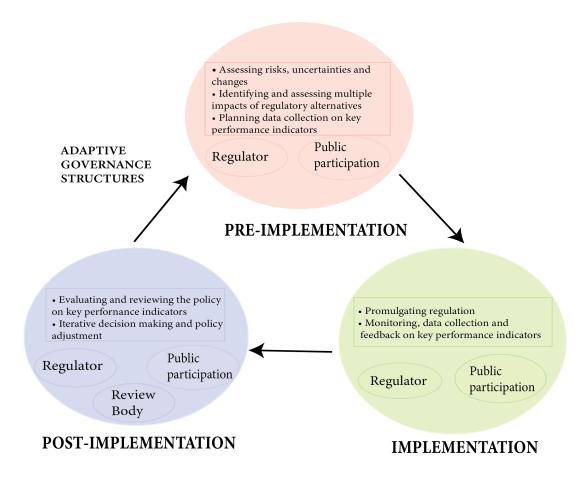


Figure 1. Adaptive Regulatory Cycle

2. Implementation

In this stage, the regulation/ policy is implemented. Adaptive regulations have built-in mechanisms of monitoring and feedback that enable policy adjustments. This implies

relevant data collection and analysis take place; policy outcomes and key performance indicators are monitored, and the outcomes of monitoring and feedback are fed back into the regulatory process i.e. inform future policies and regulations.

3. Post-Implementation

In adaptive regulations, the decision-making is not a one-time binary yes/no but a continuous process where new information and post-implementation experience inform the future decisions. This implies there are built-in provisions of policy learning and iterative decision-making, such as periodic review, retrospective review, and sunset clause. In this stage, the regulations are reviewed/ evaluated such as by comparing the ex-post assessments with the ex-ante assessments. Thus, the policy changes or improvements are based on the evaluation of policies.

4. Overarching features

Public participation and adaptive governance structures are the overarching features which play an important role in all stages of the regulatory cycle.

Public Participation- Public participation has a very broad meaning. Often the terms community participation, public participation, stakeholder participation, stakeholder engagement, community involvement, community engagement, citizen participation, etc., are used interchangeably. In adaptive regulatory cycle, the term public participation implies the right of the affected public to participate in the decision-making processes (regulatory/ policy-making). The word public includes both general public and the stakeholders/ right holders.

Adaptive Governance Structures- Adaptive governance structures represent the larger ecosystem that enables the implementation of adaptive regulations. A decentralized and polycentric approach facilitates adaptive approaches and allows for risk diversification, policy experimentation, and innovation across jurisdictions. In the adaptive regulatory cycle, these include the presence of polycentric structures and the inter-agency coordination both vertical (across different levels of government) and horizontal (at the same level of government).

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¹⁰ National Environmental Justice Advisory Council (NEJAC), Model Guidelines for Public Participation (2013), at 1

The analysis of the law and policy documents and the interviews in the following sections builds on the adaptive regulatory cycle and its three stages.¹¹

II. Summary analysis of US Health Data laws

A. Health Data Laws in the US

Federal laws have played a significant role in shaping the use of health IT by the health departments at various levels of governance including the state, tribal, and local. Several federal laws could be interpreted to regulate individually identifiable health information in certain circumstances, for example, the Gramm-Leach-Bliley Financial Services Modernization Act (GLBA),¹² Family Educational Rights and Privacy Act (FERPA),¹³ the Children's Online Privacy Protection Act of 1998 ("COPPA"), or the Privacy Act.¹⁴ However, given this chapter's focus on health information, relevant provisions of four federal laws with elaborate provisions on health data and health IT are analyzed. These are: Health Insurance Portability & Accountability Act, Health Information Technology for Economic and Clinical Health, 21st Century Cures Act, Section 5 of Federal Trade Commission Act.

B. Analysis of select Health Data Laws

To explore if the regulatory cycle in the health data sector is adaptive, in addition to the select federal laws, the US federal regulatory process has been analyzed.

1. Pre-Implementation

Under US law and related administrative rulemaking processes, many mechanisms are enabling broader impact assessments of the proposed law or regulation. Several Presidential Executive Orders emphasize such impact assessments including assessing the risks and countervailing risks of the proposed rule. In the pre-implementation stage, the

¹¹ For details, see, Chapter 1.

¹² Title V of the Financial Services Modernization Act of 1999, 16 C.F.R. Part 313 (implementing privacy rules pursuant to GLBA and regulating individual information that may derive from financial transactions related to health, such as a health savings account).

¹³ Applicable to the student health centers.

¹⁴ Applicable to the data held by the United States. For other examples, *see*, Congressional Research Service (CRS). (2019). Data Protection Law: An Overview. Available at https://crsreports.congress.gov/product/pdf/R/R45631.

agencies encourage public participation by inviting comments, conducting public hearings, webinars, etc.

a. Acknowledging risk and uncertainty

In the federal laws examined here, there are several provisions for addressing risks associated with health data. For example, the health data standards require the covered entities to conduct risk analysis¹⁵ and risk management¹⁶ as a part of their security management process for electronic protected health information (e-PHI). Further, the standards provide for flexibility and scalability allowing the covered entities to analyze their needs and decide on relevant security measures appropriate for their context. One of the factors in deciding on such security measures is the probability and criticality of the potential risk to the e-PHI.¹⁷ Other related provisions include evaluating the likelihood and impact of potential risks to e-PHI;¹⁸ a continuous process of risk analysis and regular review of records to track access to e-PHI and detect security incidents;¹⁹ and periodically evaluating the effectiveness of security measures.²⁰

b. Broader and fuller impact assessment

Examples of rulemakings on health data- There are several examples of the proposed rulemaking as well as the final rulemaking notifications where the agencies mentioned considering the regulatory alternatives. However, there is a variation vis-à-vis the details provided. For example, in a few rulemakings, the agency explains in detail various regulatory alternatives it considered.²¹ Another example is where the agency does not

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¹⁵ § 164.308(a)(1)(ii)(A). (The standards require the covered entity or business associate to conduct risk analysis by an accurate and thorough assessment of potential risks and vulnerabilities that could threaten the confidentiality, integrity, and availability of e-PHI).

¹⁶ 45 C.F.R. § 164.308(a)(1)(ii)(B) and 45 CFR § 164.308 (B). (A covered entity is required to identify and analyze potential risks to e-PHI, and implement security measures for reducing the risks and vulnerabilities to a reasonable and appropriate level complying with general requirements of security standards). Also *see*, https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html?language=es ¹⁷ 45 C.F.R. § 164.306(b)(2). Also see, Department of Health and Human Services. Summary of the HIPAA Security Rule. Available at https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html?language=es

¹⁸ 45 C.F.R. § 164.306(b)(iv).

¹⁹ 45 C.F.R. § 164.308(a)(1)(ii)(D).

²⁰ 45 C.F.R. § 164.306(e) and 45 C.F.R. § 164.308(a)(8).

²¹ Federal Register / Vol. 86, No. 12 / Thursday, January 21, 2021 / Proposed Rules. For details, see, https://www.federalregister.gov/documents/2021/01/21/2020-27157/proposed-modifications-to-the-hipaa-privacy-rule-to-support-and-remove-barriers-to-coordinated-care

explicitly mention the regulatory alternatives. In such rulemaking notifications, it merely mentions that the agency considered alternatives and the details could be seen in the responses to the comments.²² Another variation is where the agency mentions that it is unable to identify regulatory alternatives. In such rulemaking notifications, it mentions that the agency is unable to identify alternatives to the proposal and asks the public for comments as well as suggesting any alternatives for the agency's consideration.²³

c. Public participation

There is provision of public notice and comment in all stages of rulemaking- the advanced notice of proposed rulemaking, the proposed rulemaking, and the final rulemaking.²⁴

Key points:

- The US Presidential Executive Orders require agencies to consider and address relevant risks, and conduct regulatory impact analysis of economically significant regulations. Additionally, the health data standards require risk analysis and risk management by the covered entities.
- Each legislative proposal/bill is assigned to the concerned legislative committee(s) for review.
- Public hearing is an integral part of the legislative committees' functions but not a mandatory requirement. However, the legislative committee meetings are typically open to the public.
- Public notice and comment is a mandatory requirement of the federal rulemaking process including the Health agencies.
- Several examples of adaptive features are identified in the analyzed documents.

2. Implementation

Multiple agencies and committees are implementing the federal health data laws. Most of

monitoring, and evaluation.

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these agencies as well as the regulated entities have statutory obligations vis-à-vis reporting,

 $^{^{22}}$ Federal Register / Vol. 67, No. 157 / Wednesday, August 14, 2002 / Rules and Regulations at 53260. For details, see https://www.govinfo.gov/content/pkg/FR-2002-08-14/pdf/02-20554.pdf s

 $^{^{23}}$ Federal Register / Vol. 85, No. 85 / Friday, May 1, 2020 / Rules and Regulations at 25905. For details, see https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

²⁴ 5 U.S.C. § 553 (c) and (d). Advanced Notice of Proposed Rulemaking (ANPR) is a preliminary notice announcing that an agency is considering regulatory action. Also, *see*, Regulations.gov. Learn about the Regulatory Process, Available at https://www.regulations.gov/learn.

In the select federal laws and regulations examined here, there are a few monitoring and evaluation provisions for the regulated entities.²⁵ For example, as a part of administrative safeguards, a covered entity or business associate is required to meet the standard of evaluation by performing periodic evaluations both technical and non-technical. ²⁶ Under the EHR Incentive Program,²⁷ there are statutorily defined objectives along with measures. The program has three stages with defined core and menu objectives²⁸ that eligible professionals/ hospitals must achieve to demonstrate meaningful use of certified EHR technology.²⁹

In addition to the regulated entities, the laws specify multiple offices within DHHS and committees to monitor and evaluate the implementation of the statutory provisions. For example, the Office of the National Coordinator for Health Information Technology (ONC) reviews and endorses technical standards for EHR systems, and ensures that the EHR vendors develop systems that are interoperable and capable of communicating with other systems.³⁰ Examples include specifying the objectives, milestones, metrics, and measurable outcome goals while updating the federal health IT strategic plan; ³¹ reviewing the federal health IT investments to ensure the health IT programs meet the objectives of

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²⁵ e.g. covered entities (like health care providers), eligible professionals, hospitals, business associates, etc. ²⁶ 45 C.F.R. § 164.308(a)(8). (This is by comparing the initial implementation of security standards with the subsequent changes in the environment and operational settings, and assessing how well a covered entity is meeting the requirements of the security standards).

²⁷ EHR Incentive Programs (now known as the Promoting Interoperability Programs) to encourage eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) to adopt, implement, upgrade (AIU), and demonstrate meaningful use of certified electronic health record technology (CEHRT). For details, *see* https://www.cms.gov/regulations-and-

guidance/legislation/ehrincentiveprograms?redirect=/ehrincentiveprograms

²⁸ 42 CFR 495.6 - Meaningful use objectives and measures for eligible professionals, eligible hospitals, and critical access hospitals.

²⁹ Core objectives are objectives that all providers must meet. There are also a predetermined number of menu objectives that providers must select from a list and meet in order to demonstrate meaningful use. For example, to demonstrate meaningful use in Stage 1, the eligible professionals/ hospitals must meet 15 core objectives and 5 menu objectives that they select from a total list of 10. In Stage 2, the eligible professionals/ hospitals must meet 17 core objectives and 3 menu objectives that they select from a total list of 6, or a total of 20 core objectives. In stage 3, all eligible professionals/ hospitals are required to meet a single set of 8 objectives and measures. For details, see, CMS. Stage 2 Overview Tipsheet. Also, see, CMS. Stage 3 Program Requirements for Providers Attesting to their State's Medicaid Promoting Interoperability (PI) Programs.

³⁰ 42 U.S.C. § 300jj-11.

³¹ 42 U.S. C. § 300jj–11 (c) (3) (A) and (C).

the strategic plan;³² and creating a standardized process for the public to file claims related to information blocking.³³

Other examples include the Health IT Certification Program- a voluntary program of third-party conformity assessment of health IT. ONC evaluates and authorizes other organizations to perform conformance testing or issue certifications on its behalf.³⁴ Similarly, the EHR Reporting Program provides for developing reporting criteria and specifying the reporting criteria to measure the performance of EHR technology. ³⁵ The program also provides for collecting confidential feedback on such criteria from healthcare providers as well as developers of certified EHR technology. ³⁶

The Office of Civil Rights (OCR), an office within DHHS, ensures compliance with health information privacy and security laws by keeping track of breaches of protected health information (PHI), conducting compliance reviews, and investigating complaints and violations of HIPAA's Privacy & SecurityRules.³⁷ It periodically audits the covered entities and business associates for their compliance with the HIPAA Rules.³⁸

The National Committee on Vital and Health Services (NCVHS)³⁹ assists the Secretary DHHS in issuing an annual report on the state of the nation's health including recommendations for improving the health information systems;⁴⁰ studying the issues regarding adoption of uniform data standards and electronic exchange of patient's medical

³² 42 U.S. C. § 300jj–11 (c) (1) (A).

³³ 42 U.S. C. § 300jj–52 (d) (3) (A).

³⁴ ONC. (2022). Health IT Certification Program Overview at 1. Available at https://www.healthit.gov/sites/default/files/PUBLICHealthITCertificationProgramOverview.pdf. Also see, 42 U.S. C. § 300jj–11 (c)(5).

³⁵ The EHR Reporting Program was required under Section 4002(c) of the Cures Act for improving the quality and delivery of health care. For details see, ONC. HER Reporting Program. Available at https://www.healthit.gov/topic/certification-health-it/ehr-reporting-program.

³⁶ 42 U.S.C. 300jj-19a.

³⁷ Department of Health and Human Services. OCR Mission & Vision. Available at, https://www.hhs.gov/ocr/about-us/mission-vision/index.html

³⁸ 42 U.S.C. 17940. Audits are excellent monitoring mechanisms and provide opportunities to the OCR for examining the industry's compliance processes, recognizing best practices, and uncovering the risks and vulnerabilities that could have been missed during its complaint investigations and compliance reviews. In many ways, the audits enable to identify the problems before they result in breaches. The OCR has conducted audits of 166 covered entities and 41 business associates and notified these organizations of its findings. OCR generally identifies the best practices picked through the audit process and provides guidance for effective compliance. For details, see, HIPAA Audits industry Report (2016-17) may be seen at https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/index.html

³⁹ It is the statutory public advisory body to the Secretary HHS on health data, privacy, national health policy, and implementation of HIPAA.

⁴⁰ 42 U.S.C. § 242k (k) (5) (A) (vii).

record information;⁴¹ and submitting an annual report to the Congress on the implementation of part C of title XI of the Social Security Act,⁴² particularly addressing the extent of compliance to the security standards and assessment of penalties for non-compliance among others.⁴³

The Health Information Technology Advisory Committee (HIT Advisory Committee) in consultation with the ONC is required to submit an annual progress report to Congress on advancing interoperability including assessing the status of the health IT infrastructure and analyzing the gap between policy and resources.⁴⁴

The Secretary, DHHS plays a key role in monitoring and evaluation by publishing reports and investigating complaints. For example, Secretary must publish an annual report on the adoption of a nationwide system for electronic use and exchange of health information; ⁴⁵an annual report on compliance with the Privacy and Security Rules, ⁴⁶ and an annual report on the breaches of protected health information. ⁴⁷ Other ways of monitoring include biennially evaluating the Health IT regional extension centers; ⁴⁸ assessing the performance of the recipients of grants/ contracts in the EHR Reporting program every two years and re-determining the grants/ contracts; ⁴⁹ investigating complaints of non-

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⁴¹ 42 U.S.C. § 242k (k) (5) (B).

⁴² Title XI of the Social Security Act is administered by the Department of Health and Human Services, the Social Security Administration, and by the Department of Labor. Part C is entitled "Administrative Simplification." The purpose of this part is to improve the Medicare program under title XVIII of the Social Security Act and the Medicaid program under title XIX of the Act, and the efficiency and effectiveness of the health care system, by encouraging the development of a health information system through the establishment of standards and requirements to enable the electronic exchange of certain health information. For details, *see* https://aspe.hhs.gov/report/health-insurance-reform-standards-electronic-transactions/b-statutory-background

⁴³ 42 U.S.C. § 242k (k) (7).

⁴⁴ 42 U.S.C. §300jj–12 (c) (2).

⁴⁵ 42 U.S.C. 17903.

⁴⁶ 42 U.S.C. § 17953 (a) (1) and (2). (The law requires publishing the summary of complaints of alleged violations of the relevant provisions of the HITECH Act and of the HIPAA Privacy, Security and Breach Notification Rules). The annual reports submitted to the Congress are available on the department's website. For details, see, https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/reports-congress/index.html

⁴⁷ 42 U.S.C. § 17932 (i) (1). The reports to Congress on breach notification can be seen at https://www.hhs.gov/hipaa/for-professionals/breach-notification/reports-congress/index.html?language=es

⁴⁸ 42 U.S.C. § 300jj–32 (c) (8). (Regional extension centers provide technical assistance and disseminate best practices in accelerating efforts to adopt, implement, and use health IT and allowing the use of health information and electronic exchange in compliance with standards, implementation specifications, and certification criteria).

⁴⁹ 42 U.S.C. 300jj-19 c (4) (A).

compliance of administrative simplification provisions by the covered entities;⁵⁰ and conducting compliance reviews.⁵¹

The Government Accountability Office is required to submit a report on the best practices of protected health information disclosure for treatment.⁵²

b. Public Participation

Public participation includes consultation and meaningful engagement in law and policymaking process, as well as enhancing participatory capacity of people. There are examples of general statutes that increase the participatory capacity of the public, such as the Freedom of Information Act.⁵³ It provides the public the right to access information or records from federal agencies.

The laws analyzed here have many examples mandating stakeholder consultation while implementing the statutory provisions. For example, the ONC must convene appropriate public and private stakeholders in developing a trusted exchange framework⁵⁴ and in updating the Federal Health IT Strategic Plan.⁵⁵

The HIT Advisory Committee is required to conduct open public meetings and allow public comment on the policy recommendations for advancing interoperable health IT infrastructure.56

The recipients of the State grants for health IT must consult the stakeholders while planning and implementing the grants for promoting health IT. 57

⁵⁰ 45 C.F.R § 160.306 (a). Also, see, 45 CFR § 160.306 (c).

⁵¹ 45 C.F.R § 160.308 (a) (b).

⁵² 42 U.S.C. § 17953 (d).

⁵³ Office of Information Policy. US Department of Justice. Freedom of Information Act. Available at https://www.foia.gov/about.html.

⁵⁴ 42 U.S.C. § 300jj–11 (c) (9) (A) and (B).

⁵⁵ 42 U.S.C. § 300jj-11 (c) (3) (B).

⁵⁶ 42 U.S.C. § 300jj–12 (b) (6).

⁵⁷ 42 U.S.C. § 300jj−33 (g). Also, see, 42 U.S. Code § 300jj−33 (a), (b), and (c).

The DHHS Secretary must solicit stakeholder inputs on the standards for information transactions and data elements.⁵⁸ Further, the Secretary must consult stakeholders while developing the EHR reporting criteria,⁵⁹ modifying the reporting criteria,⁶⁰ and receiving confidential feedback on the established criteria.⁶¹

There are a few examples where the select federal law or the federal agency programs/ initiatives provide for encouraging public involvement and increasing consumer awareness. For example, the EHR reporting program provides additional resources to the ONC for educating and informing consumers on health IT;⁶² the privacy advisors in regional offices of the DHHS for guiding and educating the covered entities and individuals about their rights and responsibilities on protected health information (PHI);⁶³ the national education initiative for enhancing public transparency on the use of PHI;⁶⁴ and the ONC's Privacy Policy Snapshot Challenge created an online Model Privacy Notice (MPN) generator for enabling the health technology developers to customize a privacy notice.⁶⁵ A few examples of the materials developed to educate patients about their rights and choices include the health information security & privacy collaboration website,⁶⁶ the e-consent Toolkit, ⁶⁷ and the HIPAA notice of privacy practices project.

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⁵⁸ 42 U.S.C. § 1320d–2 (a) (1). (The Secretary must solicit inputs every three years from the specified entities including stakeholders on increasing standardization and uniformity in financial and administrative activities, for improving the health care systems' operation, and reducing the costs). Also, *see*, 42 U.S. Code § 1320d–2 (a) (5) (A).

⁵⁹ §300jj–19a (a) (1) and (2). (The statute mentions the stakeholders that must be consulted, e.g. health care providers, hospitals, health IT developers, patients, consumers, data-sharing networks, security experts, etc.) As per the information available on the official website, the draft reporting criteria was to be published in the Federal Register for public comment by mid-2020. Further, based on the public feedback, ONC intends to revise the criteria, plan beginning data collection, and publicly releasing EHR comparison information by late 2022. For details, see, https://www.healthit.gov/sites/default/files/page/2019-07/EHRReportingProgram072519v1.pdf

^{60 42} U.S.C. §300jj–19a (a) (4).

^{61 42} U.S.C. §300jj–19a (c) (5).

^{62 42} U.S.C. §300jj-19a (f).

⁶³ Section 13403(a). HITECH Act.

⁶⁴ U.S.C. §17933.

⁶⁵ In the challenge, designers, developers, and health data privacy experts participated and developed MPN generator that could produce customizable notices, making it easier for the consumers to understand a product's privacy and security policies. For details, *see*, ONC. Model Privacy Notice. Available at https://www.healthit.gov/topic/privacy-security-and-hipaa/model-privacy-notice-mpn

⁶⁶ It provides resources (templates, tools, and processes) to help implementers educate patients on the privacy and security aspects of electronic health information exchange and health IT in general. For details, *see*, ONC. Health Information Security & Privacy Collaboration. Available at

https://www.healthit.gov/topic/health-information-security-privacy-collaboration-hispc

⁶⁷ It provides samples of the tools, resources, and patient educational materials used in the eConsent Trial Project. The toolkit could be leveraged regardless of the particular consent approach and architecture/infrastructure models. The implementer could tailor the material to suit the requirements of his or her organizational environment. For details, *see*, ONC. eConsent Toolkit. Available at https://www.healthit.gov/topic/privacy-security-and-hipaa/econsent-toolkit

Key Points:

- Multiple offices in the Department of Health and Human Services (DHHS) and statutory committees have elaborate monitoring and evaluation functions. These include setting technical standards and reporting criteria for the covered entities, and annual reports, audits, and compliance reviews by the designated offices and committees.
- There are examples of provisions encouraging public involvement, both in terms of stakeholder engagement while implementing the statutory provisions as well as in increasing consumer awareness and education on health IT.

3. Post-Implementation

The select federal laws examined here have many provisions for post-implementation review and evaluation.

a. Iterative Decision-making and Policy Adjustment

In analyzed health data laws/regulations, the EHR Incentive Program α ould be considered an example of iterative decision-making due to its multi-phased implementation. This program had a phased-roll out with stage 1 regulations published in 2010, stage 2 in 2012, and stage 3 in 2015. Each stage has defined core and menu objectives along with measures that eligible professionals/ hospitals must achieve to demonstrate meaningful use of certified electronic health record technology and transition to the next stage.

Another example of iterative decision-making is the HIPAA Privacy Rule. This Rule has been modified several times,⁷² such as in the years 2002, 2013, 2014, and 2016, and the latest modification is under process from 2021.⁷³ However, these updates are not due to built-in regulatory provisions.

⁶⁸ See, EHR Incentive Programs, *supra* note 27.

⁶⁹ Stage 1 final rule at 75 FR 44313 through 44588; Stage 2 Final rule- Federal Register / Vol. 77, No. 171 / Tuesday, September 4, 2012 / Rules and Regulations, 53968; and Stage 3 final rule- Federal Register / Vol. 80, No. 200 / Friday, October 16, 2015 / Rules and Regulations, 62762.

⁷⁰ 42 C.F.R. 495.6.

⁷¹ For details, see, supra note 28 and 29.

⁷² Office of Civil Rights (OCR), Department of Health and Human Services (DHHS). The HIPAA Privacy Rule-Privacy Rule History. For details, *see*, https://www.hhs.gov/hipaa/for-professionals/privacy/index.html.

⁷³ See, Federal Register, supra note 21.

i. Provisions acknowledging change

Provisions related to covered entities include reviewing and modifying the security measures for protecting e-PHI;⁷⁴ periodic testing and revision of contingency plans;⁷⁵ and updating documentation in response to the environmental changes affecting the security of e-PHI.⁷⁶

Provisions related to the HIT Advisory Committee include updating recommendations on the policy framework for advancing interoperable health IT infrastructure;⁷⁷ annually updating and publishing the schedule of assessing the policy recommendations,⁷⁸ and identifying a temporary additional priority target area in response to new circumstances in the health IT community.⁷⁹

ii. Provisions of review/evaluation

The Office of National Coordinator (ONC)- Examples include, assessing the impact of health IT on communities with health disparities and identifying practices to increase the adoption of health IT in such communities;⁸⁰ evaluating and publishing the benefits and costs of electronic use and exchange of health information along with assessing to whom these benefits and costs accrue;⁸¹ establishing and updating objectives and benchmarks for advancing and measuring the advancement of the priority target areas;⁸²periodically reviewing the adopted standards and implementation specifications every three years and recommending if these are to be maintained or phased out.⁸³ Additionally, there is a non-statutory example of the ONC updating the Model Privacy Notice (MPN) of 2011 in 2016 due to significant changes in the health IT market, post-2011.⁸⁴

Secretary DHHS- Examples include, modifying a standard or implementation specification adopted as a part of Administrative Simplification standards, no more than once a year;⁸⁵

⁷⁴ 45 C.F.R. § 164.306(e).

⁷⁵ 45 CFR § 164.308 (a) (7) (i) and (ii) (D).

⁷⁶ 45 C.F.R. § 164.316(b)(2)(iii).

⁷⁷ 42 U.S.C. § 300jj–12 (b) (1) (B); (3) (A).

⁷⁸ 42 U.S.C. § 300jj−12 (b) (5).

⁷⁹ 42 U.S.C. § 300jj–12 (b) (2) (D) (i).

^{80 42} U.S.C. § 300jj-11 (c) (6) (C).

^{81 42} U.S.C. § 300jj–11 (c) (6) (D).

^{82 42} U.S.C. § 300jj–12 (c) (1).

^{83 42} U.S.C. § 300jj–12 (b) (1).

⁸⁴ See, ONC, supra note, 65.

^{85 45} C.F.R. § 160.104.

modifying the reporting criteria under the EHR Reporting Program;⁸⁶ periodically reviewing the priority target areas;⁸⁷ annual updating of the guidance on unsecured PHI,⁸⁸ and conducting biennial hearings to evaluate and review the adopted standards and operating rules, and biennially providing recommendations for updating and improving the same.⁸⁹ As a part of continuous improvement, the Secretary must annually evaluate the state grants to promote health technology and while awarding grants, implement the lessons learned from such evaluations in terms of improving quality of care, reducing costs, and building the most secure and effective electronic exchange of health information.⁹⁰

Report on the impact of provisions of the HITECH Act- The GAO is required to submit a report to Congress and the Secretary DHHS analyzing the impact of any of the provisions of this Act on (a) premiums of health insurance, (b) overall cost of health care, (c) EHR adoption by providers, and (d) reduction in medical errors including other quality improvements.⁹¹

Retrospective Review of Health Breach Notification (HBN) Rule- The Federal Trade Commission (FTC) typically reviews its rules every ten years to keep pace with the technological changes, evolving business models, and changes in the marketplace.⁹² In 2009, FTC issued the HBN Rule and reviewed it in 2020.⁹³

iii. Pilot programs

There are a few examples of pilot testing required by health IT developers as well as by federal agencies. For example, before marketing technology, the health IT developer is required to have successfully tested the technology's real-world use for interoperability.⁹⁴

^{86 42} U.S.C. 300jj-19a (1) and (4).

^{87 42} U.S.C. § 300jj-12 (c) (3).

^{88 42} U.S.C. 17932 (h)(2).

^{89 42} U.S.C. § 1320d–2 (i).

⁹⁰ 42 U.S.C. § 300jj–33 (h).

^{91 42} U.S.C. § 17953 (e).

⁹² Federal Trade Commission (FTC). Retrospective Review of FTC Rules and Guides. Available at https://www.ftc.gov/enforcement/rulemaking/retrospective-review-ftc-rules-guides. Also, see, the tenyear schedule for review of FTC rules and guides at 85 FR 20889 (Apr. 15, 2020). Available at https://www.federalregister.gov/documents/2020/04/15/2020-07757/regulatory-review-schedule.
⁹³ Federal Register / Vol. 85, No. 100 / Friday, May 22, 2020 / Proposed Rules. Available at

https://www.govinfo.gov/content/pkg/FR-2020-05-22/pdf/2020-10263.pdf

Similarly, the law requires pilot testing of the trusted exchange framework ⁹⁵ and the pilot testing of standards and implementation specifications by the National Institute of Standards and Technology (NIST).⁹⁶

Other examples include the e-Consent Trial Project of the ONC which focuses on meaningful consent and patient education. The project was implemented at four health care provider offices that formed a part of the regional clinical information exchange.⁹⁷

iv. Sunset clause

FTC's Health breach notification rule for non-HIPAA covered entities - Regarding breach of security of the unsecured personal health record, the law required FTC to promulgate a temporary breach notification requirement for the non-HIPAA covered entities. The sunset clause mentions that if Congress enacts new legislation requiring compliance by non-covered entities or business associates, the provisions of this section shall cease to apply. 98

Key points

- The legislative standing committees evaluate the implementation of laws on subject matters of their jurisdiction.
- Agencies may also review the regulations provided they follow the notice and comment process.
- In addition, the select health data laws/ regulations examined here have many examples of review and iterative decision-making, such as periodically reviewing the adopted standards, updating policy frameworks, pilot testing the standards and frameworks, evaluating the impact of health IT on community as well as evaluating the impact of HITECH Act on specified parameters.

^{95 42} U.S.C. § 300jj−11(c) (9) (B) (iii). (Trusted Exchange Framework is a common set of principles, terms, and conditions to support the development of a Common Agreement that would help enable nationwide exchange of electronic health information (EHI) across disparate health information networks).

96 42 U.S.C. 300jj−12 (b) (3) (C) and 42 U.S.C. § 17911 (a).

⁹⁷ The project used specially designed education materials and electronic decision capture technology. The project's primary objectives included- (a) gathering patients' input on areas in which they want to learn more about consent, (b) educating patients about the electronic sharing of their health information through a Health Information Exchange Organization (HIE), and (c) recording their choices. For details, *see*, ONC, *supra* note, 67.

^{98 42} U.S.C. § 17937 (g) (2). Also, see, 16 C.F.R. § 318.9.

4. US Health data laws and Adaptive governance structures

In addition to the presence of adaptive regulatory processes, there are examples of adaptive governance structures in the health IT space. These governance structures reflect polycentrism as well as inter-agency coordination.

a. Polycentric governance

The law requires the HIT Advisory Committee to have diverse stakeholders for providing input on the development and standardization of standards, implementation specifications, and certification criteria for health IT infrastructure. Of the total 25 committee members, 2 should be advocates for patients or consumers of health IT along with outside advisors with expertise in developing policies and standards for electronic exchange and use of health information.

Similarly, the law provides for the Health Care Information Enterprise Integration Research centers. These multi-disciplinary research centers are established by providing grants to the institutions of higher education including the non-profit entities ¹⁰² for developing and using health IT and researching the challenges in health care delivery systems. ¹⁰³

Interoperable Network Exchange – The ONC in consultation with NIST is required to convene public-private and public-public partnerships for consensus building and developing a trusted exchange framework of health information.¹⁰⁴

Health IT Safety Center- The FDASIA Health IT report recommended creating a Health IT Safety Center as a public-private entity with broad stakeholder engagement and involvement of federal agencies. The center would serve as a governance structure for an integrated health IT learning system to avoid regulatory duplication and improve ongoing efforts.¹⁰⁵

^{99 42} U.S.C. § 300jj-12 (b) (4).

¹⁰⁰ 42 U.S.C. § 300jj–12 (d) (2) (A) (i).

¹⁰¹ 42 U.S.C. § 300jj–12 (d) (5).

¹⁰² 42 U.S.C. § 17912 (a) (1).

 $^{^{103}}$ 42 U.S.C. \S 17912 (a) (3) (A) and (B).

¹⁰⁴ 42 U.S.C. § 300jj–11 (c) (9) (A).

¹⁰⁵ For details, *see*, FDA, FCC, and ONC (2014) FDASIA Health IT Report- Proposed Strategy and Recommendations for a Risk-Based Framework at 14,16. Available at

https://www.fda.gov/media/87886/download. Also, see, US FDA. Digital Health Reports. Available at https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-reports.

b. Inter-agency coordination

There are examples of agency coordination both horizontally (between agencies at the same level of government) and vertically (between agencies at different levels of government).

i. Horizontal coordination

Provisions indicating horizontal coordination include the National Coordinator to consult the National Institute of Standards and Technology (NIST) for establishing voluntary health IT Certification program; 106 the National Coordinator to collaborate with the NIST and other relevant agencies within DHHS for ensuring network-to-network exchange of health information;¹⁰⁷ Secretary, DHHS to consult with the FTC for promulgating regulations on information blocking; 108 the National Coordinator to serve as a technical consultant to the Inspector General and the FTC in investigating claims on information blocking; 109 the National Coordinator to coordinate the health IT policy and programs of the DHHS with relevant executive branch agencies towards a coordinated national goal;¹¹⁰ the Secretary, DHHS to consult other federal agencies for jointly reviewing the standards, implementation specifications, and certification criteria; 111 the National Coordinator to consult other federal agencies such as NIST in developing and implementing the Health IT extension program; ¹¹² and the Secretary, DHHS to consult the FTC for conducting a study on privacy and security requirements of the entities not covered under HIPAA. 113

ii. Vertical coordination

Provisions indicating vertical coordination include Health Information technology Regional extension centers - These provide technical assistance to the health care providers including best practices on health IT learned from the Center (Health Information technology Research Center). The regional centers solicit participation from

¹⁰⁶ 42 U.S.C. § 300jj–11 (c) (5).

¹⁰⁷ 42 U.S.C. § 300jj–11 (c) (9) (A).

¹⁰⁸ 42 U.S.C. § 300jj–52 (a) (5).

¹⁰⁹ 42 U.S.C. § 300jj−52 (c) (2) and (3).

¹¹⁰ 42 U.S.C. § 300jj–11 (c) (2).

^{111 42} U.S.C. § 300jj–14 (a) (1). 112 42 U.S.C. § 300jj–32 (a).

¹¹³ 42 U.S.C. § 17953 (b).

the industry, universities, and state governments, and utilize the expertise and capabilities of other federal agencies.¹¹⁴

State Health Information Exchange (HIE) Cooperative Agreement Program- It encourages the states to build capacity for exchanging health information across the health care system. The program aims to move towards interoperability at the national scale while building on the existing efforts of regional and state-level HIEs.¹¹⁵

Governance Framework for Trusted Electronic Health Information Exchange-The ONC developed guiding principles on HIE governance and provided a common foundation applicable to all types of governance models. The framework is meant for all entities that set HIE policy such as the state governments, health information exchange organizations (HIOs), private companies, and public-private partnerships.¹¹⁶

Other examples include the Secretary DHHS, establishing a program to provide state grants for promoting health IT according to nationally recognized standards;¹¹⁷ and the National Coordinator awarding competitive grants to States and Indian tribes for developing loan programs to facilitate widespread adoption of certified EHR technology.¹¹⁸

US regulatory cycle in health data- Summary analysis

The documentary analysis suggests that the US federal regulatory process has many builtin adaptive features and their compliance is mandatory for the agencies. In the preimplementation stage, the federal agencies are required to conduct risk assessment and regulatory impact assessment for all significant regulations, and public participation is a mandatory requirement of the regulatory process. Also, the health data laws have many provisions recognizing and addressing the risks related to health data, and examples of health data rulemakings where multiple policy alternatives are considered.

¹¹⁴ 42 U.S.C. § 300jj−32 (c).

¹¹⁵ In total, 56 states, eligible territories, and state designated entities received the awards. For details, *see* https://www.healthit.gov/topic/onc-hitech-programs/state-health-information-exchange.

¹¹⁶ ONC expects to update and adapt the Framework over time reflecting policy changes, technological breakthroughs, stakeholder feedback, and market innovations. For details, *see*, ONC. Governance Framework for Trusted Electronic Health Information Exchange. Available at

https://www.healthit.gov/sites/default/files/GovernanceFrameworkTrustedEHIE_Final.pdf

¹¹⁷ 42 U.S.C. § 300jj–33 (a).

¹¹⁸ 42 U.S.C. § 300jj-34 (a).

In the implementation stage, the health data laws examined here have elaborate provisions of monitoring and reporting, such as setting technical standards and reporting criteria for the covered entities and requiring annual reports, audits, and compliance reviews by the designated offices. Also, there are examples of public involvement, both in terms of stakeholder engagement while implementing the statutory provisions as well as in increasing consumer awareness of health IT.

In the post-implementation stage, the select laws/ regulations examined here have many provisions of review and iterative decision-making, such as periodically reviewing the adopted standards, updating policy frameworks, pilot testing the standards and frameworks, and assessing the impact of law on specified parameters.

In addition to the adaptive processes, there are examples of adaptive governance structures in health data indicating polycentrism and cross-agency coordination. Therefore, on the books, the US health data laws and regulations adaptiveness in all three stages of the regulatory cycle. This analysis is based only on the review of the law/policy documents. Analyzing how these laws are in practice Is beyond the scope of this study.

III. Detailed Analysis of India's Health Data laws/policies

A. Health data and Law-making in India

According to the Constitution of India, law-making can happen in three ways- at the federal level, at the state level, and both at the federal and state levels. The 7th schedule of the Indian Constitution distributes the legislative subjects into three lists- the Union list having subjects of national importance on which the Parliament can legislate, the State list having subjects of local importance on which the state legislatures can legislate, and the Concurrent list having subjects on which both the federal and the state governments can legislate.¹¹⁹

In India, health data presents a peculiar situation in law-making. 'Health' is a State list subject and 'data' per se is not mentioned in any of the three lists of the Indian

¹¹⁹ Schedule VII. Constitution of India.

Constitution. Information technology (IT), a subject that could be considered closest to data, also finds no mention in the three lists of the Indian Constitution. However, the Parliament of India has been legislating on IT-related issues including the Personal Data Protection bill 2019. This could be attributed to the Parliament's residuary powers vested by the Union list subject at serial number 97 (List I)- Parliament of India could legislate on 'Any other matter not enumerated in List II or List III including any tax not mentioned in either of those Lists.' ¹²⁰

In 2013, India introduced the Electronic Health Records Standards which were revised in 2016. However, the foundation of comprehensive policy-making on digital health was set by the National Health Policy 2017. This was followed by the National Digital Health Blueprint in 2019 and the National Digital Health Mission (NDHM) in 2020. NDHM was renamed Ayushman Bharat¹²¹ Digital Mission (ABDM) and was piloted in six union territories. Further, to implement ABDM, the Health Data Management policy and Data Privacy policy have been formulated in 2020. This chapter focuses on the federal regulations on health data because the federal government of India and the federal agencies are driving most of the regulations in this nascent area. Following policy/legal documents are analyzed in this chapter:

- 1. National Health Policy (2017)- This is the latest national health policy formulated after the situation analyses of the progress in health sector since National Health Policy 2002. The policy provides overall guidance in the health sector and outlines the government priorities in shaping and improving health systems. For this chapter, the policy provisions relevant to health data are analyzed.
- Ayushman Bharat Digital Mission Strategy Overview (2020)- This document provides an overview of ABDM in terms of the context, rationale, scope, and implementation provisions of the mission to create a digital healthcare ecosystem across the country.¹²³

¹²⁰ Ministry of External Affairs, Govt. of India (undated). Seventh Schedule (Article 246). Available at https://www.mea.gov.in/Images/pdf1/S7.pdf.

¹²¹ The word 'Ayushman' is a Sanskrit language word meaning blessed with long life and 'Bharat' is the name of India in Hindi language. Even the Constitution of India Article 1- 'Name and territory of the Union' mentions in clause (1) 'India, that is Bharat, shall be a Union of States.'

 ¹²² National Health Policy (NHP). (2017). Government of India. Ministry of Health and Family Welfare.
 ¹²³ Ayushman Bharat Digital Mission (ABDM). (2020). Strategy Overview- Making India a Digital Health Nation Enabling Digital Healthcare for all.

- 3. Ayushman Bharat Digital Mission Health Data Management policy (draft) (2020)It is a guidance document for all entities and individuals participating in the national digital health ecosystem of ABDM. It sets out the minimum standards of health data privacy protection to ensure compliance with applicable laws and regulations.¹²⁴
- 4. Ayushman Bharat Digital Mission Data Privacy policy (2020)- This policy is prepared in pursuance of the requirement of the Health Data Management policy. It sets out the minimum standards of data protection and information security principles and outlines the manner of collecting, processing, and using personal data of individuals for all entities participating in ABDM.¹²⁵
- 5. Ayushman Bharat Digital Mission Guidelines (2020)- This policy document provides guidelines for health information providers, health repository providers, health information users, and health lockers.
- 6. Personal Data Protection Bill 2019- It is a legislative bill for protecting the privacy of personal data and creating a framework of rights and responsibilities of individuals as well as the entities using/processing personal data, along with providing an organizational structure for compliance with statutory provisions.¹²⁶ In December 2019, a joint-Parliamentary committee was constituted to review the bill which presented its report to the Parliament in December 2021.

B. Analysis of select Health data laws and policies

To explore if India's health data regulatory cycle is adaptive or not, I have analyzed 6 law/policy documents and interviewed 9 key stakeholders. Additionally, the federal government sources on the law and policy-making process are analyzed.

¹²⁴ ABDM Health Data Management Policy. (2020) National Health Authority. Ministry of Health and Family Welfare. Government of India.

¹²⁵ ABDM Data Privacy Policy. (2020) National Health Authority. Ministry of Health and Family Welfare. Government of India.

¹²⁶ The Personal Data Protection Bill (The Bill). (2019). Bill no. 373 of 2019. As Introduced in Lok Sabha.

1. Pre-Implementation

The documentary analysis suggests that the law and policy-making process of India does not mandate the departments/ Ministries to conduct a risk assessment and regulatory impact assessment. There are a few mechanisms that enable broader impact assessment of the proposed laws/policies, such as the legislative committees and inter-ministerial consultations. The interview analysis suggests mixed views on the conduct of risk assessments, ranging from the policymakers adopting a risk-based approach to no risk assessments at all. For impact assessments, the interviews suggest that the agencies weigh policy alternatives or consider the costs and benefits in a practical and less structured manner. Regarding public participation, there is no legal mandate for public notice and comment. However, in practice, the federal agencies such as the National Health Authority are adopting a consultative and participatory approach to health data policy formulation.

a. Documentary analysis

i. Acknowledging risks and uncertainties

The law and policy-making process do not mandate the department/agency to assess the risks of the proposed law/policy. However, the select laws/policies analyzed here have several provisions dealing with data security and privacy protection as well as provisions related to risk assessment and management. For example, the ABDM Data Privacy policy sets minimum standards of data protection and information security principles in collecting, using, and processing personal data.¹²⁷ The ABDM Health Data Management Policy requires the data fiduciaries¹²⁸ to implement specified security standards;¹²⁹ conduct data protection impact assessment,¹³⁰ and implement personal data breach and incident management processes.¹³¹ The policy acknowledges security and privacy by design as a guiding principle.¹³²

¹²⁷ See, Data Privacy Policy, supra note, 125, Para 2.

¹²⁸ See, Health Data Management Policy, supra note, 124, Para 4 (g). ("Data fiduciary" means any person, including the State, a company, any juristic entity or any individual who alone, or in conjunction with others, determines the purpose and means of processing of personal data. For the purpose of this Policy, data fiduciaries to include Health Information Providers and Health Information Users if such entities are determining the purpose and means of processing of personal data).

¹²⁹ Id. Para 27.1 (d).

¹³⁰ *Id.* Para 27.3 (a) and (b).

¹³¹ *Id.* Para 33.1.

¹³² Id. Para 26.3.

The ABDM strategy document provides for building security based on the principle of zero trust architecture;¹³³ recognizing specific risks to be overcome while implementing and operationalizing ABDM;¹³⁴ specifying standards for risk management,¹³⁵ and establishing a security and privacy operations center for security surveillance and compliance of privacy requirements.¹³⁶

Similarly, the Personal Data Protection Bill 2019 has several provisions recognizing the risks and uncertainties of personal data, such as categorizing personal data as sensitive personal data based on several factors including the potential risk of significant harm to the data principal;¹³⁷ requiring data fiduciaries to prepare privacy by design policy;¹³⁸ implementing security safeguards based on the risks and severity of likely harm associated with personal data processing;¹³⁹ reporting of personal data breaches;¹⁴⁰ classifying data fiduciaries as significant data fiduciaries based on factors including the sensitivity of personal data and the risk of harm by processing such data;¹⁴¹ conducting data protection impact assessment by the significant data fiduciaries including assessment of potential harm and measures to mitigate such risk of harm.¹⁴²

ii. Broader and fuller impact assessment

The federal government's pre-legislative consultation policy of 2014 has provisions regarding impact assessment. It requires the concerned department/Ministry to publish the proposed legislation's financial implications, its impact on the environment, and the fundamental rights of the affected people, and their livelihoods. However, this policy is not binding on the departments/Ministries.

¹³³ See, ABDM Strategy overview, supra note, 123, Para 3.4.1.

¹³⁴ Id. Para 3.10.1.

¹³⁵ Id. Para 3.10.1.

¹³⁶ Id. Para 3.8.6.

¹³⁷ See, the Bill, supra note, 126, clause 15 (1). Also, see, clause 3 (14) ("data principal" means the natural person to whom the personal data relates)

¹³⁸ *Id.* Clause 22 (1).

¹³⁹ *Id.* Clause 24 (1).

¹⁴⁰ Id. Clause 25 (1).

¹⁴¹ Id. Clause 26 (1).

¹⁴² *Id.* Clause 27 (1).

¹⁴³ Pre-Legislative Consultation Policy (PLCP). Para 2. (February 2014). Ministry of Law & Justice, Government of India.

The inter-ministerial consultation is another avenue for assessing various aspects of the law/policy under consideration. In government, the concerned department/ Ministry initiates the legislative proposal and considers its implications from various aspects such as economic, political, social, administrative, and financial. It consults other departments and experts and prepares a self-contained memorandum which is cleared by the Ministry of Law before it reaches the Cabinet. The Cabinet generally discusses the broad aspects of the policy underlying the proposal and gives its decision.

Similarly, the legislative committees have an important role in assessing different aspects of the legislative proposal in the form of a bill. Once the Cabinet approves the memorandum, it is drafted as a bill and introduced in either of the two houses of the Parliament- Rajya Sabha (Council of States) and Lok Sabha (House of People). The Chairperson/ Speaker of the house may refer the bill to the standing committees such as the department-related Parliamentary standing committees (DRSCs). In addition, there are ad-hoc committees that are constituted for a specific purpose, such as the select committees and the joint committees. These committees examine the bill clause by clause and submit a detailed report. However, not every bill is referred to the legislative committees and many bills become laws without review by the committees.

The select health data laws/policies examined here have a few provisions indicating consideration of multiple aspects in policy-making. For example, India's National Health Policy 2017 mentions key policy principles to be considered in policymaking such as equity, affordability, universality, decentralization, and adaptiveness among others. Other provisions include conducting health impact assessments of existing and new policies of non-health departments that impact health directly or indirectly; prioritizing the inclusion of cost-benefit and cost-effectiveness studies in program design and evaluation; extending the scope of health and demographic surveys to collect information on costs of care, financial protection, and evidence-based policy planning and

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¹⁴⁴ Parliament of India. Rajya Sabha. (July 2020). The Law Making Process at 5.

¹⁴⁵ Cabinet is a key body within the council of Ministers at the federal level.

¹⁴⁶ See, Parliament of India, supra note 144, at 10. Also see, Rule 270 (b) and 273 (There are 24 DRSCs, of which 8 are under Rajya Sabha and 16 are under Lok Sabha. These committees generally have 3 months to examine the bill and submit report.)

¹⁴⁷ *Id.* at 11.

¹⁴⁸ See, NHP 2017, supra note 122, Para 2.2.

¹⁴⁹ *Id.* Para 3.2.

¹⁵⁰ *Id.* Para 12.

reforms;¹⁵¹ assessing health technology based on scientific evidence, safety, cost, and social values.¹⁵²

iii. Public Participation

In India's lawmaking, there is no legal mandate for pre-legislative public participation. It's based on the assumption that people's interests are voiced by their chosen elected representatives.¹⁵³

Several provisions of the pre-legislative consultation policy 2014 aim to increase the transparency of legislative proposals and improve public participation. For example, it requires the department/ Ministry to publish draft legislation for at least 30 days, ¹⁵⁴ publish an explanatory note with details of key legal provisions in a simple language, ¹⁵⁵ publish a summary of public feedback and comments on its official website, ¹⁵⁶ and hold additional stakeholder consultations when required. ¹⁵⁷ However, these provisions are not binding on the departments/ Ministries.

Also, for the legislative committees, it is not mandatory to consult members of the public. For example, the department-related Parliamentary standing committees may circulate the bill for eliciting public opinion. Similarly, the select committees and the joint committees also may hold stakeholder consultations and take evidence from the public bodies, experts, and relevant associations.

In the select legal documents examined here, there is evidence of stakeholder engagement and public participation. For example, the joint-Parliamentary committee on the Personal data protection bill held multiple hearings of stakeholders from the government and the

152 Id. Para 23.

¹⁵¹ Id. Para 24.

¹⁵³ Jain, Dipika. (2020). Law-Making by and for the People: A Case for Pre-legislative Processes in India. Statute Law Review. Vol. 41, No. 2, 189–206.

¹⁵⁴ See, PLCP, supra note 143, Para 2.

 $^{^{155}}$ Id. Para 5.

 $^{^{156}}$ Id. Para 6.

 $^{^{157}}$ Id. Para 7.

¹⁵⁸ See, Parliament of India, supra note 144 at 11. Also, see Rule 69.

¹⁵⁹ *Id*.

Key points:

- In India, the law and policymaking process does not formally acknowledge the need to consider and assess the risks. The analyzed health data laws/ polices have several provisions acknowledging the risks of health data, data security, and privacy protection.
- The federal government's pre-legislative consultation policy requires impact assessment of proposed regulations, but this policy does not have a legal backing, hence not mandatory. In the analyzed health data laws/ polices, there are very few provisions reflecting broader impact assessments.
- The legislative committees play an important role in assessing different aspects of the legislative proposal (bill). However, such committees are not constituted for every proposed law and many bills become laws without scrutiny by the legislative committees. In data protection, a joint- Parliamentary standing committee has been constituted to review the Personal Data Protection Bill 2019.
- Public consultation in law and policymaking is not a mandatory legal requirement.
 This practice is based on the assumption that people's interests are voiced by their chosen elected representatives.

private sector. ¹⁶⁰ Another example is the National Health Agency (NHA) which is adopting a collaborative and participatory process of policymaking. NHA introduced the practice of developing consultation papers and updating their different versions before beginning to draft the policy. Public comments are invited on such consultation papers.

b. Interview Analysis

i. Acknowledging risks and uncertainties

The interview analysis suggests a mixed trend with participants sharing three broad viewsthe policymakers adopting a risk-based approach, conducting an informal risk assessment, and not conducting any risk assessment.

• The risk-based approach in policymaking

Participant A- The participant shared that the government spends a lot of time on both risks as well as opportunity assessments.

¹⁶⁰ For details, *see*, Parliament of India. Lok Sabha (House of the People). Joint Committee on the Personal Data Protection Bill, 2019 (Tab 'sittings'). Available at

Participant E- The participant shared that the associated risks are acknowledged and addressed while formulating health data policies. For example, in the drafts of two policy papers on information security, all the risks were listed and discussed. And to address the identified risks, the agency tried to arrive at two broad types of solutions-technology/design-based and law-based.

Participant F- The participant shared that in the emerging technologies space, the policymakers are cognizant of the risks and are adopting a risk-based approach for striking the right balance, and ensuring that the regulatory interventions are proportionate. They differentiate the AI applications by assessment framework and classify them as high, medium, or low risk. This assessment is communicated to the stakeholders who are developing the solutions and they can test their technologies in a sandbox. For example, in NDHM, the sandbox is a regulatory tool to evaluate the risks of emerging technologies.

Participant F said — ["If there is a risk around data which is anonymized then you run it through them (sandbox) and try to see if there is a possibility of being able to de-anonymize the data.."].

• Less formal/ explicit acknowledgment or assessment of risks

Participant B- The participant shared that she is not sure about a formal process of risk assessment. However, in the non-personal data committee, in-depth deliberations were held to understand what should be the right approach for India. The committee members discussed the subject matter with representatives of different countries to understand their experience as well as with the industry to understand the pros and cons (of policy choices).

Participant D- The participant shared that the risk assessment may not be very explicit or formal. However, a diversity of perspectives are included in the policy draft which is generally drafted by the agency staff or consultants working for the agency. Then, it is typically shared with the experts for their review, followed by public consultation.

• No risk assessment

Participant C- The participant shared that general policymaking follows one of the two directions, either encouraging something or restricting something. Strategic risk assessment is not seen in the Indian policy space.

Participant C said — ["the word risk is generally not I think, part of the traditional vocabulary of a policymaker.."]

Participant G- The participant shared that he has not come across any information on risk assessment in policymaking.

Participant G said — ["Yeah, under NDHM- the mission is to collect individualized data for everything from everyone. To me, it's a very scary thought, given the lack of protection or lack of awareness about how to deal with personal data"].

Participant H- The participant shared that risk is not understood well in the regulatory/policy space. In policymaking, there is a need of having inputs not only from the regulatory side but also from technology and business perspectives, which is tricky.

Participant H said — ["I think risk is very poorly understood as of now because for understanding the risk, you need to also be able to understand the speed at which technology is moving"].

ii. Broader and fuller impact assessment

The interview analysis suggests that the formal impact assessments are limitedly conducted in the policy space. There are other ways in which policy options are assessed such as considering international best practices, consulting experts on the best available science, and weighing the costs and benefits though in a less formal way. However, some participants shared that weighing policy alternatives, conducting cost-benefit analysis, and considering science, are subjective and limited phenomena in policymaking. Regarding public participation, most participants shared that public participation, in particular, stakeholder engagement has increased over time. However, the participants expressed concern about transparency due to the lack of department/agency's response to public comments.

• International best practices

Participant A- The participant shared the example of the non-personal data committee which discussed the data policy choices with representatives of different countries to understand what they are doing and what could be the right approach for India.

Participant E- The participant shared that while drafting the consultation papers, the department/agency studies systems of multiple countries and draws from the available information. For example, what are the different ways adopted to classify health data, how long the countries are retaining their health data, etc.

• Weighing different alternatives

Participant C- The participant shared that the practice of considering different policy alternatives is driven by an individual policymaker and is not a part of the system.

Participant C said — ["I've seen both so many times, I think if there is significant pressure from the market for a reaction, I think policies are made very rapidly without necessarily weighing in on the various options. Whereas when the pressure is not there, it is quite strategic"].

Participant G - Echoing a similar view, the participant said — ["I think it is really driven by the whims and fancies of the decision-maker"].

Participant A- The participant shared not having the experience of seeing such a practice in the government.

Participant A said — ["I'm sure they do. Maybe it's not visible to us. I don't think that's visible to us"].

Participant E- The participant shared that the department through consultation papers frames the key issues of the policy and tests various options by listing the pros and cons of information available. And based on the feedback, a policy is formulated.

Participant E said — ["This has been a very helpful approach because (the agency comes) to know about many, many factors which otherwise probably could have missed"].

Participant F- The participant shared that in the context of policymaking in AI, the government considers different alternatives. For example, various options are weighed for investing public money in AI– should it be into research or data or compute or scaling? And while the policy takes shape, there is a great amount of consensus-building involved in the exercise.

Participant F said — ["we look at different alternatives which are available to us and we are trying to sift through the wisdom which is available and say where is the most efficient utilization of government finances that can be derived"].

Science and policy

Participant F- The participant shared that the policymakers are trying to leverage and learn from research and advocacy across academia, industry, and civil society. The policymaker's job is to harmonize the diverse interests of stakeholders and ensure that the best available knowledge and science are incorporated into the policy designs.

Participant F said — [".. with AI, there is a huge amount of opportunity for efficiencies. To be honest, most of the knowledge lies outside the government. So you bring that knowledge, incorporate it, utilize it, and make it a part of the law and policymaking"].

Participant I- The participant shared the example of COVID showing how government policymaking is not based on science. He compared how the schools were open in the western countries, whereas, the schools in India were still closed and the students were studying from home for a very long time post-COVID.

Participant I said — ["scientific bodies are clear, including WHO that kids are suffering the most due to the pandemic, because their social networks are getting cut, and you know, their overall development is contingent on their social networks. And the (Indian) government is simply not talking about (it)"].

• Cost-benefit

Participant B- The participant shared that cost-benefit analysis is a predominant factor in policymaking, however, it is more practical and intuitive, not necessarily something documented on paper.

Participant B said — ["the broader policymaking is potentially done on the qualitative, more on the long-term thinking of the opportunity at the end of the tunnel, and the more (anticipated) policy hindrances require a more detailed, you know, going through the numbers and details"].

Participant D- The participant shared that in her experience the policy subcommittees' discussions on cost-benefit analysis necessarily come down to the budget.

Participant D said — ["(Regarding AI) how do we justify spending money for an outcome that's defined 10 years down the line, 20 years down the line. And it's not responding to a certain challenge in the present"].

iii. Public Participation

Interview analysis suggests that public participation has increased in the policymaking process with more experts, stakeholders, and the public sharing their views and participating in policy consultations.

• General public participation-Low

Participant C- The participant shared that the general public does not participate however, certain interest groups actively participate.

Participant I- The participant shared that there is low public participation primarily because people are not necessarily interested to give feedback.

Participant I said — ["I think the problem is that the public participation in India is not up to the mark, the civic responsibility that we take is probably much on the lower side when compared to what you see in the West"].

• Stakeholder participation- increasing

Participant A- The government's approach to policymaking is very consultative. The policy is not considered anymore, only the domain of government because technology is changing so fast. The participant shared that in general every technology-related policy is put out for industry feedback and around three to four months are given.

Participant A said — ["I would say the appetite to listen and especially listen to criticism or you know what needs to change or improve (in the policy) is definitely there. We've had some pretty brutally honest conversations on what needs to change"].

Participant B- The participant shared that in policy-making, the government is reaching out to multiple stakeholders, there is a lot more inclusion because technology is touching everybody.

Participant B said — ["In the past, at least from a tech perspective, it was largely associations and companies that would give in submissions. Today, they're reaching out to civil society groups"].

Participant C- The participant shared several interest groups are advocating the privacy-related issues of health data. These are generally individual lawyers, developmental agencies like the World Bank, WHO, as well as the industry/vendor lobby. However, the participant shared that there is not much involvement of the academicians.

Participant D- The participant shared that there is a high degree of public consultation in technology-related policies as well as expert consultation. However, the lobbyists influence the policy discussions tremendously.

Participant D said — ["But ultimately, as with any policy decisions, you're going to be heavily lobbied and influenced by solutions that have worked with the past and voices that have tested the time-invested perspectives in the past. So, I think that is a big question"].

Participant E- The participant shared that the department/agency is adopting an extensive consultation process of stakeholder engagement in a phased manner. For example, the agency consults experts, people of the industry, academicians, officers of the state governments, and lawyers in the federal government. In stakeholders, such as doctors, the government covers a wide spectrum- engaging consultants from big super-specialty hospitals as well as the doctors practicing in a small rural village.

Participant F- The participant shared that in the non-personal data, the government adopted a policy paper approach in which an industry-led body prepared the draft policy by researching the demand and supply side of data.

• Access

Most participants shared that access to draft law and policy documents is not a problem. The drafts are available on various platforms including the ministry's official website and sometimes on other platforms like my.gov, press releases in the newspapers, as well as posts on social media.

• Transparency- feedback on public comments

Participant A- The participant shared that there is no established process for responding to public feedback. An individual providing feedback may not know what happened to his/her feedback.

Participant B- The participant shared that with the size and scale of India, it may not be possible for the government to respond to a hundred thousand queries.

Participant H- Echoing a similar view, the participant said — ["the data-driven policy feedback, you cannot take feedback from 1.36 billion people, it's very, very hard. We don't have systems to do that"].

Participant G- The participant expressed concern about the agency's lack of response to public comments.

Participant G said — ["it's very strict, typically sort of black box. So, this idea of public consultation by putting the document out on a website, I think, is, to me, it is more going

through the motions, and you know, that you can say that you've done this, but how much does it actually get taken up in spirit? I think is limited".

Participant E- The participant shared that it is difficult for the public to understand the policy related to health data. There is a challenge in explaining the jargon in plain language.

Participant E said — ["unlike let us say, an easy to understand policy, like a wage employment scheme or a policy of housing, this is a fairly complex topic that we are dealing with"].

Participant F - The participant shared that it is challenging to respond to every comment due to time and other constraints. And this also varies from Ministry to Ministry. To that extent, there is no mechanism where an email of acknowledgment is sent apart from the portal (my gov) notification a person gets that his/her comment has been recorded. Thus, there is a need to improve the public engagement process.

Key points:

- Formal risk assessment and impact assessment are not part of the law/policy-making. These processes could be subjective and based on the legislative committee's discretion or a policymaker's choice.
- Participants views range from the government adopting a risk-based approach, conducting less formal risk assessments, to conducting no-risk assessments.
- Similarly, there are mixed views on the government agencies' weighing policy alternatives, considering science, and conducting cost-benefit analysis.
- Participants shared that public participation, in particular the stakeholder engagement has increased over time. However, most participants expressed concern on transparency due to lack of a mechanism for providing response to public comments.

2. Implementation

In the implementation stage, the adaptive regulatory cycle emphasizes the need for relevant data collection and effective monitoring and evaluation (M&E) mechanisms to gauge policy performance. The documentary analysis suggests that there are several policy provisions related to maintaining records, third-party auditing, periodic reporting, monitoring, and compliance as well as a few examples of public consultation/participation. The interview analysis suggests that there are several ways in which

monitoring and evaluation of policies/schemes take place in the government such as by staff within the department/ agency and by the external agencies. However, the participants shared that there are gaps such as lack of transparency in the monitoring processes and a lack of availability of data in public domain.

- a. Documentary analysis
- i. Monitoring, evaluation, and feedback
- Data- collection and reporting

ABDM Health Data Management Policy 2020 has several provisions for reporting, maintaining records, and auditing. For example, the data fiduciaries are required to certify or audit the standards related to security practices at least once a year;¹⁶¹ notify incidents of the personal data breach;¹⁶² maintain updated records of personal data lifecycle including collection, transfer, and erasure;¹⁶³ periodically review the security safeguards;¹⁶⁴ maintain an audit trail of all personal data processing activities;¹⁶⁵ and ensure that the data processors conduct the third-party audits periodically¹⁶⁶ Similarly, the health information users are required to maintain record of all personal data disclosed to another entity, in a format that enables audit and review.¹⁶⁷ The data protection officer is authorized to ensure compliance with the statutory requirements.¹⁶⁸

The ABDM strategy document provides for developing a health data analytics platform based on the aggregated data from all health information providers¹⁶⁹ and using advanced analytic tools to generate a variety of reports useful for policymakers and the public in general.¹⁷⁰

163 *Id.* Para 27.4 (a).

¹⁶¹ See, Health Data Management Policy, supra note, 124, Para 27.1 (e).

¹⁶² Id. Para 33.2

¹⁶⁴ *Id.* Para 27.1 (c).

¹⁶⁵ *Id.* Para 27.5 (a).

¹⁶⁶ *Id.* Para 27.5 (b).

¹⁶⁷ *Id.* Para 30.4 (a) and (b).

¹⁶⁸ *Id.* Para 34.1

¹⁶⁹ See, ABDM Strategy overview, supra note, 123, Para 2.6.2.

¹⁷⁰ *Id.* Para 2.6.3.

• Monitoring and compliance

Data Monitoring and Evaluation Office (DMEO) is a federal office in NITI Aayog, India's apex public policy think tank. DMEO developed a 'Data Governance Quality Index' based on six parameters: data generation; data quality; use of technology; data analysis, use, and dissemination; data security and HR capacity; and case studies.¹⁷¹ This index is used to assess the data preparedness of the ministries/departments in a standardized way.

Additionally, using the output-outcome monitoring framework, the DMEO along with the concerned department created nearly 5,000 output and outcome indicators for around 500 schemes of the government of India including health sector schemes. DMEO along with the respective department monitors and quarterly tracks the progress, collects scheme performance data, and facilitates review meetings.¹⁷²

The state health index is another way of assessing the performance of the states and union territories (UTs). It is an annual evaluation tool and a weighted composite index based on 24 indicators. This index is being published since 2017 and has been instrumental in shifting the focus of the States/UTs from inputs and budget spending to outputs and outcomes.¹⁷³

For M&E capacity building in government departments/agencies, the DMEO has partnered with academic institutions for building M&E resources, organizing M&E workshops, and conducting evaluation studies. DMEO has signed statements of intent with many academic and research institutions.¹⁷⁴ Further, in consultation with key knowledge partners, the DMEO prepared an M&E curriculum and competency framework for the government officials. Knowledge partners included the World Food Programme (WFP), United Nations Children's Fund (UNICEF), Abdul Latif Jameel Poverty Action Lab (J-PAL), and others.¹⁷⁵

¹⁷¹ Data Monitoring and Evaluation Office (DMEO). NITI Aayog. Overview: Data Governance Quality Index. Available at https://dmeo.gov.in/content/dgqi-overview#.

¹⁷² NITI Aayog. Annual Report 2021-22, at 30.

¹⁷³ *Id.* at 44.

¹⁷⁴ *Id.* at 34. (Institutes include Asia-Pacific Evaluation Association, the Institute for Competitiveness, Bill and Melinda Gates Foundation (BMGF), Tata Institute of Social Sciences, the National Council of Applied Economic Research (NCAER), Atal Bihari Vajpayee Institute of Good Governance and Policy Analysis, and Grassroots Research and Advocacy Movement -GRAAM).

¹⁷⁵ *Id.*

In the select laws/policies examined here, there are many provisions for monitoring and compliance. For example, the ABDM strategy document provides for geography and demography-based monitoring to help inform health policies and programs;¹⁷⁶ measuring and displaying performance and accountability of all health institutions against agreed key performance indicators (KPIs);¹⁷⁷ monitoring and regulating the protection of personal health records against unauthorized access or use by any entity;¹⁷⁸ monitoring each state's performance at the level of mission steering group;¹⁷⁹ including state's progress in NDHM implementation as a factor in the state health index;¹⁸⁰ setting up a national-level system to recognize the best performing stakeholders;¹⁸¹ establishing security and privacy operations center for security surveillance and monitoring compliance of privacy requirements,¹⁸² and evaluating compliance of all legacy systems with ABDM guidelines through appropriately designed assessment tools. ¹⁸³

The Personal Data Protection Bill 2019 requires significant data fiduciaries as well as the State to maintain up-to-date records of - all operations in the data life cycle, periodic review of security safeguards, and data protection impact assessments.¹⁸⁴ Other examples include the independent data auditors annually auditing the data fiduciary's compliance with statutory provisions;¹⁸⁵ and data fiduciaries reporting the personal data breaches to the appropriate authority.¹⁸⁶ Similarly, the bill provides for the data protection authority of India to register qualified persons as data auditors under the Act,¹⁸⁷ to submit returns and statements including a statement on enforcement action taken to the federal government;¹⁸⁸ and to table the annual report on authority's activities before each House of the Parliament.¹⁸⁹

¹⁷⁶ See, ABDM Strategy overview, supra note, 123, Para 1.5.4.

¹⁷⁷ Id. Para 1.6.2 (5).

¹⁷⁸ Id. Para 2.2.9 (4).

¹⁷⁹ Id. Para 3.2.5.2 (f).

¹⁸⁰ Id. Para 3.2.5.2 (g).

¹⁸¹ *Id.* Para 3.2.5.2 (j).

¹⁸² *Id.* Para 3.8.6.

¹⁸³ *Id.* Para 1.6.3 (5). (assessed through an appropriately designed assessment tool to evaluate the current conformance and effort required to integrate them with NDHM).

¹⁸⁴ See, the Bill, supra note, 126, clause 28 (1) and (2).

¹⁸⁵ Id. Clause 29 (1) and (2).

¹⁸⁶ *Id.* Clause 25 (1).

¹⁸⁷ *Id.* Clause 29 (4).

¹⁸⁸ *Id.* Clause 81 (1).

¹⁸⁹ Id. Clause 81 (2) and (3).

ii. Public Participation

Public participation includes consultation and meaningful engagement in law and policymaking process, as well as enhancing participatory capacity of people. In India, the Right to Information Act plays an important role in enhancing the participatory capacity of the people. The Right to Information Act 2005 is a federal Act providing the right to citizens to access information from the government.¹⁹⁰

In the law/policy documents analyzed here, there are a few examples where public participation is required in implementing the legal/policy provisions. For example, the Personal Data Protection Bill 2019 requires the Data protection authority of India to issue codes of practice for promoting good practices of data protection and complying with the Act's provisions. Before issuing such codes of practice, the authority must consult the stakeholders including the public.¹⁹¹ Similarly, the ABDM strategy document emphasizes stakeholder engagement and inputs during the conceptualization, development, and rollout of the mission.¹⁹²

Key points:

- The analyzed law/policy documents have several provisions related to maintaining data records by the data fiduciaries/ data processors, as well as by the state agencies.
- There are provisions of periodic reporting, reviewing the security safeguards, and third-party auditing.
- The law/policies provide for registering the data auditors, appointing the data protection officers, and establishing the authorities such as the Data protection authority of India for monitoring statutory compliance.
- There are limited examples of public participation/ stakeholder engagement in implementing the law/policy provisions.

b. Interview Analysis

i. Monitoring, evaluation, and feedback

The interview analysis suggests that there are several ways in which monitoring and evaluation of policies/schemes take place in the government, such as through a department's internal monitoring process, through an independent agency such as

¹⁹⁰ Department of Personnel & Training. Government of India. About Right to Information Act 2005. Available at https://rti.gov.in/.

¹⁹¹ See, the Bill, supra note, 126, clause 50 (1) and (4).

¹⁹² See, ABDM Strategy overview, supra note, 123, Para 3.6.1.

DMEO's output-outcome monitoring framework, as well as through stakeholders' feedback. However, the participants shared several gaps such as not planning relevant data collection for monitoring, not adequately using the available data to inform policies, and the lack of availability of data in public domain.

Monitoring and feedback

Participant A- The participant shared that the government is interested in knowing how a particular policy works once implemented. In this, the stakeholders such as industry associations play an important role in doing the impact analysis and giving feedback to the government. Though there is no formal process, such feedback results in further changes in the law and policy. The participant shared a recent example of the Ministry of Communications revising its guidelines for other service providers (OSPs) and allowing work from home/ work from anywhere due to the COVID-19 impact. In this policy change, industry feedback played a crucial role.

Participant B- The participant shared that generally, the policies with timelines and interim deliverables are monitored by the government agencies/departments. Whereas, the policies which are one-time announcements and without specific timelines are not monitored. In such policies, only if the stakeholders face issues, they will share feedback.

Participant C- The participant shared that the National Health Authority is including many elements of monitoring and evaluation in its policies. He further shared that generally, feedback from four sources results in a department/agency action - if there is a news article from a credible or powerful media house, a TV talk, an influential person's tweet, or a parliamentary question related to the policy.

Participant F- The participant shared that the most significant and concurrent evaluation is done by NITI and its Data Monitoring and Evaluation Office (DMEO).

Participant G- The participant shared that there is very little constructive feedback in the government. He gave the example of a health scheme called the 'Mother and Child Tracking System' which had state-wise and district-wise targets of registering pregnant

mothers. If the targets were not achieved, there were reprimands and salary cuts for the field workers.

Participant G said — ["I think the whole culture in (the) government is feedback in terms of reprimand"].

• Data availability and use to inform future policies

Participant F- The participant shared that the DMEO has devised an output outcome monitoring framework (OOMF) which has the key performance indicators (KPIs) and key performance areas (KPAs) decided by the departments. Every department fills the KPIs and KPAs quarterly. Thereafter, the DMEO does the concurrent evaluation of these datasets from OOMF and shares its analysis with the departments to frame the expectations and the future course of policy interventions.

Participant E- The participant shared the example of the 'Health benefits package' (in health insurance) where based on evidence, the agency revised the rates upwards. The participant further shared that the agency is considering formula-based inflation linked rates for various types of procedures so that the rates remain dynamic.

Participant G- The participant shared that COVID is an example where the policymakers were using evidence actively in policy formulation and its revisions.

Participant G said — ["I do think the COVID may be a game-changer in that way to try to link information and action"].

Participant C – The participant shared that many times, the decision-making is not evidence-based. However, he shared the example of a health insurance scheme for economically disadvantaged families called 'Ayushman Bharat' where dashboards with clear metrics were used, and over time, some of the new policies were based on the experience gained from this scheme and its data.

• Data availability and use- Gaps

Participant I – The participant shared that non-availability of healthcare data is a major concern. Its repercussion is the emergence of a market of fake data leading to a lot of speculation and fake research about the country.

Participant I said — ["most of us actually run to the World Bank website for getting data on healthcare sector in India, I mean, as to why the government could not be collecting data and disseminating it for (the) public is a mystery to me"].

Further, the participant shared that the researchers are not able to evaluate a law or policy because the government has all the data and the researchers have no way to figure out if the data collection is right.

Participant I said — ["one of the most fundamental aspects of research (is) replicability. Can you replicate the impact evaluation that you're actually seeing in policy circles? Not so much"].

Participant G- The participant shared that in the government, the volume of data collection is exponentially increasing with a lot of redundancy but the information is not being put to sensible use.

Participant G said — ["we are exponentially increasing the data being collected and moving from districts to blocks to, to sub-centers to individuals and households, I think without a clear plan for what they want the data for"].

Further, the participant shared that typically the collected information is rarely public-facing. It goes into the black box of bureaucracy and the Ministry of Health does not have public health experts who can discern the value of such data.

Participant C – The participant shared that the metrics are not set when the policy is designed. The monitoring and evaluation is usually thought later, thus, limiting the collection of relevant data as well as its quality.

Participant C said — ["Most of the data that any policymaker seeks, ultimately starts by saying whether you instrument the data collection for those metrics in that IT system? Because without instrumenting it into the process, you're never going to get the data"].

Participant H- The participant shared that Indian policymaking is very pragmatic but not necessarily driven by data.

Participant H said — ["And it is hard designing a policy without having the data coming in which they are at present. It's an art, I would say it's an art. It's not a science yet, hopefully, five, six years down the line, it might become science"].

Capacities

Participants did not express much of a concern about the capacities as the government agencies are hiring people with required skills.

Participant C – There is clarity in the agency about its role of monitoring and evaluation, and the agency hires the necessary staff.

Participant E - The participant shared that the department can hire skilled people from other government agencies or the industry.

Key points:

- Monitoring and evaluation of policies/schemes takes place in many ways such as based on a department/agency's internal monitoring process, through an independent agency such as DMEO's output-outcome monitoring, and through the stakeholders' feedback on policy performance.
- Participants shared a few examples where the monitoring, evaluation, and feedback are informing future policies or revisions.
- Participants also shared the lack of planned data collection for monitoring and the lack of availability of data in public domain; the latter limiting the ability to validate the claims of government on policy impact.
- A few participants noted that policymaking in India is largely pragmatic and not evidence-based.

3. Post-Implementation

The documentary analysis suggests that the select law/policy documents have many provisions of iterative decision-making, such as acknowledging new and emerging

technologies, changing the policy on a need basis, conducting periodic reviews, establishing regulatory sandboxes, implementing policies based on agile methodology, and revising the draft policy documents based on feedback. The interview analysis suggests that the health data policies are being formulated with a flexible approach. Also, the government agencies are becoming open to the idea of experimenting before rolling out a policy and creating regulatory sandboxes for testing new technologies. However, such experimentation and processes are not institutionalized yet.

a. Documentary Analysis

i. Iterative decision-making and policy adjustment

Acknowledging change

The analyzed law/policy documents have a few provisions acknowledging change such as the ABDM Health Data Management Policy recognizes that the policy is dynamic and may be revised from time to time as needed;¹⁹³ and that the specific details of governance structures may be stipulated from time to time.¹⁹⁴ The Personal Data Protection Bill 2019 authorizes the federal government to make provisions as may be necessary for removing any difficulty in implementing the Act within five years from the Act's commencement.¹⁹⁵ The ABDM strategy document acknowledges the need to leverage emerging technologies such as AI, and Blockchain, for increasing equitable access to health services;¹⁹⁶ and including user-generated data such as from IoT and wearables in the design of the federated health record ecosystem.¹⁹⁷

• Review

The ABDM Health Data Management Policy requires a data fiduciary to periodically review its security safeguards. 198 It requires the NDHM officials to periodically review the

¹⁹⁵ See, the Bill, supra note, 126, clause 97(1).

¹⁹³ See, Health Data Management Policy, supra note, 124, Para 1.

¹⁹⁴ *Id.* Para 6.

¹⁹⁶ See, ABDM Strategy overview, supra note, 123, Para 1.4.3

¹⁹⁷ *Id.* Para 2.2.8 (1) h.

¹⁹⁸ See, Health Data Management Policy, supra note, 124, Para 27.1 (c).

security safeguards and update such safeguards as needed, and periodically review the technical processes and anonymization protocols.²⁰⁰

The ABDM strategy document mentions the ABDM implementation to be based on Agile methodology with a minimalist and iterative approach followed by continuous evaluation and improvement.²⁰¹

The Personal Data Protection Bill 2019 requires the data fiduciaries and data processors to periodically review their security safeguards, 202 the federal government to periodically review its findings on the transfer of sensitive personal data and critical personal data;²⁰³ and the Data Protection Authority of India to review, modify, or revoke its codes of practice.204

The DMEO carries out evaluations of the centrally sponsored schemes to consider if these should be continued. Based on these evaluations and studies, DMEO creates a 'compendium of best practices,' and shares it with the states. To enable rapid assessment of a new scheme/ policy and to provide quick feedback to decision-makers for making changes and mid-course corrections, the office has developed a toolkit for conducting quick assessment studies. To provide input on the scheme's strengths and limitations, and recommend interventions for required course corrections, the office prepares performance notes of government schemes. These are based on desk review, key informant interviews, and using secondary sources.²⁰⁵

To improve evidence-based interventions, all schemes of the government of India are mandated to undergo third-party evaluations from 2021-22 to 2025-26.²⁰⁶

²⁰⁰ *Id.* Para 29.6.

¹⁹⁹ Id. Para 27.1 (f).

²⁰¹ See, ABDM Strategy overview, supra note, 123, Para 3.3.1. Also, see, Ministry of Electronics and Information Technology Government of India. (2019). Agile IndEA- Vision, Velocity, at 17, 19, and 21.

²⁰² See, the Bill, *supra* note, 126, clause 24 (2).

²⁰³ *Id.* Clause 34 (b)

²⁰⁴ Id. Clause 50 (7).

²⁰⁵ See, NITI, supra note, 172. Annual report 2020-21. Also, see, DMEO. Overview. Available at https://dmeo.gov.in/content/overview-0.

²⁰⁶ Development Monitoring and Evaluation Office (DMEO). (2021). NITI Aayog, Government of India. Health Sector Report.

• Pilot Programs and Phased-implementation

ABDM sandbox- The ABDM provides for a sandbox to enable the integration of any software system with the digital building blocks and for testing compliance to the digital health standards. Once the software is integrated and tested in the sandbox, it can apply for ABDM compliance certification.²⁰⁷

Phased implementation- ABDM has adopted a phased implementation methodology to implement the mission in three phases -gradually increasing the geographical coverage area and the services offered.²⁰⁸ Further, the mission document specifies that initially the ABDM will be implemented by the national health authority (NHA), however, based on the learnings of phase-1, a suitable model for implementing the mission will be selected.²⁰⁹ The Personal Data Protection Bill 2019 also provides for creating a sandbox to encourage innovation in emerging technologies.²¹⁰

• Revising laws, policies, and guidelines

There are examples where despite no specific provision in the policy to revise the policy/guidelines, the same are revised over time. For example, the National Health Policy has been revised two times.²¹¹

Considering the dynamic nature of regulating health data, the National Health Authority (NHA) has introduced the practice of developing consultation papers and updating their versions before beginning to draft a policy. Even the draft policies are updated as separate versions. This practice is new and not followed in most of the ministries/ departments.

²⁰⁷ National Digital Health Mission. Guidelines for Health Information Providers, Health Repository Providers, Health Information Users and Health Lockers. August 2020. P-2.

²⁰⁸ See, ABDM Strategy overview, *supra* note, 123, Para 3.2.1. (Phase -I was a pilot stage where certain services were test implemented in six union territories. After this, in phase-II, the mission was to be implemented in additional states by expanding the services, and in phase-III, a national rollout was planned. For details see, Chaper-3- Implementation Arrangement pp-16-23)

²⁰⁹ *Id.* Para 3.9.4.

²¹⁰ See, the Bill, *supra* note, 126, clause 40 (1).

²¹¹ See, NHP 2017, supra note 122, Para 1.

Key points:

- The analyzed law/policy documents have provisions acknowledging change in the future, recognizing the emerging technologies, and adopting 'agile' processes which are iterative in nature.
- There are provisions of periodically reviewing the health data safety standards and protocols.
- The law/policies provide for regulatory sandboxes to test new technologies and to encourage innovation.
- The National Health Authority has started a participatory process of developing consultation papers and updating their versions before beginning to draft a policy. Even the draft policies are updated as separate versions.

b. Interview Analysis

i. Iterative Decision-making and Policy adjustment

The interview analysis suggests that the recent health data policies are being formulated with a flexible approach and acknowledging the need to change the policy from time to time. Also, the government agencies are becoming open to the idea of experimenting before rolling out a policy and creating regulatory sandboxes. However, such experimentation and processes are not institutionalized.

• Review

Participant C – The participant shared that the National Health Authority has realized that the health data policies should allow for evolution. Though NHA is taking decisions today, it acknowledges the need to look back at the same decisions in the future. Therefore, such review provisions are built-in the policies and guidelines, though not in the regulations.

Participant F – The participant shared many examples of schemes in the Ministry of electronics and information technology where mid-term review is generally conducted and based on the recommendations, the changes are incorporated in the subsequent policies. For example, the mid-term review of Capex linked incentive by the National Productivity Council, resulted in policy recommendations on what part of the value chain or the supply chain needs to be incentivized.²¹² The participant shared that the government is considering introducing sunset clauses in public financing for AI.

²¹² Another example is of the mid-term review of the electronic development fund. Based on the review, recommendations were made on the right mix of start-ups to be supported, the stage they should be supported, and how much funding should be put for different stages of development. Another example is

Participant E – In the health data context, the participant shared the example of ISO standards for information security which evolve with time. Similarly, he shared that the International Classification of Diseases (ICD) version 10 is applicable at present and version 11 is coming up. The participant further shared that the NHA is adapting the standards for medical terminologies to the AYUSH system of medicines²¹³ which will be revised from time to time.

Participant G and I- Both participants shared that they have not seen explicit examples of review.

However, participant I shared that, ["COVID policy is probably the best example of adaptive regulation in India"].

• Pilot programs and Phased-implementation

Participant E - The participant shared the example of a health insurance program where the government gave flexibility to the states to choose any of the three models of implementation²¹⁴ based on their administrative capacities and legacy issues. Twice the federal government carried out extensive studies and assessments on the pros and cons of each of the three models and shared information with the states to make choices. Over time, the assessments show that a lot of states switched from the insurance model to the trust model.

Participant F - The participant shared that 10-15 major priority sectors are considered to build public digital platforms and the government is of the view that regulatory sandboxes should be an important ingredient of such digital platforms. He gave the example of the national urban digital mission and urban data exchange building regulatory sandbox to allow solutions to be deployed and tested. Also, in the national language translation

of the mid-term review of the cluster program that provides infrastructure support for large electronic manufacturing clusters in the country.

²¹³ AYUSH is an acronym for Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy - the six Indian systems of medicine practiced in India as well as in a few Asian countries.

²¹⁴ (i) Insurance model - appoint an insurance agency, pay the premium, and let the hospital payments be made by that insurance company. (ii) Trust model- whatever bills are raised by hospitals are directly paid by government through some registered society. (iii) Hybrid model - in which the claim upto a particular limit is through insurance, which helps bring down the premium and beyond that the additional expenditure is done through trust.

mission, the government is looking at building text-to-speech and speech-to-speech conversion facilities, along with a sandbox.

Participant C – The participant shared the example of the phased implementation of ABDM. However, he expressed concern that there are no clear criteria to demarcate when one phase completes and the next begins. In the participant's view, this aspect is quite subjective.

Participant I- The participant shared that the government is changing its attitude and is willing to experiment before starting to make a law or policy. He shared that even in the districts, the district collectors are conducting pilots which could be scaled. For example, a district in Haryana state, with the collaboration of researchers from Oxford and Northwestern universities conducted a random control trial on how to change gender perceptions. Therefore, one can see such changes taking place in the pockets, however, such processes are not institutionalized yet.

Policy response to change

Participant E – The participant shared that all recent health data policy documents acknowledge that these documents are dynamic and subject to revisions from time to time. Further, the participant shared the example of different healthcare providers using different data standards in the country. Therefore, while framing the policy, all types of data standards are allowed to begin with.²¹⁵ Once policy adoption takes place, over a period of time, there will be a shift to the standardized version and accordingly, the policy will be revised.

The participant shared that based on the learnings from the pilot implementation of NDHM in six union territories, the health ID policy was revised. Also, post-COVID, the National Medical Council changed the telemedicine policy. Earlier the policy was very restrictive, whereas post-COVID, a lot of changes were introduced bringing clarity to the process of telemedicine, removing ambiguities about its status, and providing guidance on how to conduct teleconsultations.

²¹⁵ Such as the unstandardized nonmachine readable, unstandardized machine readable, and standardized machine readable data.

Participant F- The participant shared that the AI policies cannot afford to be rigid, therefore, the policy recommendations are generally broad-based.

["The National program on AI is being formulated and envisaged to be implemented using the agile framework"].

Participant H- The participant shared the example of an AI-driven platform for rapid screening of COVID 19 using chest x-ray interpretation over WhatsApp for doctors.²¹⁶ The solution called 'XraySetu' could work with low-resolution images sent via mobiles, was quick and easy to use, and could facilitate detection in rural areas. The app was adopted by thousands of doctors in rural areas. The participant shared that NHA was very receptive to this idea and during COVID, the agency approved the use of this app as a scalable diagnostic.

Key points:

- Most participants shared that the recent policies on health data are acknowledging the need to change from time to time. However, a few participants noted that they have not seen such examples of reviews.
- Considering the risks and uncertainties surrounding health data, the agencies
 are undertaking pilot programs such as through test beds and sandboxes, as
 well as through phased-implementation of policies.
- The government agencies are becoming open to the idea of experimenting before rolling out a policy, however, such experimentation is not institutionalized.

4. India's laws and policies and Adaptive governance structures

In addition to the presence of adaptive regulatory processes, there are several examples of adaptive governance structures in the health data space. The national digital health ecosystem envisaged in the ABDM is federated in structure. Thus, its implementation will need inter-agency coordination at both the federal level as well as between federal and state governments. However, the interview analysis suggests that there are gaps in inter-agency coordination.

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²¹⁶ ARTPARK (AI & Robotics Technology Park), a not-for-profit foundation established by the Indian Institute of Science (IISc), Bengaluru, with support from the Department of Science & Technology (DST), Govt. of India, in collaboration with Bangalore based Health Tech start-up Niramai and the Indian Institute of Science (IISc), has developed XraySetu specifically designed to identify COVID positive patients from low-resolution Chest X-Ray images sent over WhatsApp.

a. Documentary Analysis

i. Polycentric governance

The National Health Policy 2017 suggests collaboration with the non-government sector and the private sector participation in developing and linking the health information systems.²¹⁷ For example, by adopting consistent standards and electronic health records, creating registries of patients, and documenting diseases and health events.²¹⁸

The ABDM Health Data Management Policy requires the Data protection officer to communicate with regulators and external stakeholders on matters related to data privacy and present those views for informed decision-making on data governance.²¹⁹

The ABDM strategy document provides for a federated structure of health records with patient data to be held at a point of care at the closest possible location to where it was created.²²⁰ Further, it provides for a stakeholder engagement plan and recognizes the important role of the private ecosystem particularly the health information providers, such as the hospitals and labs.²²¹

ii. Inter-agency coordination

In the analyzed documents, following are the examples of horizontal coordination (between agencies at the same level of government) and vertical coordination i.e. between different levels of government (i.e. federal, state, local).

• Horizontal coordination

At the federal government level, the Development Evaluation Advisory Committee (DEAC) is constituted with the objectives of building an evaluation culture, institutionalizing the evaluation of government schemes, conducting evaluation studies, and capacity building of evaluation in the states. This committee has members from multiple departments/ ministries.²²²

²¹⁷ See, NHP 2017, supra note 122, Para 13.

²¹⁸ *Id.* Para 13.12.

²¹⁹ See, Health Data Management Policy, supra note, 124, Para 6.

²²⁰ See, ABDM Strategy overview, supra note, 123, Para 2.2.4 (1). This is similar to the concept of subsidiarity.

²²¹ *Id.* Annexure 4. Para 3.

²²² See, NITI, supra note, 172. (Members include CEO, NITI Aayog, Secretary Department of Finance, Secretary Department of Expenditure, Secretary Department of Rural Development; Director, National Institute of Public Finance and Policy, Director General, DMEO, along with two experts).

The ABDM Health Data Management Policy provides for the Ministry of Health and Family Welfare, and the Ministry of Electronics and Information Technology to guide on important aspects of the digital health ecosystem in ABDM.²²³ The Personal Data Protection Bill 2019 requires the Data Protection Authority of India to consult and coordinate with another authority or regulator in cases of overlapping jurisdiction.²²⁴

• Vertical coordination

The ABDM Health Data Management Policy provides a multi-level governance structure for the national digital health ecosystem consisting of committees and authorities at federal, state, health facilities, and others as necessary. The ABDM strategy document requires the NHA to coordinate with different ministries/departments of the federal government, state governments, as well as the private sector and civil society organizations in implementing the mission. 226

b. Interview Analysis

The interview analysis suggests that there are many coordination challenges and the agencies largely work in silos. Regarding the scale of governance in health data, most participants preferred a federated model.

i. Inter-agency coordination

Regarding inter-agency coordination, most of the participants think such coordination is weak.

Participant B - The participant shared that when it comes to data sharing, the existing governance system is very siloed. Therefore, there is a need for something like the India data office that works across government departments, across states, and creates a cohesive data strategy and utilization strategy for India.

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²²³ See, Health Data Management Policy, supra note, 124, Para 6.

²²⁴ See, the Bill, supra note, 126, clause 56.

²²⁵ See, Health Data Management Policy, supra note, 124, Para 6.

²²⁶ See, ABDM Strategy overview, supra note, 123, Para 3.1.7 (1).

Participant E- The participant acknowledged that there are many coordination challenges in healthcare. For example, setting up a hospital requires more than 60 permissions across various authorities and ministries. The participant shared that NHA's concept of 'verifier' is a policy intervention to simplify the processes and increase inter-agency coordination. In this process, if one of the agencies/departments verifies a particular aspect of the hospital, it would be tagged with a date and this information could be used by other departments, instead of duplicating the effort.

Participant C - The participant shared that inter-departmental coordination is very less. For example, COVID data is located in silos between the Indian Council of Medical Research (ICMR), the National Centre for Disease Control (NCDC), the National Health Authority (NHA), and many other agencies.

Participant C said — ["vaccination data is in Co-win (NHA's web application), the hospital administration data is available only with the hospital today, not even available, with the government. The RTPCR and infection-related data are with ICMR. There isn't really a way to stitch this together so easily in our context"].

Participant G - The participant shared the example of universal health coverage which by design needs coordination across sectors such as combining the health and finance data. However, the agencies are working in silos and not sharing the data.

Participant G said — ["Integrated Child Development Services (ICDS) Scheme is under the Ministry of women & child development and Universal health coverage, is under the Ministry of Health. They're both collecting data on children. But the data is not shared"].

Participant I – The participant highlighting the lack of agency coordination said — ["Each sectoral regulator giving you his or her own view of things and not necessarily be agreeing with the overall picture"].

ii. Scale of governance

Regarding the scale of governance in health data, most participants shared that the federated model is good, where the federal government lays out the broad policies and guidelines, and the states have the flexibility to contextualize, based on their specific

requirements. However, one participant felt that the state governments should have a key role.

Participant G – The participant shared the need to decentralize the role of the federal government.

Participant G said — ["at least with the health data it is very centralized, even though health is a state subject, you know, they (federal government) specify what software you should use and everything, which should be a state prerogative"].

Participant E – The participant shared that the scale of governance should vary depending on what aspect of health data is being discussed. For example, one aspect relates to data storage, the other is data transfer, and still, another is data use.

Participant E said — ["When it comes to data storage, the best authority to take care of is the facility, which is generating that data"].

["For epidemiological perspective, very well seen in the recent past, still require that the data from all the hospitals in India should be pulled in a central server.. So, for this type of policy, it has to be the government of India"].

5. Need of Adaptive Regulations

The interview participants were asked about their views on the need for adaptive regulation in general as well as in health data. Most of the participants acknowledged the importance of adaptive regulations, however, they also shared the potential challenges for implementing such regulations.

a. For

Participant B- The participant shared that the laws have to change because the technology is changing and disrupting the business models, it is disrupting how we work, from where we work.

Participant B said — ["the regulatory mindset has to change where you have to regularly realize that a law once framed will have to be revisited frequently because very soon, it's going to get outdated"].

Participant C - The participant shared that the COVID pandemic is an excellent example that showed how the common person started using data and started questioning the government that the numbers are not dropping, that there is not enough testing, etc.

Participant C said — ["And therefore, adaptive regulation is, in my mind (a) very normal evolution on how new policymaking should happen and we are in a good point of time for this concept to actually push"].

Participant F- The participant shared that it is necessary for policymaking to be consistent, agile, and relevant.

Participant F said — ["by consistent, I mean that... because the ecosystem changes much too frequently, so, you have to respond to that and you cannot be remaining stuck in a particular kind of institutional mechanism or a thought process"].

Participant H- The participant shared that we need to have adaptive policies to regulate IT because as the technology grows, we will probably discover more facets of it, and there should be the flexibility of doing course correction in the future.

Participant H said — ["If you have to look at the long-term competitiveness of India as a country, I think we should adopt this (adaptive regulation)"].

b. Challenges

Participant A – The participant shared that the challenge is to figure out how to disrupt the regulatory mindset where one thinks that the policies and laws are long-standing, say for the next 20 years.

Participant B – The participant shared that there is an expectation that a policy must have a long-term direction. Therefore, this should not be tinkered with frequently because people make investment decisions based on the policies.

Participant D – Adaptive regulation is the way to go but it seems idyllic. Neither the regulators seem ready nor is there a high degree of sensitization in the government to push it in a unified manner.

Participant D said — ["I think this answer is going to be very heavily influenced by our current policymaking climate, which is deemed to be very politically influenced, and very less process influenced at the moment"].

Participant G – Echoing a similar concern, the participant shared that there is a crying need for adaptive regulation but he thinks the system is not ready for it.

Participant G said — ["Because bureaucracy is very inward-looking and very black-boxed. It will be very difficult to implement these kinds of systems in this environment"].

Participant H – The participant shared that COVID is a great example. Our public health system (globally) was based on the thought that what happened in the past will happen in the future. There was no anticipation that the future could be so different than the past.

Participant H said — ["the fundamental perspective of policymaking is that unless you understand this exponential nature of change and predict the future state of health, and your policy is flexible enough to accommodate that exponential nature of change in the future state, it's always going to fail"].

Participant I – The participant shared that unless there is transparency and data availability, implementing adaptive regulation could be a challenge. If the general public or the researcher does not have data to do analysis, then one has to believe what is being told.

Participant I said — ["Is it (regulation) adapting or is it changing because stakeholders are going to benefit from it, a certain set of stakeholders are going to benefit from it? This is a question that I think our country simply is not in a position to answer as of now"].

India's regulatory cycle in health data- Summary analysis

In the pre-implementation stage, the adaptive features of assessing risks and assessing impacts of proposed law/policies are not built-in the regulatory process and are limitedly followed in practice. Though public participation in law and policymaking is not a mandatory requirement, there is evidence of increased public consultation and stakeholder engagement in health data policymaking.

In the implementation stage, the analyzed documents have elaborate provisions for maintaining records, reviewing safety standards and protocols, reporting, and monitoring compliance. In practice, due to nascent health data policies, it is difficult to establish the effectiveness of the given M&E provisions. The interviews suggest that the government is responding to feedback and informing future policies. However, there are gaps in terms of planning relevant data collection for monitoring, using available data to inform policies, and making data available in the public domain.

Lastly, in the post-implementation stage, there are several examples of provisions acknowledging change, requiring periodic reviews, piloting new technologies through sandboxes, and implementing the policy in phases. Also, the interviews suggest that the government agencies are becoming open to the idea of iterative decision-making and experimenting before rolling out a policy, however, such processes are not institutionalized yet.

In addition to the adaptive processes, the analyzed documents have a few examples of provisions indicating cross-agency coordination and reflecting polycentric governance. However, interviews suggest that generally agencies work in silos and there are challenges in data sharing as well as agency coordination.

Overall, India's health data regulatory cycle seems to indicate a low degree of adaptiveness in the pre-implementation stage whereas, it shows a moderate to a high degree of adaptiveness in the implementation and post-implementation stages. However, due to the nascence of these law/policy documents, it is too early to say how these adaptive provisions will be implemented in practice.

IV. US and India- Comparison and Effectiveness of Health Data laws

A. High-level comparison of US and India

Based on the documentary analysis of the Health data law/policies of the US and India, following are the stage-wise summary findings:

- i. In the pre-implementation stage, of the three adaptive features (i.e. assessing risks, broader and fuller impact assessment, and public participation), the US law in general requires the federal agencies to adopt all three features in the regulatory process. Whereas, in India, there is no legal requirement for the same. However, the examples identified in the select health data law/policy documents indicate a comparable picture for both countries for all three features.
- ii. In the implementation stage, the two adaptive features (i.e. monitoring & evaluation and public participation) show high presence in the analyzed documents of the US and relatively moderate presence in the analyzed documents of India.
- iii. In the post-implementation stage, there is one adaptive feature i.e. iterative decision-making and the health data documents of both countries indicate high presence of this adaptive feature. Further, the US law in general requires the agencies to conduct ex-post reviews, though, it has been limitedly implemented by the agencies. In India, though there is no general legal requirement for ex-post reviews, recent health data policies have been revised from time to time in consultation with the public.

Combining the general regulatory requirements with the examples identified in the health data regulations suggests that in the pre-implementation and implementation stages, the US regulatory cycle is more adaptive than India's regulatory cycle. Whereas, in the post-implementation stage, both US and India's regulatory cycles are similarly adaptive.

The regulatory risk assessment, impact assessment, and monitoring and evaluation are more structured, elaborate, and rigorous in the US than in India. However, it is important to understand whether such different regulatory processes actually result in meeting the larger policy goals and objectives and whether more adaptive regulatory processes result in policy success than the less adaptive processes.

B. Examples of impact assessment of US health data laws

1. Evaluating the impact of law/regulation

The Federal Trade Commission (FTC) typically reviews its rules every ten years to keep pace with changes in the economy, technology, and market.²²⁷ In 2009, FTC issued the Health Breach Notification Rule and reviewed it in 2020.²²⁸ The review report is not available, however, the Commission sought public comments on questions related to the rule's effectiveness and benefits; the need to retain, change or eliminate the rule; the implications for enforcement raised by direct-to-consumer technologies such as mobile health apps and virtual assistants; and how the rule should address new developments in healthcare products, among others. Based on the retrospective review of the rule, the Commission issued two guidance documents for the companies to aid in compliance with the rule requirement.²²⁹

Another example is the HITECH Act requiring the Government Accountability Office (GAO) to analyze the impact of the HITECH Act on (a) premiums of health insurance, (b) overall cost of health care, (c) EHR adoption by providers, and (d) reduction in medical errors including other quality improvements. Pursuant to this provision, the GAO analyzed the effect of the Act on health insurance premiums. However, it did not conduct a detailed assessment and just mentioned a few anecdotes/ speculation by the representative organizations²³⁰ such as suggesting evidence that the payment and delivery reforms have resulted in reductions in healthcare utilizations and generated savings (in some cases); sharing concerns on the increased administrative costs of implementing the HITECH Act and other Acts such as the Patient Protection and Affordable Care Act; ²³¹ and expressing difficulty in isolating the effects of the HITECH Act as health insurance premiums are affected by other drivers. ²³²

²²⁷ See, FTC, supra note, 92.

²²⁸ Federal Register / Vol. 85, No. 100 / Friday, May 22, 2020 / Proposed Rules. Available at https://www.govinfo.gov/content/pkg/FR-2020-05-22/pdf/2020-10263.pdf

²²⁹ FTC. Revised Health Breach Notification Rule resources spell out companies' legal obligations. Business Blog. Jan 21, 2022. Available at https://www.ftc.gov/business-guidance/blog/2022/01/revised-health-breach-notification-rule-resources-spell-out-companies-legal-obligations.

²³⁰ GAO(2014). EHR Programs. Participation Has Increased, but Action Needed to Achieve Goals, Including Improved Quality of Care. GAO-14-207. Available at https://www.gao.gov/assets/gao-14-207.pdf. P-48,49.

⁽To describe the effect of the HITECH Act on health insurance premiums, GSA contacted representatives from seven organizations including the America's Health Insurance Plans, the American Academy of Actuaries, the Blue Cross Blue Shield Association, and four health insurance companies. None of these had done any research to look at the HITECH Act's impact on health insurance premiums). ²³¹ *Id.*

²³² Id.

2. Agency reports on the implementation of health data laws

Over time, several government agencies have been publishing reports on the implementation/scope of the health data laws. These reports are good indicators of how well these law/regulations are working and how these could potentially be improved. For example, the GAO in two reports on health information technology highlighted that the agencies have developed performance measures for the EHR program but have not developed measures to assess the program outcomes, such as in terms of achieving patient safety, healthcare quality, and efficiency.²³³

In another report, the Department of Health and Human Services (DHHS) analyzed the scope of HIPAA and found large gaps in policies related to access, security, and privacy of health information that is collected, shared, and used by the non-covered entities. The report concluded that the US health data laws and regulations have not kept pace with new technologies such as wearable fitness trackers, mobile health apps, and health social media.²³⁴ In ONC's 2018 report to Congress,²³⁵ the agency acknowledged that electronic health information is not accessible across the systems and to the end-users in ways that can generate value for them.²³⁶

3. Research studies assessing the effects of the health data laws

A few research studies are available that assessed the effects of health data laws. For example, one study evaluated the effect of the HIPAA 'Privacy Rule' on health research and found that since its implementation in 2003, the Privacy Rule had a negative effect on

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²³³ *Id.* Also, *see*, GAO-17-305. (2017). HHS Should Assess the Effectiveness of Its Efforts to Enhance Patient Access to and Use of Electronic Health Information. Available at https://www.gao.gov/assets/gao-17-305.pdf.

²³⁴ U.S. Department of Health and Human Services. (2016). Examining Oversight of the Privacy and Security of Health Data Collected by Entities not covered by HIPAA, at 17. Available at https://www.healthit.gov/sites/default/files/non-covered entities report june 17 2016.pdf. See, NCVHS, supra note, 3. Also, see, Cohen and Mello, supra note, 5.

²³⁵ The HITECH Act requires the Office of National Coordinator (ONC) to submit an annual report to Congress on the progress of the adoption of a nationwide health information system.

²³⁶ The Office of National Coordinator for Health Information Technology (ONC), The U.S. Department of Health and Human Services. (2018). Annual Update on the Adoption of a Nationwide System for the Electronic Use and Exchange of Health Information. Available at

https://www.healthit.gov/sites/default/files/page/2018-12/2018-HITECH-report-to-congress.pdf. (For example, the health care end users lack modern tools for accessing information; the patients lack electronic access to their health information affecting their ability to manage health such as shopping for medical care at lower prices; the health care providers often lack electronic access to patient data at the point-of-care, such as longitudinal data maintained in different health IT systems; and the payers often lack electronic access to clinical data on groups of covered individuals hindering the beneficiaries' assessment of the value of services).

the researchers' abilities to conduct meaningful research.²³⁷ Another study examined the effects of the HIPAA omnibus rules (2013) on the medical privacy breaches among business associates in the US healthcare system. The study found that the rules implementation prevented privacy breaches from happening, which could have affected 18 million Americans (approx.). It concluded that the federal policy seems to have achieved its intended goal of strengthening privacy protection efforts and reducing privacy breaches among business associates.²³⁸

Another study assessed the implementation of the HITECH Act in the first 5 years of its enactment. It found that there is an increase in EHR prevalence among providers and it has been easier for the providers/hospitals to adopt EHR to start with, potentially, due to incentive payments. However, it is challenging to create a robust IT infrastructure that enables sharing and using the EHR information for improving healthcare outcomes.²³⁹ Similarly, another study found an increase in the EHR adoption rates and attributed the increase to the HITECH Act.²⁴⁰

C. Examples of impact assessment of India's health data law/ policies

In India, the health data policies started developing 2018 onwards, and a few are still in draft stage.²⁴¹ Therefore, studies on their implementation or impact assessment are not available. However, a few evaluation studies in the health sector by the Data Monitoring and Evaluation Office (DMEO) at the federal level are worth mentioning.

Between April 2019 and February 2021, the DMEO evaluated 125 centrally sponsored schemes²⁴² under 10 sectors including health, covering approximately 30% of the government of India's development expenditure amounting to USD 43 billion per

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²³⁷ Institute of Medicine (IOM). (2009). Chapter 5: Effect of the HIPAA Privacy Rule on Health Research. Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research. Washington, DC: The National Academies Press.

²³⁸ Yaraghi, N., & Gopal, R. D. (2018). The Role of HIPAA Omnibus Rules in Reducing the Frequency of Medical Data Breaches: Insights from an Empirical Study. The Milbank quarterly, 96(1), 144–166.

²³⁹ Gold, Marsha and McLaughlin Catherine. (2016). Assessing HITECH Implementation and Lessons: 5 Years Later. The Milbank quarterly, 94 (3): 654-687.

²⁴⁰ Milstein. A. Julia and Jha. K. Ashish. (2016). HITECH Act Drove Large Gains In Hospital Electronic Health Record Adoption. Health Affairs. 36 (8).

²⁴¹ Most health data policies are in draft stage and with different versions being updated since 2019-2020. The Personal Data Protection Bill 2019 is not yet passed by the Parliament.

²⁴² In India, the word, 'scheme' means a government sponsored plan or program to achieve policy objectives and sometimes used interchangeably with policy. In this context, this word does not have any negative connotation (as considered in American English).

annum.²⁴³ The schemes are assessed based on the internationally recognized REESI framework -relevance, efficiency, effectiveness, sustainability, and impact. The framework is contextualized to India's priorities by adding equity (REESI+E). These evaluation reports are shared with the Department of Expenditure and the respective Ministries/ Departments for their consideration.²⁴⁴

In health sector report, the DMEO combined qualitative and quantitative approaches for evaluation using primary and secondary data.²⁴⁵ The report identified the intended and the actual contribution of the government schemes to health sector outcomes. This included identifying areas needing focused effort to achieve national priorities/Sustainable Development Goals as well as identifying opportunities for convergence of the schemes.²⁴⁶ Additionally, this report presented an analysis of 21 health sector regulations/legislations and identified the gaps in the regulatory framework based on official reports and academic studies.²⁴⁷

Also, three studies were conducted on the National Health Mission²⁴⁸ to understand its impact on health outcomes; healthcare and finances; and health systems and governance. The studies brought out in quantifiable terms what worked and what did not work in the mission and suggested actionable recommendations.²⁴⁹

Based on this dissertation study, it is difficult to say how different regulatory processes actually result in meeting the larger health data policy goals or whether more adaptive regulatory processes result in health data policy success than less adaptive processes. However, in India's context, the interview participants shared that during the pilot phase of the Ayushman Bharat Digital Mission (ABDM), the National Health Authority faced resistance from stakeholders while creating their health IDs. Based on the learnings of pilot implementation, the agency introduced changes to improve the mission implementation strategy. There is limited information to corroborate the changes and the

²⁴³ See, DMEO, supra note, 206, at 75 to 85.

²⁴⁴ See, NITI, supra note, 172, at 33,34.

²⁴⁵ See, DMEO, supra note, 206, at 61.

²⁴⁶ Id.

²⁴⁷ *Id.* P-75 to 85.

²⁴⁸ The National Rural Health Mission (NRHM) was launched in 2005 by the Government of India (GoI) with focus on 18 States. In 2013, GoI launched the National Health Mission (NHM), which subsumed NRHM and the National Urban Health Mission. In 2018, the NHM was extended to continue till 2020. ²⁴⁹ NITI Aayog. Annual Report 2020-21 at 128. Available at

https://www.niti.gov.in/sites/default/files/2021-02/Annual-Report2020-2021-English 0.pdf

learnings from the pilot program. However, it could be said that incorporating changes based on the pilot program improved the chances of policy success due to reduced stakeholder resistance. But whether the policy succeeds in achieving its objectives could only be seen with time.

To assess if the health data law/policies are effective and achieving their objectives, one of the best approaches is to evaluate their impact by comparing the ex-ante regulatory analysis with the ex-post regulatory analysis. 250 Though beyond the scope of this research study, the impact assessment could be in terms of the costs, benefits, and unintended consequences of the law/policy as proposed (ex-ante) and as implemented (ex-post). Further, the agencies in both countries may focus on improving the regulatory learning by introducing multi-rule reviews.²⁵¹ Mostly, the agencies focus on reviewing one rule at time thus they miss out on the learnings that could be gained from reviewing multiple past rules within an agency as well as from the interactive effect of multiple rules across agencies. Such collective analysis could provide lessons to improve future rules through better choice of policy designs, better methodologies, and better overall assessments.²⁵²

V. Conclusion and Recommendations for India

Based on the documentary and interview analysis, India's health data regulatory cycle indicates a low degree of adaptiveness in the pre-implementation stage whereas, it shows a moderate to a high degree of adaptiveness in the implementation and the postimplementation stages. However, most of the analyzed health data policies are nascent and one has to wait and watch how these policies play out in the future. While analyzing the health data policy documents and the interviews, a few policy gaps are identified. To address those gaps, following are the recommendations:

1. Introduce structured decision-making processes

Structured decision-making processes are excellent ways to optimize learning based on planned processes to collect, assess, and use information, such as the practice of regulatory

²⁵⁰ Bennear, Lori S. and Wiener, Jonathan B. (2021). Institutional Roles and Goals for Retrospective Regulatory Analysis. Journal of Benefit-Cost Analysis, 12 (3), 466-493. Also see Cropper et al., (2017). Looking Backward to Move Regulations Forward. Science, 355 (6332): 1375-1376, and Dudley et al., (2019). Crossing the Aisle to Streamline Regulation. Wall Street Journal, May 13, 2019, available at https://www.wsj.com/articles/crossing-the-aisle-tostreamline-regulation-11557788679.

²⁵¹ See, Bennear & Wiener, supra note, 250.

²⁵² Id.

impact assessment. However, this may be introduced in a phased manner and may not be required for all the proposed laws/policies e.g. limiting to the major impact laws/policies (such as the laws/regulations which have immense economic, social, or environmental impact). Further, simple and flexible methodologies are recommended for conducting impact assessments. Examples of simplified assessments are available with the Data Monitoring and Evaluation Office of NITI in the government of India. Similar approach could be adopted by the agencies in law/policymaking. Further, DMEO could handhold the agencies and provide the required capacity building support.

2. Build a culture of using available M&E data

Most government agencies do not have a culture of collecting relevant data and using the same to inform policies. Interview analysis suggests that generally data collection and monitoring are afterthought phenomena in policymaking. Also, the departments/agencies are collecting an exponential amount of data but not putting them to meaningful use. This could be streamlined by identifying relevant data at the stage of policy formulation and building in provisions to monitor such data. Also, the ongoing efforts of DMEO in building M&E capacities of government officials could be emphasized further.

3. Make data publicly available

The data on monitoring and evaluation, and policy performance is generally not public-facing. Whether a particular scheme/ policy is a success or not is inferred based on the government reports. The data forming the basis of impact assessment is not available in the public domain. Therefore, it is recommended that such data be made public so that independent bodies and researchers could validate the scheme/policy impact.

4. Introduce retrospective reviews and multi-rule reviews

Evaluating a policy/regulation by comparing the costs and benefits as projected (ex-ante) and the actual costs and benefits (ex-post), could help inform the policy's effectiveness as well as relevance. Such retrospective reviews, could be built-in the policy/regulation and preferably with a specified period. The time period to conduct such reviews could vary depending on the value of new information that a review could generate and the expected cost of conducting such a review.²⁵³ Further, India should consider introducing multi-rule

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²⁵³ Id.

reviews i.e. learning from the multiple past rules/policies and using their analyzes to improve future rules/policies and assessments. A review of policies impacting one another could be planned together for the maximum benefit of the evaluation process and to potentially reduce the cost.²⁵⁴

5. Mandate pre-legislative consultation

A pre-legislative consultation increases the legitimacy of the proposed law/policy. It provides the scope of deliberating the proposal with the public and interested stakeholders. In India, pre-legislative consultation is not mandatory. Considering the magnitude of risks and the privacy and security concerns of personal data, any health data law or policy without public participation and consultation may not be effective. Though the National Health Authority is adopting a participatory process in developing the health data policies, there is a need to end agency discretion and make pre-legislative consultation a statutory requirement.

6. Educate the public and raise awareness of health data

India's ABDM is based on voluntary participation. An individual's consent is the basis for collecting and using his/her personal data by the health data fiduciaries and health data processors. India's adult literacy rate is 74%, suggesting that there are 26% of adults who are not literate.²⁵⁵ Therefore, public education and awareness in terms of digital rights and responsibilities seem crucial for the effectiveness of health data laws and policies.

²⁵⁴ *Id*.

²⁵⁵ Adult literacy figures include people aged 15 years and above. For details, see, The World Bank. Literacy rate, adult total—India. Available at

Chapter-6

Adaptive regulations – Descriptive and Normative Analysis

Summary: This chapter builds on the document and interview analysis mentioned in the earlier three chapters on Groundwater, Electric Vehicles, and Health data, and the interview analysis of six political leaders of India which are not sector-specific. For the document analysis, to depict the presence of six adaptive features on the books, three categories are created as low, medium, and high. This is based on the count of identified law/policy provisions. Similarly, for the interview analysis, to depict the presence of six adaptive features in practice, three categories are created as low, medium, and high. This is based on the ratio of the responses indicating the presence of adaptive feature in practice and the total number of effective responses. Combined document analysis and interview analysis for the three sectors in India show gaps between the law on the books and the law in practice. These gaps are further explored such as where the sector is more adaptive in practice than theory, or more adaptive in theory than practice, or is similarly adaptive in both theory and practice- low, medium, and high. To address the identified gaps, recommendations are given for the three sectors. On the other hand, the normative analysis compares the actual adaptive regulatory practices of the US and India with the best practices recommended by the international bodies and academic researchers. Based on this analysis, recommendations for India are summarized in the form of an adaptive regulatory cycle. To successfully implement the recommendations and the adaptive regulatory practices in general, behavioral insight strategies are identified. The chapter concludes with the contribution of this research study to the advancement of knowledge.

I. Descriptive Analysis

A. Overview

This section builds on the sector-wise analysis of India carried out in three earlier chapters. The following sections present a combined document analysis and interview analysis (24 key stakeholders) for the three sectors of study and include summary analysis of the interviews of six political leaders which is not sector-specific.

B. Combined documentary analysis of three sectors

The documentary analysis is based on the review of the law/policy documents of EVs, groundwater, and health data. While reviewing the law/policy documents, NVivo software is used to identify and code the specific law/policy provisions for each of the six broad features of adaptive regulation.² Based on the number of coded references, three categories are created as low, medium, and high and each is given a color for distinction. These categories indicate the level of presence of the six adaptive features in the analyzed law/policy documents.

| No. of coded | Category |
|--------------|----------|
| references | |
| 0-15 | Low |
| 16-30 | Medium |
| > 31 | High |

Table.18 Summary of combined document analysis of three sectors of India

¹ The count of documents sector-wise is as follows: (i) EV sector- 23 documents (237 pages), Groundwater sector-8 documents (259 pages), (iii) Health data sector-6 documents (159 pages). This variation is inherent due to differences in the length of the analyzed documents. In health data sector, it could be attributed to the nascence of law/policymaking.

² For details of methodology, see Chapter 2.

| Adaptive feature | Ground water | Electric Vehicle | Health Data |
|---|--------------|------------------|-------------|
| Assessing Risks and Uncertainties | | | |
| Broader and Fuller Impact Assessment | | | |
| Monitoring & Evaluation | | | |
| Iterative Decision- making | | | |
| Public Participation | | | |
| Adaptive Governance structures | | | |

1. Assessing risks and uncertainties

This feature indicates very limited presence in the EV sector with least number of identified provisions, followed by health data, and groundwater. The limited presence could be attributed to the lack of formal requirement of risk assessment in law/policymaking. Whereas, a relatively better presence in groundwater documents could be attributed to the two bills (Legislative Bill and the Model Bill) which are comprehensive in their approach and are considered significant improvements over the provisions of earlier bills/ proposed laws.

Table 19. Comparative document analysis of three sectors of India (Assessing Risks and Uncertainties)

| Sector/Sector | In specific law/ policy | Reference examples of coded text |
|----------------------|-------------------------------------|---|
| Groundwater | Number of provisions identified -18 | Environmental screening (ABY scheme); Risk and vulnerability assessment (Model Bill); Risk assessment in extracting saline groundwater (Punjab Draft guidelines) |
| Electric Vehicles | Number of provisions identified – 3 | Government taking measures to de-risk industry investments in EV sector (NEMMP); Safety assessment programme for electrical safety of charging station (CEA notification) |
| Health Data | Number of provisions identified 15 | Data protection impact assessment (ABDM Health data management policy); minimum standards of data protection (NDHM Data Privacy Policy); data protection impact assessment (Personal Data protection Bill). |

2. Broader and fuller impact assessment

This feature indicates varying levels of presence in the three sectors. Health data has the least number of identified provisions, followed by moderate number in EV sector, and the highest number in groundwater sector. The limited to moderate presence could be attributed to the lack of formal requirement of impact assessment in law/policymaking, therefore consideration of policy impacts is variably reflected in the law/policy documents. On the other hand, in groundwater, the high number of identified provisions could be attributed to the two bills (Legislative Bill and the Model Bill) which are comprehensive in their approach and are considered significant improvements over the earlier bills/proposed laws.

Table 20. Comparative document analysis of three sectors of India (Broader and Fuller Impact Assessment)

| Sector/Sector | In specific law/policy | Reference examples of coded text |
|---------------|------------------------|--|
| Groundwater | Number of provisions | Environmental impact assessment (ABY scheme); |
| | identified – 41 | Environmental and social impact assessment (Model |
| | | Bill) |
| Electric | Number of provisions | Cost-benefit analysis, scenario analysis, etc (NEMMP); |
| Vehicles | identified - 17 | Determining demand incentives based on several factors |
| | | (FAME-I). |
| | | |
| Health Data | Number of provisions | Identified benefits and impact of NDHM (ABDM |
| | identified - 15 | strategy); Data protection impact assessment (ABDM |
| | | Health data management policy) |

3. Monitoring and Evaluation

This feature has high presence in all three sectors though there are more examples of monitoring than evaluation. In many documents, the M&E provisions are clubbed together (under a common heading) without differentiating between them.

Table 21. Comparative document analysis of three sectors of India (Monitoring & Evaluation)

| Sector/Sector | In specific law/ | Reference examples of coded text |
|----------------------|--------------------------------------|--|
| | policy | |
| Groundwater | Number of provisions | Disbursement linked monitoring indicators (ABY scheme); |
| | identified - 114 | Annual water auditing (Federal Guidelines) |
| Electric Vehicles | Number of provisions identified - 49 | Data analysis based on performance parameters (FAME-I); Monitoring incentive disbursal (PLI Auto) |
| Health Data | Number of provisions identified - 67 | Geography and demography-based monitoring to inform health policies (ABDM strategy); Reporting personal data breaches (Personal Data Protection Bill). |

4. Iterative decision-making and policy adjustment

This feature has high presence in EV and Health data sectors and a moderate presence in groundwater sector. This difference could be attributed to the inherent nature of the EV and Health data sectors being more dynamic and witnessing a faster pace of technological changes than the groundwater sector. However, even in groundwater sector, the prevalence is categorized as medium indicating there are many provisions of iterative decision-making. This could be attributed to the uncertainty surrounding the groundwater resource, thus, keeping the review provisions to update the policy with time.

Table 22. Comparative document analysis of three sectors of India (Iterative Decision-making)

| Sector/Sector | In specific law/policy | Reference examples of coded text |
|----------------------|--------------------------------------|--|
| Groundwater | Number of provisions identified - 25 | Updating village level water budgets regularly (ABY scheme); periodic review of groundwater protection zones (Model Bill) |
| Electric Vehicles | Number of provisions identified - 38 | Continued review, monitoring and mid-course corrections (NEMMP); Pilot programs and phased implementation (FAME I and II). |
| Health Data | Number of provisions identified - 33 | Regulatory sandboxes (ABDM guidelines); Implementing policies based on agile framework (ABDM strategy) |

5. Public participation

This feature has high presence in groundwater and health data sectors and a moderate presence in EV sector. However, even in EV sector, the prevalence is categorized as medium indicating there are many provisions of public participation. The documentary analysis suggests that the groundwater law/policy documents provide for a decentralized institutional framework at four levels of government – state, district, block, and village. And at each level, there are provisions of engaging public. This could be attributed to the highest number of identified provisions of public participation in this sector. Whereas, such a decentralized institutional framework is not provided in the health data and the EV documents.

Table 23. Comparative document analysis of three sectors of India (Public Participation)

| Sector/Sector | In specific law/ | Reference examples of coded text |
|----------------------|--------------------------------------|--|
| | policy | |
| Groundwater | Number of provisions identified - 61 | Notice and comment; developing water security plans and water budgets; approving village groundwater security plans |
| Electric Vehicles | Number of provisions identified - 18 | Notice and comment; consumer surveys and focus group discussions; stakeholder engagement while preparing the scope of pilot programs |

| Health Data | Number of provisions | Notice and comment; developing versions of policies |
|-------------|----------------------|--|
| | identified - 36 | through consultation papers; involving and collaborating |
| | | with stakeholders for adoption and expansion of |
| | | Ayushman Bharat Digital Mission |

6. Adaptive Governance Structures

This feature has low presence in both EV and Health data, whereas it has moderate presence in groundwater sector. The documentary analysis suggests that the groundwater law/policy documents provide for a decentralized institutional framework at four levels of government — state, district, block, and village. Therefore, the number of provisions indicating inter-agency coordination is higher in groundwater than other two sectors where such a framework is not a part of the law/policy documents.

Table 24. Comparative document analysis of three sectors of India (Inter-Agency Coordination)

| Sector/Sector | In specific law/policy | Reference examples of coded text |
|----------------------|--------------------------------------|---|
| Electric Vehicles | Number of provisions identified - 15 | Project Implementation and Sanctioning Committee is an inter-ministerial body (FAME-I and II); State and Central nodal agencies to consult in making changes in the prescribed norms of public charging infrastructure (Ministry of Power). |
| Groundwater | Number of provisions identified - 29 | Inter-Departmental Steering Committee at national and state levels (ABY scheme); the district groundwater council to coordinate groundwater security plans' preparation between panchayats and wards sharing aquifers (Model Bill). |
| Health Data | Number of provisions identified - 9 | Multi-level governance structure for the national digital health ecosystem (ABDM Health Data Management Policy); NHA to coordinate with different ministries/departments of the federal government and state governments (ABDM strategy). |

C. Combined Interview analysis of three sectors

The interview analysis is based on the review of 24 key stakeholder interviews across three sectors of study. While analyzing the interview transcripts, NVivo software was used to identify and code the responses for each of the six broad features of adaptive regulation.³ Based on the number of coded responses, three categories are created as low, medium, and high and each is given a color for distinction. These categories indicate the prevalence of six-features of adaptive regulation in practice. If the number of responses are one -third

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 $^{^{3}}$ For details of methodology, see Chapter 2.

or less of the effective responses,⁴ the prevalence is categorized as low. If the number of responses are more than one -third but less than/equal to two-third of the effective responses, the prevalence is categorized as medium. If the number of responses are more than two-third of the effective responses, the prevalence is categorized as high. The three categories are color-coded with grey representing low prevalence, yellow representing medium prevalence, and green representing high prevalence of the adaptive feature in practice.

| Responses indicating presence of adaptive feature in practice / Effective | Color | |
|---|--------|--|
| responses* | code | |
| (1/3 or less of the effective responses) | Low | |
| $(>1/3 \text{ but } \le 2/3 \text{ of the effective responses})$ | Medium | |
| (> 2/3 of the effective responses) | High | |
| *Effective response= 'Number of total participants' minus 'Number of participants | | |
| who did not respond' i.e. non-response | _ | |

Table.25 Summary of combined interview analysis of three sectors of India

| Adaptive feature | Ground water | Electric Vehicle | Health Data |
|---|--------------|------------------|-------------|
| Assessing Risks and Uncertainties | | | |
| Broader and Fuller Impact Assessment | | | |
| Monitoring & Evaluation | | | |
| Iterative Decision- making | | | |
| Public Participation | | | |
| Adaptive Governance structures | | | |

1. Assessing risks and uncertainties

The interview analysis suggests that EV sector indicates a high prevalence of assessing risks (coded high) whereas for groundwater and health data, it is a mixed picture (coded medium). In EV sector, of the total eight responses, six indicate that the agencies conduct some form of risk assessment,⁵ one response indicates that the agencies do not conduct

⁴ Effective response= 'Number of total participants' minus 'Number of participants who did not respond' Information about total participants and non-responses are given in detail for every feature in the paragraphs, however, the tables show only the effective responses.

⁵ It includes 1 response (assessments are conducted by the consultants/ policy think tanks working for the government and the agencies are aware of the risks and uncertainties in the sector due to membership in

risk assessment,⁶ and one did not respond to this aspect. In groundwater, of the total ten responses, four indicate that the agencies conduct some form of risk assessment,⁷ four indicate that the agencies do not conduct risk assessment, and two did not respond to this aspect. In health data, of the total nine responses, five indicate that the agencies conduct some form of risk assessment,⁸ three responses indicate that the agencies do not conduct risk assessment,⁹ and one did not respond to this aspect.

Table 26. Comparative interview analysis of three sectors of India (Assessing Risks and Uncertainties)

| Sector/Sector | In practice | Reference examples of coded interview text |
|----------------------|---|--|
| Groundwater | Of 8 responses, 4 indicate some form of risk assessment and 4 indicate no risk assessment. | ["As far as the risks and environmental concerns are concerned, I think that surely these are addressed at the national level"]. ["What is going to be the impact if we hit the zero day when they do the impact analysis? No, nobody is even thinking along these lines"]. |
| Electric Vehicles | Of 7 responses, 6 indicate some form of risk assessment and 1 indicates no risk assessment. | ["there's definitely risk assessment in a qualitative fashion that occurs in the design of most policy or vision documents"]. ["I think everything is done in a very ad hoc manner. We don't give sufficient autonomy to even the domain experts in the bureaucracy"]. |
| Health Data | Of 8 responses, 5 indicate some form of risk assessment and 3 indicate no risk assessment. | ["there is definitely a lot of time that is spent on both risk as well as opportunity assessments"] ["the word risk is generally not a part of the traditional vocabulary of a policymaker"]. |

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key international bodies e.g. UN Working Party 29 (India heads some of the sub-committees in WP 29); 1 response (qualitative risk assessment while drafting the advanced chemistry cell battery manufacturing scheme); 1 response (qualitative risk assessment of deploying e-buses in public transportation at the city level); 1 response (general tendency to minimize risk in policy making, uncertainties associated with policy outcomes are assessed); 1 (experts are consulted), and 1 response (in EV sector, government considered risks of potential unemployment and reskilling the workforce).

⁶ It includes 1 response (general tendency in the government to minimize risk of policy failure however, no risk assessment) and 1 response (ad hoc approach and a general disregard to experts' inputs).

⁷ It includes 1 response (detailed assessment at the federal level) 1 response (risk assessment at the state level); 1 response (consider risks surrounding groundwater based on empirical data), and 1 response (assessing the policy challenges).

⁸ It includes 1 response (agency spends lot of time on risk as well as opportunity assessment); 1 response (all risks are identified and discussed through consultation papers); 1 response (For different AI applications, the agency uses a risk assessment framework to categorize sectors/application as high-risk, medium risk, and low risk, and such assessments are communicated to the stakeholders); 1 response (It is more deliberative not a structured formal approach) and 1 response (Not a formal process such as identifying different risks or emphasizing degree of risks).

⁹ It includes 2 responses (not having seen any risk assessment reports ever) and 1 response (risk is poorly understood in policymaking).

2. Broader and fuller impact assessment

The interview analysis suggests a mixed picture for all three sectors (coded medium). In the EV sector, of the total eight responses, five indicate that the agencies conduct relatively broader impact assessments¹⁰ and three responses indicate that the agencies' impact assessments are limited/ skewed. 11 In groundwater, of the total ten responses, four indicate that the agencies conduct broader impact assessments, ¹² four indicate that the agencies conduct limited/skewed impact assessments, 13 and two did not respond to this aspect. In health data, of the total nine responses, four indicate that the agencies conduct broader impact assessments, 14 four indicate that the agencies conduct limited/ skewed impact assessments, 15 and one did not respond to this aspect.

Table 27. Comparative interview analysis of three sectors of India (Broader and Fuller Impact Assessment)

| 1 | | |
|---------------|----------------------------|--|
| Sector/Sector | In practice | Reference examples of coded interview text |
| Groundwater | Of 8 responses, 4 indicate | ["in the policy yes; you kind of weigh different alternatives. |
| | broader impact | In the law, not completely"]. |
| | assessments and 4 | |
| | indicate limited/skewed | ["we don't do scenario planning a lot. I think the answer |
| | assessments. | lies in the degree of uncertainty that we face in India. If |
| | | things are very uncertain, you don't want to spend a lot of |
| | | energy, building a scenario, figuring out its consequences. |
| | | Because the probability that a particular scenario will |
| | | actually occur is very small"]. |
| | | , , , |
| Electric | Of 8 responses, 5 indicate | ["In FAME scheme, xxxx has done analysis on both the |
| Vehicles | broader impact | economic and the environmental benefits of the policy"]. |
| | assessments and 3 | , , , , , , , , , , , , , , , , , , , |
| | indicate limited/ skewed | ["the highest emitter emitters are actually (petrol) two |
| | assessments. | wheelers and three wheelers and in the odd even scheme, |
| | assessificates. | these were exempt in fact, the cleanest part of the fleet |
| | | was targeted"]. |
| | | was targetee j. |
| | | |

¹⁰ For example, based on stakeholder consultations, international best practices, qualitative assessments,

¹¹ It includes 1 response (government promoting multiple clean fuels without sharing the comprehensive thought process/ planning behind the same); 1 response (example of state government policy which indirectly incentivizes polluting vehicles to be on road and disincentivizes cleaner vehicles to ply on road); 1 response (government policymaking aims at arriving consensus not necessarily weighing all alternatives and choosing the best one).

¹² It includes 2 responses (agencies weigh different policy alternatives in policymaking); 1 response that (agencies conduct cost-benefit analysis and feasibility studies), and 1 response (relying on science in policymaking).

¹³ It includes 2 responses (disconnect between science and policy); 1 (no cost-benefit analysis and domination of political interests); and 1 (no weighing of policy alternatives).

¹⁴ It includes 1 response (qualitative cost-benefit analysis), 3 responses (agency considers different policy alternatives including discussing policy choices with representatives of different countries).

¹⁵ It includes 2 responses (agency decision-making driven by the decision-maker's personality which influences the policy choices, and there is quick policymaking in pressure situations); 1 response (disconnect between policy and science), and 1 response (cost-benefit analysis discussion comes down to the budget).

Health Data

Of 8 responses, 4 indicate broader impact assessments and 4 indicate limited/skewed assessments.

["we spoke to so many different countries to understand if they were doing anything, we spoke to industry to understand the pros, the cons. And once we had all this understanding, then we went into a deliberation of what's right for India?"].

["No, I think it is really driven by the whims and fancies of the decision maker"].

3. Monitoring and Evaluation

Interview analysis focused on two aspects of M&E i.e. quality of monitoring mechanisms and emphasis on evaluation. The analysis suggests a mixed picture in EV and health data sectors (coded medium) whereas low prevalence in groundwater (coded low).

In EV area, of the total eight responses, six indicate presence of less structured monitoring mechanisms with equally divided views on their quality (adequate/ not adequate) and two did not respond to this aspect. In Groundwater area, of the total ten responses, seven indicate that mechanisms are not adequate and three did not respond to this aspect. In Health data, of the total nine responses, four indicate presence of adequate monitoring mechanisms, ¹⁶ four indicate the monitoring mechanisms are not adequate, ¹⁷ and one did not respond to this aspect.

Regarding evaluation, in the EV area, of the total eight responses, three indicate that the agencies focus on policy evaluation, one indicates that the agencies do not focus on policy evaluation, two indicate their lack of surety due to non-availability of M&E information in public domain, and two did not respond to this aspect. In Groundwater, of the total ten responses, seven indicate that agencies do not focus on policy evaluation, and three did not respond to this aspect. In Health data, of the total nine responses, four indicate that agencies focus on policy evaluation, four indicate agencies do not focus on evaluation, and one did not respond to this aspect.

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¹⁶ 2 responses indicate structured monitoring processes (such as monitoring key performance indicators (KPIs), key performance areas (KPAs), and relevant data collection post policy implementation to keep track of performance) and 2 responses indicate less structured monitoring processes (such as the Ministry asking the industry for feedback, particularly the big impact policies).

¹⁷ 4 responses (Monitoring a policy is generally an afterthought; collecting lots of irrelevant/ redundant data; indicators are not carefully determined; and data-driven policy feedback is rare).

Table 28. Comparative interview analysis of three sectors of India (Monitoring & Evaluation)

| Sector/Sector | In practice | Reference examples of coded interview text |
|-------------------|---|--|
| Groundwater | Monitoring- Of 7 responses, all indicate that monitoring mechanisms are inadequate | ["I would say that the monitoring system of the government is less. It's only when the research highlights something then the government creates a committee on it"]. |
| | | ["they've got a very good database even though there are data deficiencies, but even this database is not utilized"]. |
| | Evaluation- Of 7 responses, all indicate that agencies do not focus on policy evaluation | ["the comprehensive evaluation of the policy, I mean, what the policy has done, or the policy has been operationalized, for example, or where are the problems, I think there's very little critical reflection which is done"]. |
| Electric Vehicles | Monitoring- Of 6 responses, all indicate presence of less structured monitoring | ["I haven't seen a great M&E framework for the (EV) policies that I have worked on"]. |
| | mechanisms with equally divided views on their quality (adequate/inadequate) | ["But there are other channels like the industry, the market, there are various educational institutions, research bodies which do it, and they bring out directly or indirectly their findings, which are brought to the government which gives it kind of an idea of how the policy is faring"]. |
| | Evaluation- Of 6 responses, 3 indicate agency focus on policy evaluation, 1 indicates agencies do not focus on policy evaluation, and 2 indicate lack of surety due to non-availability of information in public domain | ["They don't have to abide by an established methodology, or even clear metrics for evaluation. And so, it's rather sort of subjective"]. |
| Health Data | Monitoring- Of 8 responses, 4 indicate presence of adequate monitoring mechanisms and 4 indicate monitoring mechanisms | ["the output outcome monitoring framework has been devised and put in place for each of the department"]. |
| | are inadequate | ["I think the problem is at the design stage, and then I don't believe that there are formal and empirical ways to study the indicators once data is collected and make decisions on those indicators"]. |
| | Evaluation- Of 8 responses, 4 indicate that agencies focus on policy evaluation and 4 indicate agencies do not focus on | ["We are collecting a huge amount of data, evidence and analyzing it from time to time"]. |
| | evaluation | ["M&E should happen during the pilot and the experimental phase, as much as it should happen once it becomes policy and implemented in a real world, real life scenario. But I don't think it's happening as much as it should have in the realm of Technology Policy"]. |

4. Iterative decision-making and policy adjustment

Interview analysis suggests high prevalence of iterative decision-making in all three sectors (coded high). In EV sector, of the total eight responses, all indicate iterative decision-making based on planned reviews, ¹⁸ new developments, ¹⁹ or post-implementation issues. ²⁰ However, most of them also shared that the information regarding the rationale of policy revisions and planned reviews is not available in public domain. In groundwater, of the total ten responses, seven indicate iterative decision-making though mostly unplanned, ²¹ two responses indicate that the laws/policies take long to adapt, ²² and one did not respond to this aspect. In Health data, of the total nine responses, eight indicate iterative decision-making based on new developments, ²³ or built-in provisions of policy learning, ²⁴ and one response indicates not having seen any explicit examples of review in this sector.

Table 29. Comparative interview analysis of three sectors of India (Iterative Decision-making)

| Sector/Sector | In practice | Reference examples of coded interview text |
|---------------|------------------------------|--|
| Groundwater | Of 9 responses, 7 indicate | ["I think right now, iterative lawmaking is more |
| | iterative decision-making | situational than experiential"]. |
| | mostly unplanned and 2 | |
| | indicate that the | ["In state, (many) age old laws need to get changed or |
| | laws/policies take very long | repealed. Because there's a lot of change in the ground |
| | to adapt. | reality, but no one takes the initiative. Because it's not |
| | | written anywhere that it needs to be changed or |
| | | amended"]. |
| | | |
| Electric | All 8 responses indicate | ["there is always a kind of refining or making changes |
| Vehicles | iterative decision-making | through whatever policy is made, that is done on a |
| | based on planned reviews, | continuous basis"]. |
| | new developments, or post- | |
| | implementation issues. | ["In terms of FAME-II, the government very recently |
| | | revised or updated the subsidies"]. |
| | | |

¹⁸ 4 responses include the example of planned review of FAME-I which resulted in an improved FAME-II.
¹⁹ It includes 1 response (change due to new technological developments) and 1 response (tightening the

emission norms for vehicles).

20 It includes 1 response (post-implementation deferral of timelines to meet with changed circumstances) and 1 response (policy revisions to fix issues arising from implementation including the launch of incomplete policies)

²¹ It includes 5 responses (revision of federal guidelines; iterative state laws or Model Groundwater Bills; change in water policies in the light of new data, information as well as political changes; policy revisions without formal policy evaluation; reviewing past policies in formulating the new national water policy); 1 response (example of groundwater extraction directions (in Punjab) which are required to be reviewed after three years) and 1 response (implementation of pilot program which focuses on incentivizing to save groundwater through saving electricity).

²² Two responses indicate that the laws/policies take a lot of time to respond to changed situations- 1 response (example of the British era law (Irrigation and Drainage Act) which is still on the books) and another response (state level policy changes which lag behind the changes in the field).

²³ It includes 2 responses (policy changes based on stakeholder feedback); 1 response (iterative policy consultation papers by NHA); 1 response (revision in Health ID policy based on learnings from the pilot implementation of ABDM in six union territories); 1 response (phased implementation of ABDM); 1 response (COVID policy, as an example of adaptive regulation in India);

²⁴ Two responses relate to the regulatory sandboxes/ test-beds for testing new technologies.

| Health Data | Of 9 responses, 8 indicate | ["I think there is a realization that, you know, these are |
|-------------|----------------------------|--|
| | iterative decision-making | not really hard policies,(and) there were several |
| | based on new developments, | sectors where we felt that we should allow for |
| | or built-in provision of | evolution"]. |
| | policy learning, and 1 | |
| | response indicates no such | ["No. I think on the contrary, I would say we tend to |
| | reviews. | repeat the same mistakes"]. |
| | | |

5. Public participation

Interview analysis suggests high public participation in all three sectors (coded high), though the participants shared concerns on transparency, accessibility, and general lack of response to public comments. In EV sector, of the total eight responses, five indicate high public participation including stakeholders (information and consultation),²⁵ one indicates mixed trend,²⁶ and two did not respond. In groundwater, of the total ten responses, seven indicate an increase in public participation including stakeholder participation (information and consultation), two responses indicate overall low public participation, and one did not respond. However, they expressed mixed views on the effectiveness on such participatory processes.²⁷ In health data, of the total nine responses, seven indicate high public participation including stakeholders (information and consultation) and two indicate low general public participation.

Table 30. Comparative interview analysis of three sectors of India (Public Participation)

| Sector/Sector | In practice | Reference examples of coded interview text |
|-------------------|---------------------------------|---|
| Groundwater | Of 9 responses, 7 indicate high | ["policymaking is becoming more stakeholder |
| | public participation including | friendly'']. |
| | stakeholders and 2 indicate low | |
| | general public participation. | |
| Electric Vehicles | Of 6 responses, 5 indicate high | ["The stakeholders who participate the most |
| | public participation including | are the OE manufacturer, component |
| | stakeholders and 1 indicates | manufacturers, testing agency"]. |
| | mixed trend. | |
| Health Data | Of 9 responses, 7 indicate high | ["I believe, in technology policy in India as |
| | public participation including | opposed to any other (policy) there's a lot of, |
| | stakeholders and 2 indicate low | there's a high degree of public sector |
| | general public participation. | consultations, expert consultations"]. |
| | | |

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²⁵ It includes one response indicating low general public participation.

²⁶ Public participation varies from state to state depending on literacy levels, access to technology, etc.

²⁷ These include variation between federal and state (federal processes more participatory than the states), between states (variation based on literacy levels, technology penetration, etc), and between law and policymaking (policymaking processes more participatory than lawmaking).

6. Adaptive Governance Structures

The interview analysis suggests that EV and groundwater sectors show mixed trends in inter-agency coordination (coded medium) whereas the health data sector shows lack of inter-agency coordination (coded low). In EV sector, of the total eight responses, three indicate inter-agency coordination, two indicate lack of agency coordination, ²⁸ and three did not respond to this aspect. In groundwater, of the total ten responses, four indicate inter-agency coordination, ²⁹ five indicate lack of agency coordination, ³⁰ and one did not respond to this aspect. In health data, of the total nine responses, one indicates interagency coordination, seven indicate lack of agency coordination, ³¹ and one did not respond to this aspect.

Table 31. Comparative interview analysis of three sectors of India (Inter-Agency Coordination)

| Sector/Sector | In practice | Reference examples of coded interview text | |
|-------------------|--|--|--|
| Groundwater | Of 9 responses, 4 responses indicate agency coordination and 5 indicate lack of coordination | ["I think, there is a structure to collaborate. There's a structure to facilitate dialogue and communicate. But I think what is lacking is a strategy"]. | |
| | | ["I would say broadly is that there is an effort to consult the different departments and try to get their viewpoints"]. | |
| Electric Vehicles | Of 5 responses, 3 indicate agency coordination and 2 indicate lack of coordination | ["Especially in the EV sector, there is a lot of collaboration that has happened between Ministry of power in this case and DHI"]. | |
| | | ["there isn't that much feedback and cross talk among agencies"]. | |
| Health Data | Of 8 responses, 1 indicates agency coordination and 7 indicate lack of coordination | ["the sad part of the bureaucracy, to some extent, in my opinion, is that it's still very, very, territorial, so to speak. So, I think interdepartmental collaboration tends to be still much weaker than it should"]. | |
| | | ["There a lot of examples when these committees are formed, they have | |

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²⁸ It includes 1 response (coordination issues between multiple agencies dealing with EVs) and 1 response (delays due to disagreement by different departments on policies).

²⁹ All agencies give feedback to the lead agency driving the law/policymaking process. This process is consultative, therefore the policy/law is largely steered from the perspective of the lead agency's goals and objectives. However, if inter-agency differences persist, there is a mechanism of committee formation to arrive at consensus. In practice, this mechanism is limitedly resorted to.

³⁰ It includes 1 response (different agency policies working cross-purpose with one another, such as the subsidies on water-intensive crops by the Ministry of Agriculture put stress on available water looked after by the Ministry of Water Resources); 2 responses (lack of umbrella structure to coordinate different agencies/departments dealing with water); 2 responses (lack of coordination between water agencies as well as between surface water and groundwater agencies)

³¹ It includes 2 responses (lack of sharing of data); 2 responses (agencies being very territorial in their approach); 2 responses (coordination issues between multiple agencies dealing with health and data) and 1 response (fragmented approach at the policy design stage each agency pitching for its own agenda).

representation from all stakeholders, be it different ministries, be it different associations, be it different departments, state, centre. So that's where that it all comes together'].

D. Summary analysis of political leaders' interviews

As a part of the interviews conducted in India, six political leaders were interviewed. Of the six participants, two are the Members of Parliament (and former Union Ministries) and four are the Members of State Legislative Assembly. Their views are not sector-specific and are summarily presented below. Details may be seen in Appendix II.

- i. In the pre-implementation stage, the adaptive features of assessing risks and assessing impacts of proposed law/policies are limitedly followed in practice. And public participation in law and policymaking is largely considered inadequate.
- ii. In the implementation stage, the M&E is not viewed as a systematic process. It is based on informal channels of information and feedback. The processes are discretionary and subjective resulting in a limited M&E or even complete absence of it. However, the M&E processes are relatively better at the federal level than the state level (Punjab).
- iii. In the post-implementation stage, the participants shared limited examples of pilot programs and phased-implementation of policies. However, they acknowledged that the laws and policies at the federal level are reviewed and changed based on multiple factors including the need to change, stakeholder feedback as well as court judgments. Whereas, changing laws/policies at the state level is time-taking and not undertaken frequently owing to several factors such as vested political interests.
- iv. Regarding the inter-agency coordination, the interviews suggest that generally the agencies work in silos and there are gaps in agency coordination, however, there is a practice of agencies consulting each other in formulating laws and policies.

Overall, at the federal level, the regulatory processes seem to indicate a low degree of adaptiveness in the pre-implementation stage, a moderate degree of adaptiveness in the implementation stage, and a high degree of adaptiveness in the post-implementation stage.

E. Theory and Practice in three sectors

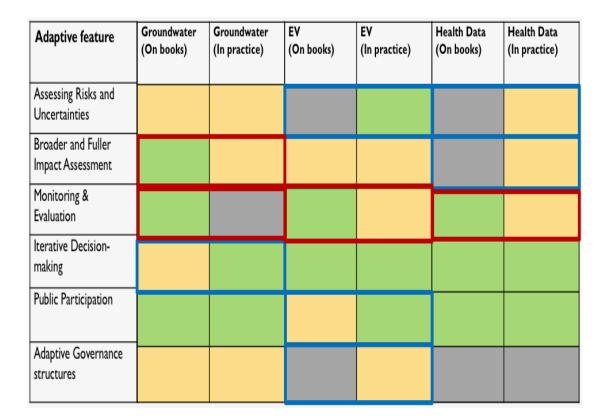


Figure 3. Matrix- Theory and Practice in three sectors of study

| Color code | Highlighted Rectangles |
|------------|---|
| Low | Blue highlight- More adaptive in practice than on books |
| Medium | Red highlight- More adaptive on books than practice |
| High | No highlight- Similarly adaptive on books and in practice |

1. More adaptive in practice than on the books

There are six rectangles in the matrix (highlighted as blue) where the practice is better than the law/policy on the books.

Electric Vehicles- There are three rectangles in EV sector that indicate three adaptive features where the practice is better than the law/policy on the books.

i. Assessing risks and uncertainties- This rectangle indicates very limited examples of relevant provisions on the books (coded low), whereas high-prevalence in practice (coded high) i.e. the agencies assess the risks though qualitatively/ in less structured ways. This gap could be attributed to the absence of a legal mandate to assess risks

in law/policymaking in general, therefore limitedly reflected on the books. However, its prevalence in practice could be attributed to the uncertainties and the fast pace of technological changes inherent in EV sector, thus, resulting in the agencies assessing the uncertainties/risks though in discretionary and variable ways.

- ii. Public participation- This rectangle indicates moderate number of examples of relevant provisions on the books (coded medium), whereas high stakeholder participation in practice (coded high). This gap could be attributed to the absence of a legal mandate to consult public in law/policymaking. Also, the general tendency in government to rely more on the informal mechanisms than formal could result in limited reflection of public participation processes on the books than the actual reality. Further, due to dynamic nature of the sector and a lot of technological issues involved in law/policymaking, the agencies are consulting and collaborating with stakeholders in practice.
- iii. Inter-agency coordination- This rectangle indicates lack of inter-agency coordination on the books (coded low), whereas better agency coordination in practice (coded medium). The limited number of relevant provisions in the EV law/policy documents could be attributed to the absence of a decentralized institutional framework (unlike the groundwater documents which provide for such an institutional framework, thus leading to more examples of inter-agency coordination across different levels of the governments and agencies in groundwater sector). However, better coordination in practice could be attributed to the clear roles and responsibilities of the concerned agencies and the lead role played by NITI Aayog in bringing all agencies together.

Groundwater- There is one rectangle in groundwater sector that indicate one adaptive feature where the practice is better than the law/policy on the books.

i. Iterative decision-making- This rectangle indicates moderate number of relevant provisions on the books (coded medium), whereas, high iterative decision-making in practice (coded high). This gap could be attributed to the lack of adaptability on the books i.e. not acknowledging the need to change, whereas, in practice due to

the worsening groundwater situation, the agencies are revising the policies and guidelines from time to time. Overall, it is a good thing that the policies are changing and are being revised, however these changes and revisions are mostly unplanned, and not based on the formal evaluation of the earlier policies.

Health Data-There are two rectangles in health data sector that indicate two adaptive features where the practice is better than the law/policy on the books.

- i. Assessing risks and uncertainties- This rectangle indicates limited examples of relevant provisions on the books (coded low), whereas moderate prevalence in practice (coded medium) i.e. mixed views on the agencies assessing the risks or not. This gap could be attributed to the absence of a legal mandate to assess risks in law/policymaking in general, therefore limitedly reflected on the books. However, due to inherent uncertainties in this sector e.g. concerns on data privacy and the impact of emerging technologies on data, the agencies are assessing the uncertainties/risks in practice, though in less structured and discretionary ways.
- ii. Broader and fuller impact assessment- This rectangle indicates limited examples of relevant provisions on the books (coded low), whereas, moderate prevalence in practice (coded medium) i.e. mixed views on the agencies assessing the policy impacts in a broader or skewed manner. This gap could be attributed to the absence of a legal mandate to conduct impact assessment in law/policymaking in general, therefore limitedly reflected on the books. Further, this sector is nascent in law/policymaking and most of the analyzed law/policy documents are in draft stage or being updated. However, in practice, due to the dynamic nature of the sector and the inherent uncertainties e.g. concerns on data privacy and the impact of emerging technologies on data, the agencies are assessing the policy impacts though in less structured ways.

2. More adaptive on the books than practice

There are four rectangles in the matrix (highlighted as red) which indicate the law/policy on the books is better than practice.

Electric Vehicles- There is one rectangle in EV sector that indicates one adaptive feature where the law/policy on the books is better than the practice.

i. Monitoring and Evaluation- This rectangle indicates high number of relevant provisions on the books (coded high) whereas, moderate prevalence in practice (coded medium) with mixed views on the quality of M&E processes. This gap could be attributed to several factors, such as less structured M&E processes, transparency, and staff capacities. The agencies are largely monitoring the programs and policies through informal ways such as stakeholder feedback, studies by research bodies, media reports, etc. Though there are examples of the government collecting data and considering reports of the testing agencies. Overall, there is limited planning on relevant data collection and identifying the key performance indicators/ policy outcomes in advance. Lack of transparency is another factor making it difficult to corroborate the agency practices. And lastly, this gap could be partially attributed to the limited skills and capacities of the staff in the government.

Groundwater- There are two rectangles in groundwater sector that indicate two adaptive features where the law/policy on the books is better than the practice.

- i. Broader and fuller impact assessment- This rectangle indicates high number of relevant provisions on the books (coded high) whereas, moderate prevalence in practice (coded medium). This gap could be attributed to the recency of the analyzed documents and also that a few are in draft stage. ³² Therefore, it may be too early to gauge their implementation in practice. Also, the agencies are not transparent about their impact assessments and limited information is available in public domain. Therefore, it is difficult to corroborate the degree of implementation of such impact assessment provisions in practice.
- ii. Monitoring and Evaluation This rectangle indicates high number of relevant provisions on the books (coded high) whereas, limited prevalence in practice (coded low). The above mentioned factors of recency of implementation, the draft

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³² Of the eight documents, three are at draft stage, and of the remaining five, three are legislated/formulated in 2020.

stage of documents, and the difficulty of corroborating agency practices apply here as well. Additionally, the complex interplay of federal and state jurisdictions in regulating groundwater could be attributed to this gap. The Central Ground Water Board monitors and assesses the groundwater situation across the country, however, it has limited regulatory powers and staff constraints to monitor the implementation of the federal guidelines. The State Ground Water Boards and the state government officials play an important role in monitoring though there are challenges including vested interests and the local power dynamics which dilute the process. Additionally, the M&E processes focus more on the project/ program than the policies and within M&E, there is more emphasis on monitoring than evaluation. All these factors among others could be attributed to the low prevalence of M&E in practice.

Health Data-There is one rectangle in health data sector that indicates one adaptive feature where the law/policy on the books is better than the practice.

i. Monitoring and Evaluation- This rectangle indicates high number of relevant provisions on the books (coded high) whereas, moderate prevalence in practice (coded medium) with mixed views on the overall quality of M&E. This gap could be attributed to factors such as less structured M&E processes, gap in setting up monitoring mechanisms, and transparency. In health data, there are mixed examples of the agencies adopting both structured as well as less-structured M&E processes. Agencies are monitoring the programs and policies using the output-outcome monitoring framework as well as through stakeholder feedback and media reports. Further, the M&E mechanisms are set up quite late after the roll out of the policy, thus potentially resulting in the gap. And lastly, this gap could be attributed to the lack of transparency. Limited information in public domain makes it difficult to corroborate the agency practices or claims.

3. Similarly adaptive on the books and in practice

There are eight rectangles in the matrix broadly divided into three categories: (i) Low-Low (where both theory and practice are not good); (ii) Medium-Medium (where both theory and practice are moderate), and High-High (where both theory and practice are good)

Low-Low- Health Data

There is only one such rectangle in the matrix in health data sector which indicates that both the law on the books and in practice is not good.

i. Inter-agency coordination- This rectangle indicates limited number of relevant provisions on the books (coded low) as well as limited inter-agency coordination in practice (coded low). On the books, this could be attributed to the relative absence of a decentralized institutional framework in the analyzed law/policy documents. Though the Ayushman Bharat Digital Mission (ADDM) provides for a federated structure for implementing the mission, the provisions in the documents are not elaborate. Therefore, the identified examples are limited in number (unlike the groundwater documents which provide for a decentralized institutional framework with elaborate provisions, thus leading to more examples of inter-agency coordination across different levels of governments in groundwater sector). In practice, the lack of inter-agency coordination could be attributed to several factors, chiefly being the divided nature of health data as an sector of lawmaking. 'Health' is a state subject and 'data'/ 'technology' is in the federal jurisdiction.³³ However, law and policymaking in health data sector is being led by the federal government. Limited data sharing between the agencies could be another factor leading to less coordination.

Medium-medium- There are three rectangles in the matrix which indicate that both the law on the books and in practice are moderate.

Electric Vehicles- There is one rectangle in EV sector that indicates one adaptive feature where the law/policy on the books and in practice are moderate.

i. Broader and fuller impact assessment - This rectangle indicates moderate number of relevant provisions on the books (coded medium) as well as moderate prevalence in practice (coded medium). Despite the lack of legal mandate to assess impacts in law/policymaking, there are moderate number of provisions identified

³³ 'Data' or 'technology' is not specified in any of the three Constitutional lists which define the lawmaking jurisdictions of the federal and the state governments. However, the federal government has legislated on the Information Technology (IT) matters in the past and including the latest Personal Data Protection Bill 2019.

on the books indicating impact assessment, which is a good thing. In practice, the moderate prevalence is attributed to the mixed views on the agencies conducting broader or skewed assessments. This could be due to the lack of legal mandate, thus, resulting in agencies adopting less standardized practices.

Groundwater- There are two rectangles in groundwater sector that indicate two adaptive features where the law/policy on the books and in practice are moderate.

- i. Assessing risks and uncertainties- This rectangle indicates moderate number of relevant provisions on the books (coded medium) as well as moderate prevalence in practice (coded medium). Despite the lack of legal mandate to assess risks in law/policymaking there are moderate number of provisions indicating risk assessment, which is a good thing. In practice, the moderate prevalence is attributed to the mixed views on the agencies conducting risk assessments or not. This could be due to the lack of legal mandate, thus, resulting in agency discretion to conduct risk assessment or not.
- ii. Inter-agency coordination- This rectangle indicates moderate number of relevant provisions on the books (coded medium) as well as moderate prevalence in practice (coded medium). On the books, the moderate number of relevant provisions is attributed to the decentralized institutional framework provided in groundwater documents, which is higher than the other two sectors. Therefore, not much could be commented on improving the provisions on the books. However, the moderate prevalence in practice could be attributed to the siloed approach of agency working and failure to see the big picture impact of multiple policies. In practice, the agencies hold inter-ministerial consultations and get feedback on the proposed law/policy by all departments/ agencies. However, the consultations seem to miss out the larger picture which is evidenced by the existence of policies that sometimes work cross-purpose. This highlights the need to strengthen the existing inter-ministerial consultation process.

High-high - There are four rectangles in the matrix which indicate that both the law on the books and the law in practice are high.

Electric Vehicles- Thee is one rectangle in EV sector that indicates one adaptive feature where the law/policy on the books and in practice are high.

i. Iterative decision- making- This rectangle indicates high number of relevant provisions on the books (coded high) as well as high prevalence in practice (coded high). On the books, provisions include review of the policy, review of specific provisions, flexibility to change the provisions in the future, pilot programs and phased implementation. In practice, the iterative decision-making is attributed to factors including planned reviews, stakeholder feedback, new developments such as court rulings, and post-implementation issues such as deferral of timelines to meet with changed circumstances. It is good that the laws and policies are changing/ reviewed over time. However, most of the revisions are not based on the formal evaluation of the earlier policies. Also, in case of the planned reviews, the information on the processes adopted or other details are not available in public domain.

Groundwater- There is one rectangle in groundwater sector that indicates one adaptive feature where the law/policy on the books and in practice are high.

i. Public Participation- This rectangle indicates high number of relevant provisions on the books (coded high) as well as high prevalence in practice (coded high). On the books, despite the absence of a mandatory public notice and comment, there is evidence of the agencies following the same in most cases. Also, there are provisions indicating four levels of public participation- inform, consult, involve, and empower. In practice also, the evidence suggests an increase in public participation including stakeholder engagement. However, there are concerns of language barriers (draft law/policies mostly published in English and Hindi thus posing barrier for the population which does not understand these languages), transparency, and lack of response to public comments.

Health Data- There are two rectangles in health data sector that indicate two adaptive features where the law/policy on the books and in practice are high.

- i. Iterative decision-making This rectangle indicates high number of relevant provisions on the books (coded high) as well as high prevalence in practice (coded high). On the books, provisions include review of the policy, regulatory sandboxes, agile framework, pilot program and phased implementation. In practice, the iterative decision-making is attributed to factors including learning from pilot implementation, stakeholder feedback, National Health Authority's iterative policy papers, regulatory sandboxes and testbeds for testing new technologies as well as new developments. It is good that the laws and policies are learning from implementation and keeping provisions for introducing changes in future. However, considering the nascence of law/policymaking in this sector, it is an opportunity to build a culture of learning based on planned ex-post reviews of the laws/policies.
- ii. Public Participation- This rectangle indicates high number of relevant provisions on the books (coded high) as well as high prevalence in practice (coded high). On the books, despite the absence of a mandatory public notice and comment, there is evidence of the National Health Authority engaging public through iterative policy consultation papers. Also, there are provisions indicating four levels of public participation- inform, consult, involve, and collaborate. In practice, the evidence suggests high public participation including stakeholder engagement and consulting public on iterative policy consultation papers. However, there are concerns of transparency and lack of response to public comments.

Based on the above analysis, following are the sectors where the law on the books and the law in practice need to be improved.

Table 32. Improvement in theory and practice in three sectors of India

| Sector | Improve law on the books | Improve law in practice | Improve both law on the books and in practice | Best performance on the books and in practice |
|----------------------|-----------------------------------|----------------------------|---|---|
| Electric Vehicles | Assessing risks and uncertainties | Monitoring & Evaluation | Broader and fuller impact assessment | Iterative decision- making |
| | Public Participation | | | |
| | Inter-agency coordination | | | |
| Groundwater | Iterative decision- making | Monitoring & Evaluation | Assessing risks and uncertainties | Public Participation |

| | | Broader and fuller impact assessment | Inter-agency coordination | |
|-------------|-----------------------------------|--|------------------------------|-------------------------------|
| Health Data | Assessing risks and uncertainties | Monitoring & Evaluation | Inter-agency coordination | Iterative decision- making |
| | Broader and fuller | | | Public Participation |

Overall, the three sectors vary immensely in their law/policies and the agency practices, therefore, it is difficult to draw generalizations across the sectors. However, based on the documentary and interview analysis, it could be concluded that monitoring and evaluation (M&E) is one feature where all three sectors show a gap in practice. Further, iterative decision-making is indicated to be high in practice in all three sectors. However, across the sectors, the interview analysis also suggests that these iterations and policy revisions are not informed by formal policy evaluations. Therefore, this finding connects back with the less effectiveness of M&E in practice.

4. Recommendations for three sectors

Based on the above summary table, following are the recommendations applicable to all three sectors. In case, the recommendation is applicable only to one particular sector, it is specified in the parentheses.

- i. Introduce risk assessment and impact assessment in law/policy making as tools of structured decision-making to optimize regulatory learning. (All three sectors)
- ii. Improve M&E processes by planned data collection, emphasize on policy evaluation, and require the use of M&E data to inform future policies. (All three sectors)
- iii. Introduce built-in provisions of periodic review of law/policies. Groundwater sector could potentially learn from the examples of iterative decision-making in the EV and health data laws/policies. (Groundwater)
- iv. Make law/policymaking process more participatory such as by mandating prelegislative public consultation and building in provisions to engage public in various stages of law/policymaking. EV sector could potentially learn from the examples of public participation provisions in the groundwater and health data laws/policies.

(Electric Vehicles)

v. Strengthen inter-agency coordination by introducing 'multi-policy reviews.' Form inter-agency working groups to identify the rules/policies impacting more than one agency and conduct reviews to assess their collective impact. (All three sectors)

II. Normative Analysis

A. Overview

The following section presents a normative framework of adaptive regulations which is developed based on the literature review of the recommended best practices. Further, it builds on the high level comparative analysis of the US and India's regulatory cycle included in the earlier three chapters such as by comparing the actual and the ideal regulatory practices in US and India and summarizing the potential lessons for the two countries.

B. Normative Framework of Adaptive Regulations

The normative framework is informed by the best practices in regulatory space and builds on the recommendations of international bodies and academic researchers. Considering the comparative analysis of the US and India, the best practice examples are taken primarily from the OECD and European Commission, and academic research studies. Based on the literature review, the recommendations/ best practices are identified for each of the six broad features of adaptive regulatory cycle.³⁴

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³⁴ Note: For simplicity, the recommendations are listed feature-wise. Not all the listed practices/recommendations are mutually exclusive and there could be overlap within/ across the features.

Adaptive Regulation Assessing Risks Broader and Fuller Public Monitoring and Iterative Inter Agency and Uncertainties Impact Assessment Decision-making Participation Coordination **Evaluation** M&E as an Independent Risk focused and decision-making by agencies integrated part of assessment in all risk proportional regulations of ex-post reviews information regulatory stages policy cycle Policies with clear Institutiona Institutional Right to Communicating Objective and problem identification and mechanism of with other framework for M&E participate in data driven risk conducting exagencies decision-making assessment post reviews Right to review Consulting other Identifying data and indicators Multi-risk Full portfolio Criteria to identify procedure (access to justice) agencies assessment and regulations for ex-Avoiding management post review Simple and flexible differences Outcome-based Criteria to identify methodology Multiple-rule between agend regulations with risk as an indicator policies for M&E assessment Stakeholder Finding interengagement and communication of results Criteria of Considering all resources for exevidence on risk post reviews divergencies objective and Behavioral insights subjective Public participation and between agencies in policy making Culture of M&E and learning Transparent public Determining clear government priorities dissemination of Independent regulatory M&F information oversight body Guidance on publicly available Whole of Enabling Enabling retrospective government strategy reviews legislation

Normative Elements of

Figure 4. Normative Elements of Adaptive Regulation

1. Best practices in assessing risks and uncertainties

The identified best practices/ recommendations are given in the table followed by detailed description.

Table 33. Best Practices/ Recommendations (Risk and Regulations)

| Best practices/ Recommendations | Source |
|---|---|
| Regulations designed in a risk-focused and risk proportional way | OECD (2021) |
| Objective and data-driven risk assessment | OECD (2021) |
| Multi-risk assessment and multi-risk management | Wiener (2020) |
| Outcome-based regulations with risk as an indicator | OECD (2021), Blanc (2018) |
| Policymaking informed by all relevant evidence on risk (objective and subjective) | Aven and Renn (2018) |
| Transparent public engagement on risk | OECD (2021), De Benedetto, M. (2018), Aven and Renn (2018) |
| Enabling legislation for risk-based regulation | OECD (2021) |

i. Regulations designed in a risk-focused and risk proportional way- While designing regulations, decision-makers should focus on both risk-prioritization and their proportionality. In general, risk-based prioritization focuses on prioritizing the resources commensurate with the level of risk (such as priority to the highest level of risk followed by the lower levels of risk). Whereas, risk-proportionality considers both the level and the characteristics of risks to determine the most appropriate

choice of regulatory instruments (e.g. permits, certification, registration) and the content for regulations (e.g. level of standards).³⁵

- ii. Risk assessment in an objective and data-driven way- To the extent possible, decision-makers should emphasize better use of existing data to assess risks. With the development of digital governments, spread of technology, development of capacities in the governments, and breakthrough in computing power, data-based risk assessments are easier to adopt. ³⁶
- iii. Multi-risk assessment and multi-risk management- Decision-makers should acknowledge the reality of a multi-risk world where people are exposed to multiple risks at a time. Therefore, risk assessment should transition from assessing one risk at a time to cumulative risk assessment. Similarly, in risk management, the decision-makers should acknowledge a multi-risk reality, consider risk holistically, plan and weigh multiple potential consequences for each of the regulatory alternatives, choose alternatives that reduce the overall risk, and innovate to choose 'risk superior moves' that reduce multiple risks. ³⁷
- iv. Outcome-based regulations with risk as an indicator- Decision-makers should consider designing outcome-focused regulations based on risk. For example, instead of measuring compliance/ non-compliance, the outcomes could be defined in terms of risk mitigation thus, enabling meaningful compliance as well as achieving regulatory goals.³⁸
- v. Policymaking informed by all relevant evidence on risk- Decision-makers should consider all evidence on risk (both objective and subjective) from all relevant stakeholders. This includes considering data and statistics, as well as knowledge in terms of justified beliefs. These beliefs could be based on observations, modeling, reasoning, dialogue, etc.³⁹

³⁵ OECD Regulatory Policy Outlook. (2021). OECD iLibrary. Chapter 6. Risk-based regulation: Making sure that rules are science-based, targeted, effective and efficient.

³⁷ Jonathan B. Wiener. (2020). Learning to Manage the MultiriskWorld. Risk Analysis, Vol. 40, No. S1.

³⁸ Blanc, F. (2018), "Tools for Effective Regulation: Is "More" Always "Better"?", European Journal of Risk Regulation, Vol. 9/3, pp. 465-482. Also, *see*, OECD, 2021, *supra* note 35.

³⁹ Aven, Terje and Renn, Ortwin. (2018). Improving government policy on risk. Reliability Engineering and System Safety 176, 230-241.

- vi. Transparent public engagement on risk- Public engagement on risk is important for the success of risk-based regulations. Decision-makers should go beyond merely communicating the risk to inviting and responding to the public inputs on risk. 40 Recent research suggests that non-risk based/ non-risk proportional regulatory approaches (such as rigid approaches to achieve the ideal zero-risk scenario) contribute to reduced public trust in the government instead of strengthening it. 41
- vii. Enabling legislation for risk-based regulation- An enabling legislation helps in establishing the legal foundations for risk-based regulations and in overcoming legal bottlenecks due to existing laws/provisions. Another related aspect is of 'political buy-in' which is an important factor in the successful adoption and implementation of the risk-based regulations.⁴²

2. Best practices of Broader and Fuller impact assessment

The identified best practices/ recommendations are listed in the table followed by detailed description.

Table 34. Best Practices/ Recommendations (Impact Assessment)

| Best practices/ Recommendations | Source |
|--|--|
| Regulatory impact assessment (RIA) integrated in all | OECD (2021), OECD (2020) |
| stages of regulatory process | |
| Policies with clearly defined problem and objectives | OECD (2021), OECD (2020), World Bank Group (2010) |
| 'Full' portfolio assessment | OECD (2021a), OECD (2020), Wiener (2020), Revesz |
| • | and Livermore (2020, 2008), Graham & Wiener (1995) |
| Simple and flexible methodology | OECD (2020) |
| RIA proportional to the significance of regulation | OECD (2020), World Bank Group (2010) |
| Applying behavioural insights (BI) in policymaking | OECD (2021a), OECD (2019) |
| Stakeholder engagement and communication of | OECD (2021), OECD (2020), World Bank Group |
| assessment results | (2010) |
| An independent regulatory oversight body | OECD (2021a), OECD (2020), World Bank Group |
| | (2010) |
| Enabling legislation requiring RIA | OECD (2020), World Bank Group (2010) |

i. An integrated Regulatory impact assessment (RIA) - A stand-alone RIA is not a success unless integrated in the entire regulatory cycle right from the design stage

⁴⁰ See, OECD, 2021, supra note 35 and Aven and Renn, supra note 39.

⁴¹ De Benedetto, M. (2018). Effective Law from a Regulatory and Administrative Law Perspective, European Journal of Risk Regulation. 9(3), 391-415.

⁴² See, OECD, 2021, supra note 35.

to post-implementation. Additionally, it should be integrated with other existing regulatory management tools such as of data collection, monitoring and evaluation, relevant assessments done as a part of budget process, etc.⁴³

- ii. Policies with clearly defined problem and objectives- For successful RIAs, it is important to define the policy context and objectives and clearly articulate the underlying cause(s) of the identified policy problem.⁴⁴ Research suggests that poor problem identification such as not identifying the failure of public institutions or private markets underlying the need for regulatory action contributes to lower net benefits than correctly identifying them.⁴⁵
- iii. 'Full' portfolio assessment- The decision-makers should consider the entire portfolio of potential solutions including regulatory and non-regulatory. ⁴⁶ Further, while assessing the impacts of potential solutions, scholars recommend doing the full impact analysis including countervailing harms and co-benefits. ⁴⁷ They emphasize the need of adopting non-siloed and holistic approaches which internalize the full impacts akin to 'treating the whole patient' concept of medicine. ⁴⁸
- iv. Simple and flexible methodology- RIA methodology should be appropriate to the administrative context and capacities, not always the full-fledged quantitative costbenefit analysis.⁴⁹ The methodology should be targeted and flexible but ensure certain key features are covered such as identifying all possible direct and indirect impacts of regulation and its alternatives to address the policy problem.⁵⁰

⁴³ OECD Regulatory Policy Outlook. (2021). OECD iLibrary. Chapter 2. Evidence-based policy making and stakeholder engagement. Also, see, OECD. (2020). Regulatory Impact Assessment, OECD Best Practice Principles for Regulatory Policy, OECD Publishing, Paris, https://dx.doi.org/10.1787/7a9638cb-en.

⁴⁴ World Bank Group. (2010). Global Indicators of Regulatory Governance: Worldwide Practices of Regulatory Impact Assessments. (English). Washington, D.C. Also, *see*, OECD, *supra* note 43.

⁴⁵ Dudley, S. et al. (2017). Consumer's Guide to Regulatory Impact Analysis: Ten Tips for Being an Informed Policymaker. Journal of Benefit-Cost Analysis, 8 (2), 187-204.

⁴⁶ See, OECD (2020), supra note 43. Also, see, OECD. (2021a). Regulatory Policy Outlook. Regulatory policy 2.0. OECD iLibrary.

⁴⁷ See, Wiener, supra note 37. Also, see, Graham, J. D. and Wiener J. B. (Eds.) (1995). Risk vs risk: Tradeoffs in protecting health and the environment. Cambridge, MA: Harvard University Press. Also, see, Revesz, R. L., & Livermore, M. A. (2008). Retaking rationality. Oxford: Oxford University Press, and Revesz, R. L., & Livermore, M. A. (2020). Reviving rationality. Oxford: Oxford University Press.

⁴⁸ See, Wiener, supra note 37.

⁴⁹ See, OECD (2020), supra note 43.

⁵⁰ *Id*.

v. RIA proportional to the significance of regulation- Implementing RIA should be proportional to the extent of regulatory impact of the regulation.⁵¹ This could be based on a variety of factors, such as setting quantitative thresholds (e.g. regulations with economic impact of more than X amount of money), or setting multiple criteria (e.g. defining the extent of economic, social, and environmental impacts), or introducing a two-step approach – a preliminary RIA to screen /identify regulations that needs a detailed RIA. However, all such criteria should be transparent and publicly shared.⁵²

vi. Learnings from behavioural insights in policymaking-Behavioural insights (BI) are based on the principles of psychology, cognitive science, and social sciences and anticipate the behavioural consequences of the policies.⁵³ The BI approach focuses on how the decision-makers' bias and context influences policymaking, thus, BI informed strategies could guide in designing better and effective policies.⁵⁴

vii. Stakeholder engagement and communication - RIA should have a systematic process of engaging stakeholders in the regulatory process from early stages. It enables conducting better impact assessments in various ways, such as getting important information and data from the stakeholders, inputs on the feasibility of proposals and alternatives, feedback on the likelihood of compliance to the proposed regulation, strengthening assumptions and data used in RIA, etc.⁵⁵ Further, the results of RIA should be communicated in a simple and easy to understand manner by not obfuscating crucial information or skewing the analysis.⁵⁶

viii. An independent regulatory oversight body - A regulatory oversight body is essential for the successful RIA adoption. This body should have a clear mandate and be independent from the agency whose draft regulations it assesses/ reviews.⁵⁷

⁵¹ See, OECD (2020), supra note 43. Also, see, World Bank Group, (2010), supra note 44.

⁵² Id.

⁵³ OECD, 2019, Tools and Ethics for Applied Behavioural Insights: The BASIC Toolkit, OECD Publishing, Paris, https://doi.org/10.1787/9ea76a8f-en.

⁵⁴ See, OECD 2021a, supra note 46.

⁵⁵ See, OECD (2021 and 2020), supra note 43. Also, see, World Bank Group, (2020), supra note 44.

⁵⁶ See, Dudley, S. et al., supra note, 45.

⁵⁷ See, OECD (2020), supra note 43.

Through their active role, such bodies could oversee the quality of regulatory reviews, agency compliance, and coordinate implementation of other regulatory management tools.⁵⁸

ix. Enabling legislation- A legislation requiring RIA helps in consolidating the adoption and implementation of RIA. It also reflects the 'political buy-in' and government commitment to regulatory reforms which includes garnering stakeholder support.⁵⁹

3. Best practices in Monitoring and Evaluation

A robust M&E framework is important to ensure that the government policies are achieving their intended goals. The identified best practices/ recommendations are listed in the table followed by detailed description.

Table 35. Best Practices/ Recommendations (Monitoring & Evaluation)

| Best practices/ Recommendations | Source |
|--|--------------------------|
| M&E as an integrated part of policy cycle | EC (2021), Lazaro (2015) |
| Institutional framework for M&E | EC (2021), OECD (2017) |
| Identifying data and indicators absolutely necessary for monitoring policy | EC (2021), OECD (2020) |
| performance | OECD (2019a) |
| Established criterion to identify policies for M&E | OECD (2019) |
| Established criterion of evaluation | EC (2021) |
| A culture of M&E and learning | OECD (2017), Lazaro |
| | (2015) |
| M&E information readily available to the public | Lazaro (2015), OECD |
| * | (2015) |

- i. M&E an integrated part of policy cycle- Monitoring and evaluation should be builtin the policy cycle and implemented across all stages of a policy/regulation.⁶⁰ Monitoring is necessary to generate data which feeds into evaluation, thus, providing the evidence for policymaking as well as policy revisions.⁶¹
- ii. Institutional framework for M&E- An institutional framework provides the legal mandate to undertake M&E. It should clearly identify the institutional actors responsible for collecting and disseminating information along with allocated

⁵⁸ Id. Also, See, OECD (2021a), supra note 46, and World Bank Group, (2020), supra note 44.

⁵⁹ See, OECD (2020), supra note 43. Also, see, World Bank Group, (2020), supra note 44.

⁶⁰ Lazaro, B. (2015), Comparative Study on the Institutionalization of Evaluation in Europe and Latin America, Eurosocial.

⁶¹ European Commission. (2021). Better Regulation Toolbox. Chapter 5- Monitoring the application of interventions. Tool # 43.

resources for carrying out M&E.⁶² Additionally, it should specify how and when the information will be collected, including the time of evaluation.⁶³ Further, there could be a centralized body/institution for developing a whole-of-government M&E through conduct of M&E across the agencies and promoting the use and quality of M&E.⁶⁴

- iii. Identifying data and indicators for policy performance- It is important to plan relevant data collection at the design stage of a regulation. For example, identifying and collecting data which reflects the regulatory outcomes than merely inputs or outputs. Identifying the relevant data at the outset improves monitoring and evaluation in implementation and post-implementation stages.⁶⁵
- iv. Established criterion to identify policies for M&E- The government could establish criteria to identify the policies which should be monitored and evaluated. For example, it could be based on the government priorities or the budgetary thresholds.⁶⁶
- v. Established criterion of evaluation- It is important to establish the criteria of evaluation for transparency and comparability of impact assessments. Such as EU's evaluation is based on five criteria- efficiency, effectiveness, relevance, sustainability, coherence, EU value-added.⁶⁷
- vi. A culture of M&E and learning- Steps should be taken to foster a culture of M&E among the public officials and the stakeholders, such as by promoting the quality of M&E, using the results of evaluation across government, capacity building of government officials, and establishing stakeholder engagement mechanisms.⁶⁸

⁶² OECD. (2017). Recommendation of the Council on Open Government, (14 December 2017). Available at https://www.oecd.org/gov/Recommendation-Open-Government-Approved-Council-141217.pdf.

 ⁶³ European Commission. (2021). Better Regulation Toolbox. Legal Provisions on M&E. Tool # 42 at 310.
 ⁶⁴ OECD. (2019). OECD Public Governance Reforms. Open Government in Biscay. Chapter 4. Building a monitoring and evaluation framework for open government.

⁶⁵ See, OECD (2020), supra note 43. Also, see, EC (2021), supra note 61, and, see, OECD, (2019a), The path to becoming a data-driven public sector, Paris, https://dx.doi.org/10.1787/059814a7-en.

⁶⁶ See, OECD (2019), supra note 64.

⁶⁷ See, EC (2021), supra note 61.

⁶⁸ See, OECD (2017), supra note 62, and Lazaro, supra note 60.

vii. M&E information available to the public- The results of monitoring and evaluation should be used by decision-makers, both political and managerial. These results should be made available to the public.⁶⁹ This is in in-sync with the open government reforms of OECD which aims to improve citizen participation in policy cycle.⁷⁰

4. Best practices in Iterative decision-making

The identified best practices/ recommendations are listed in the table followed by detailed description.

Table 36. Best Practices/ Recommendations (Ex-post reviews)

| Best practices/ Recommendations | Source |
|--|--|
| Built-in provision of ex-post review | Bennear and Wiener (2021a), Bennear and Wiener |
| · · | (2019a,b), Dudley and Katzen (2019), Cropper et al. |
| | (2017), Miller (2015), Aldy (2014), McCray et al. (2010) |
| Institutional mechanism of conducting/ reviewing | Bennear and Wiener (2021a,b), Dudley and Mannix |
| ex-post reviews (e.g. third party) | (2018), Balleisen et al. (2017), Aldy (2014), Mandel & |
| | Carew (2013) |
| Established criterion to identify regulation/ policy | Bennear and Wiener (2021a), Bull (2015), Aldy (2014) |
| for ex-post review | |
| Multi-rule assessment | Bennear and Wiener (2021a), EC (2021), Wiener |
| | (2020), Aldy (2014) |
| Allocated resources for ex-post reviews | Bennear and Wiener (2021a), Aldy (2014) |
| Public participation and dissemination of results | Bennear and Wiener (2021a), Aldy (2014) |
| Guidance on retrospective reviews by an | Bennear and Wiener (2021), Cropper et al. (2017), Aldy |
| independent regulatory oversight body | (2014) |

i. Built-in provision of ex-post review - Creating built-in provisions of ex-post review while designing the regulations strengthens the agency incentive to conduct such reviews.⁷¹ This should include a prospective plan for relevant data collection and monitoring along with specific periodicity of reviews where appropriate (such as

⁷⁰ OECD (2015), OECD Survey on Open Government Co-ordination and Citizen Participation in the Policy Cycle.

⁶⁹ See, Lazaro, supra note 60.

⁷¹ Bennear, Lori S. and Wiener, Jonathan B. (2021a). Institutional Roles and Goals for Retrospective Regulatory Analysis. Journal of Benefit-Cost Analysis, 12, 466-493. Also, *see*, Aldy, Joseph E. (2014). Learning from Experience: An Assessment of the Retrospective Reviews of Agency Rules and the Evidence for Improving the Design and Implementation of Regulatory Policy. Report prepared for the Administrative Conference of the United States, November 18, 2014, and *see*, Miller, Sofie E. (2015). Learning from Experience: Retrospective Review of Regulations in 2014. The George Washington University Regulatory Studies Center, and *see*, Cropper, Maureen, Arthur Fraas, and Richard Morgenstern. (2017). Looking Backward to Move Regulations Forward. Science, 355(6332), 1375–1376, and *see*, Dudley, Susan, and Sally Katzen. (2019). Crossing the Aisle to Streamline Regulation. Wall Street Journal, May 13, 2019.

determining the periodicity based on the value of new information and its associated cost).⁷²

- ii. Institutional mechanism for ex-post reviews There should be an institutional mechanism to evaluate the ex-post reviews of agencies and give recommendations such as an independent body or an inter-agency group/ committee. Such a body should have expertise and mandate to follow up with agencies on its recommendations.⁷³
- iii. Established criterion to identify regulation/policy for ex-post review- The rules could be selected for retrospective review based on a variety of factors, such as where there is a likelihood to improve the net social benefits including magnitude of benefits; where there is uncertainty about the ex-ante estimates of costs and benefits; and where the rules relate to changing economic and technological conditions.⁷⁴ Further, the rule selection could be informed by public input in the form of comments, complaints, or suggestions on the rule selection.⁷⁵
- iv. Multi-rule assessment- Generally, the agencies adopt single-rule assessment which is too narrow in its scope, such as evaluating the rule relevance or its costs and how the cost could be reduced. Whereas, multi-rule assessment is quite broad in its scope and helps improve regulatory learning, such as by evaluating the interactive impacts of multiple rules (cumulative regulatory burden);⁷⁶ focusing not only on

⁷² Bennear, Lori S., and Wiener, Jonathan B. 2019a. "Built to Learn: From Static to Adaptive Environmental Policy." In Daniel C. Esty (ed.) A Better Planet: Forty Big Ideas for a Sustainable Future. New Haven, CT: Yale University Press. Also, see, Bennear, Lori S. and Wiener, Jonathan B. (2019b). Adaptive Regulation: Instrument Choice for Policy Learning over Time, Draft working paper. and see, McCray, et al., (2010). Planned Adaptation in Risk Regulation: An Initial Survey of US Environmental, Health, and Safety Regulation. Technological Forecasting and Social Change, 77(6), 951–959. ⁷³ See, Bennear and Wiener, *supra* note 73. Also, *see*, Lori S. Bennear and Jonathan B. Wiener, Periodic Review of Agency Regulation (2021b) (report to the Admin. Conf. of the U.S.), and, see, Mandel, Michael, and Carew, Diana G. (2013). Regulatory Improvement Commission: A Politically-Viable Approach to US Regulatory Reform. Progressive Policy Institute, 3, 1–24, and see, Aldy, supra note, 73, and see, Dudley, Susan E., and Mannix, Brian F. (2018). Improving Regulatory Benefit-Cost Analysis. The Journal of Law and Politics, 34 (1), and see, Balleisen, Edward J. et al., (2017). Institutional Mechanism for Investigating the Regulatory Implications of a Major Crisis: The Commission of Inquiry and the Safety Board. In Balleisen, Edward J., Lori S. Bennear, Kimberly D. Krawiec, and Jonathan B. Wiener (Eds.) Policy Shock: Recalibrating Risk and Regulation after Oil Spills, Nuclear Accidents, and Financial Crises. Cambridge: Cambridge University Press.

⁷⁴ See, Aldy, supra note, 71. Also see, Bennear and Wiener, 2021a, supra note, 71, and see, Bull, Reeve T. 2015. "Building a Framework for Governance: Retrospective Review and Rulemaking Petitions." Administrative Law Review, 67: 265.

⁷⁵ Id.

⁷⁶ See, Aldy, supra note, 71.

the cost of the rule but also its benefits including ancillary impacts (unintended consequences as well as co-benefits); and improving the methodologies for ex-ante impact estimates among others.⁷⁷

- v. Allocated resources for ex-post reviews- Without adequate staff and budget, agencies with limited resources may perceive conducting ex-post reviews as an additional burden. Therefore, agency allocation of resources is important to serve as an incentive to conduct retrospective reviews and improve the overall quality of reviews.⁷⁸
- vi. Public participation and dissemination of results- Agencies should proactively engage public in ex-post reviews, such as seeking public input on the rule effectiveness, including impact on the economy, and interplay with other regulations as well as soliciting data and analysis from stakeholders/ academic researchers.⁷⁹ Further, the results of reviews should be publicly disseminated to promote replication of agency analyses along with running additional analyses of the rule's effectiveness.⁸⁰
- vii. Guidance on conducting retrospective reviews- Guidance from a regulatory oversight body could support agencies in adopting consistent approaches to conduct as well as institutionalize retrospective reviews. Such unifying guidance documents could focus on selecting the rules, establishing baselines and counterfactuals, identifying the scope of impacts to be assessed, identifying appropriate methodology, among others. See

⁷⁷ See, Wiener, 2020, supra note 37. Also, see, Bennear and Wiener, 2021a, supra note 71, and see, European Commission (EC). (2021). Better Regulation-Joining Forces to make better laws, at 18,19. ("Fitness checks of entire policy sectors (rather than evaluations of specific legislative acts) are particularly useful in this regard. Apart from assessing the extent to which a policy initiative is achieving its objectives, they look at the cumulative impacts of legislation, overlaps and inconsistencies, and so give a more complete picture of the benefits brought to and burdens borne by businesses, individuals and public administrations").

⁷⁸ See, Bennear and Wiener, 2021a, and Aldy, supra note, 71.

⁷⁹ *Id*.

⁸⁰ Id.

⁸¹ See, Aldy, supra note, 71.

⁸² See, Bennear and Wiener, 2021a, and Cropper, et al., supra note 71.

5. Best practices in Public Participation

The United Nations Economic Commission for Europe (UNECE) Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters was adopted in 1998 at Aarhus (called the Aarhus Convention).⁸³ This convention established a number of public rights regarding environment and required public authorities to make provisions to give effect to the identified public rights. Considering the relevance of this convention to the research study (from the lens of effective public participation), its key provisions are being used for the normative analysis.

The convention provides three rights to the public:

- i. Access to information- It includes the right to access information held by the public authorities within a stipulated time of requesting such information. It also includes proactive dissemination of information by the public authorities;
- ii. Participation in decision-making- It includes the right to participate in environmental decision-making through comment by the affected public and the non-governmental organizations. The public authorities should consider these comments in decision-making and inform the public about the final decision, along with reasons;
- iii. Access to justice- It includes the right to review procedures to challenge decisions made in violation of the above two rights.⁸⁴

Table 37. Best Practices/ Recommendations (Public Participation)

| Rights | Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters | | |
|----------------------------------|---|--|--|
| Access to information | Right to access information held by the public authorities within a stipulated time; proactive dissemination of information by the public authorities | | |
| Participation in decision-making | Right to participate in environmental decision-making; notice and comment; consider comments in decision-making; inform the final decision with reasons | | |
| Access to justice | Right to review procedures to challenge decisions made in violation of above two rights | | |

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⁸³ United Nations Economic Commission for Europe. (1998). Aarhus Convention.

⁸⁴ *Id.* Also, *see*, The Council of the European Union. (2005). Council Decision. Official Journal of the European Union.

6. Best practices in Inter-Agency coordination

The following levels of inter-agency are based on the modified Metcalfe scale of Inter-agency coordination. So Over time, OECD has refined and built on the Metcalfe scale in its work on policy coordination. The scale has 9 levels ranging between the agencies taking independent decisions to the government establishing clear priorities as a part of holistic strategy. It is a useful tool to address inter-agency coordination from a center of government perspective. However, the tool has limitations such as, in practice, the interagency coordination does not follow a unified pattern of progress as indicated in the scale. Such limitations could be attributed to the inherent complexity of the topic as well as limited academic work on it. (The words Ministry/ Agency are used inter-changeably in the analysis)

Table 38. Best Practices/ Recommendations (Agency Coordination)

| Levels of Inter-Agency coordination | Source: Modified Metcalfe scale-Dogaru and Matel (2012), World Bank (2019) | |
|--|--|--|
| Agencies take independent decisions | Agencies acting independently in their public policy domain | |
| Agencies communicate with other agencies | Agencies exchanging information | |
| Agencies consult with other agencies | Agencies consulting in formulating policies | |
| Avoid differences between agencies | Agencies not taking divergent positions and government acting | |
| | with one voice | |
| Finding inter-agency agreement | Agencies reaching consensus on complementary policies | |
| Judging the divergences between | Resolving differences by a third actor (e.g., a central agency) | |
| agencies/actors | | |
| Setting the parameters for organizations | Defining agencies discretion (e.g. by a central actor/agency) | |
| Governmental prioritization | Determining clear government priorities after collaboration | |
| Overall government strategy | Developing whole of the government strategy | |

- Ministries take independent decisions- Each agency/ Ministry is independent in its public policy domain and plays a major role in decision-making in its respective domain.
- ii. Ministries communicate with other ministries- The agencies exchange information such as about important issues the agency is dealing and the way it approaches the policy problems in its domain. This could be done in a variety of ways such as by developing information systems accessible to other agencies.

⁸⁵ World Bank Group. (2018). Improving Public Sector Performance: Through Innovation and Inter-Agency Coordination. Global Report Public Sector Performance;. World Bank, Washington, DC. Also, see, Matei, Ani and Dogaru, Tatiana C. (2012). Coordination of Public Policies in Romania. An Empirical Analysis. 1st World Congress of Administrative & Political Sciences (ADPOL-2012). Procedia - Social and Behavioral Sciences 81 (2013) 65 – 71.

⁸⁶ Metcalfe, L. (1994). "International Policy Co-ordination and Public Management Reform." International Review of Administrative Sciences 60, 271–290.

- iii. Ministries consult with other ministries- This is the next level where the communication between agencies is bi-directional. Such as the agencies while formulating policies consult other agencies and solicit their views and provide feedback on the proposals.
- iv. Avoid differences between ministries- At this level of coordination, divergences are avoided and the government acts with one voice, through processes like the agencies discussing and directly contacting other agencies before finalizing the policies and sharing in the public.
- v. Finding inter-ministerial agreement- This level of coordination recognizes the mutual interest and inter-dependence. The agencies work together to find consensus on complementary policies and achievement of common goals, such as through committees and working groups.
- vi. Judging the divergences between actors- There could be deeper divergences between the agencies that may not be resolved through earlier stated levels of coordination. To address such impasses, there is a third actor who judges the interministerial differences and resolves them.
- vii. Setting the parameters for organizations- At this level, there is a central body that sets parameters for all agencies/ministries including setting limits on their policy discretion by defining what they must not do.
- viii. Governmental prioritization- At this level, the government sets clear priorities with clear set of expectations for the agencies/ ministries. This is a deeply analytical and a collaborative process unlike issuing a party manifesto or a government mission statement.
 - ix. Overall government strategy- The government has a comprehensive strategy with clearly defined roles and responsibilities for all agencies/departments, such as a strategic framework for all public policies.

C. Comparing actual and ideal adaptive regulatory practices in the US and India

This section compares the actual and the ideal adaptive regulatory practices in the US and India. The ideal is informed by the normative framework components. The actual is based on the documentary analysis, interview analysis, and literature review.⁸⁷ The prevalence of actual practices is divided into three categories- low, medium, and high, each given different colors for distinction- grey indicates low prevalence, yellow indicates medium prevalence, and green indicates high prevalence.

| Prevalence of normative practices in US and India | Color code |
|---|------------|
| Low | |
| Medium | |
| High | |

This categorization is subjective and based on the author's judgment of the review of the entire evidence gathered as a part of the research study. Certain practices are not color-coded and kept blank due to the limited availability of information.

1. Assessing risks and uncertainties

Most of the recommended best practices of risk assessments show high prevalence in the US whereas moderate prevalence in India. For example, the President's Executive Order 12866 requires the agencies to consider the degree and nature of the relevant risks while setting the agency regulatory priorities. Circular A-4 requires the agencies to identify the undesirable side-effects (countervailing risks) of the proposed regulatory action and its alternatives. In the analyzed law/policy documents, there are several provisions indicating risk assessment in the health data and groundwater sectors, though limited examples in the EV sector. Further, the secondary literature suggests that the federal agencies (in general) have established standard procedures to conduct risk assessments.⁸⁸ Regarding public engagement in risk assessment, the framework for environmental health risk management

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⁸⁷ In case of India, the assessment is based on the documentary and interview analysis along with secondary literature review. Whereas, in case of the US, the assessment is based on the documentary analysis and secondary literature review.

⁸⁸ U.S. General Accounting Office. (2001). Chemical Risk Assessment. Select Federal Agencies' Procedures, Assumptions, and Policies. (Report to Congressional Requesters). Retrieved from https://www.gao.gov/assets/gao-01-810.pdf. Also, see, Environment Impact Agency (EPA). (2021). Publications that Cite EPA's CO-Benefits Risk Assessment (COBRA) Health Impacts Screening and Mapping Tool. Retrieved from https://www.epa.gov/sites/default/files/2021-04/documents/cobra-publications-4-13-21.pdf; Also see, U.S. Department of Health and Human Services (HHS), Guidance on Risk Analysis. Retrieved from https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html

requires stakeholder involvement in all phases of risk-assessment/ risk management⁸⁹ and emphasizes consideration of public values and perceptions in risk-based decision-making.⁹⁰

In India, there is no legal mandate for assessing risks in law/policymaking. However, for a list of identified development activities, there is a federal statutory requirement to conduct environmental impact assessment including risk assessment. In the analyzed law/policy documents, there are several provisions on risk assessment in health data and groundwater sectors, though there are limited examples in EV sector. Further, the interview analysis suggests that risk assessment is not an institutionalized practice in law/policymaking and most risk assessments are qualitative and less formal.

Table 39. Comparing the risk assessment practices in the US and India

| Best practices/ | Prevalence in the United States | Prevalence in India |
|---|---|---|
| Recommendations | | |
| Regulations designed in a risk- focused and risk proportional way | Requirement of Executive Order 12866 and Circular A-4* Relevant examples identified in the analyzed law/policy documents | Risk assessment is not a part of formal law/policymaking process* Risk assessment is a statutory requirement as a part of Environmental Impact Assessment for identified development activities# |
| | | Relevant examples identified in the analyzed law/policy documents* |
| Objective and data-driven risk assessment | Federal agencies in general have standard procedures for conducting risk assessments * | Risk assessments are qualitative/less formal Ψ |
| Multi-risk assessment and multi-risk management | Evidence of federal agencies undertaking cumulative risk assessment such as EPA # | Inadequate information |
| Outcome-based regulations with risk as an indicator | Inadequate information | Inadequate information |

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⁸⁹ Presidential/Congressional Commission on Risk Assessment and Risk Management (PCCRARM). Framework for environmental health risk management. Vol. I and II. Washington, DC: National Academy Press; 1997. Also, see, Sexton, Ken. (2013). Evolution of public participation in the assessment and management of environmental health risks: a brief history of developments in the United States. Journal of Public Health Research, 2(2), e18. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4147733/

⁹¹ Ministry of Environment and Forests (MoEF). Notification on Environmental Impact Assessment (EIA) of Development Projects. (1994). S.O. 60(E). Also, *see*, Ministry of Environment and Forests, Notification (2006). The Gazette of India: Extraordinary. S.O. 1533 (E).

| Policymaking informed by all relevant evidence on risk (both objective and subjective) | Presidential/Congressional Commission on Risk Assessment and Risk Management # | Agencies consider subjective evidence on risk Ψ |
|--|--|--|
| Transparent public engagement on risk | Presidential/Congressional Commission on Risk Assessment and Risk Management # | Inadequate information |
| Enabling legislation for risk- based regulation | Requirement of Executive Order 12866 and Circular A-4* | No legal mandate for assessing risks in law/ policymaking* Risk assessment is a statutory requirement as a part of Environmental Impact Assessment for identified development activities# |
| * Documentary Analysis | Ψ Interview Analysis | # Secondary Literature Review |

2. Broader and Fuller Impact assessment

Most of the recommended practices of impact assessment show high prevalence in the US and moderate prevalence in India. Though there are a few practices which show high prevalence in India as well, such as application of behavioural insights in policymaking.

In US, the President's Executive Orders from time to time have emphasized on the agencies conducting good regulatory analyses. ⁹² On the environment side, the National Environmental Policy Act (NEPA) requires the federal agencies to assess environmental impacts of their proposed actions. ⁹³ Additionally, laws such as the Unfunded Mandates Reform Act and the Regulatory Flexibility Act require the agencies to evaluate the costs and benefits of specified rulemakings. The process of conducting ex-ante RIA is institutionalized, however, there are limited ex-post assessments (retrospective reviews). ⁹⁴ The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget is an oversight body which reviews the agency RIA's and provides guidance on the conduct of broader impact assessments. ⁹⁵ Regarding the application of behavioural insights in policymaking, in addition to the President's Executive Order, ⁹⁶ the Social and Behavioral Sciences Team (SBST) was constituted under the National Science and

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⁹² Executive Orders such as 12866, 13563, and 13579 establish principles and guidance for the rulemaking process. These EOs require the agencies to estimate the costs and benefits of the proposed regulatory actions and determine if the benefits of the regulations justify their costs. The agencies must examine the alternative approaches, and assess the potential risks, ancillary benefits, as well as distributional effects of the proposed regulatory action.

⁹³ National Environmental Policy Act. NEPA.Gov. Retrieved from https://ceq.doe.gov/index.html.

⁹⁴ See, Aldy, supra note, 71.

⁹⁵ OIRA OMB issued the Circular A-4 (Regulatory Impact Analysis: A Primer).

⁹⁶ The White House. Office of the Press Secretary. (2015). Executive Order- Using Behavioral Science Insights to Better Serve the American People. Retrieved from https://obamawhitehouse.archives.gov/the-press-office/2015/09/15/executive-order-using-behavioral-science-insights-better-serve-american.

Technology Council (NSTC) White House Office of Technology and Science.⁹⁷ Further, the secondary literature suggests that many federal agencies apply the principles of behavioural insights such as the Department of Agriculture, the Department of Treasury, the Consumer Financial Protection Bureau, the Department of Labor, Internal Revenue Service, and the Environmental Protection Agency.⁹⁸

In India, the federal government's pre-legislative consultation policy of 2014 provides for impact assessment. It requires the concerned department/Ministry to publish the proposed legislation's financial implications, environmental impacts, and impact on the fundamental rights of the affected people, and their livelihoods. 99 However, this policy is not binding on the departments/Ministries. Additionally, there is a federal statutory requirement of environmental impact assessment for a list of identified development activities. 100 Inter-ministerial consultation is another mechanism of assessing the broader impacts of a proposed law/policy, though in a less structured way. The National Institute for Transforming India (NITI) is an independent body with a key role to design strategic policy frameworks and monitor the federal agencies' performances. It is chaired by the Prime Minister of India. Thus, NITI could be considered as an agency serving the 'whole of government' policy. Regarding the behavioural insights in policymaking, NITI has a Behavioural Insights Unit (BIU) and its recent report suggests the application of behavioural insights in policymaking across multiple sectors including Health, Women and Child Development, Rural Development, Urban Development and Human Resource Development sectors. 101

Table 40. Comparing the impact assessment practices in the US and India

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⁹⁷ Afif, Zeina, et al., (2019). Behavioral Science Around the World: Profiles of 10 Countries (English). eMBeD brief. Washington, D.C.: World Bank Group. Retrieved from https://documents1.worldbank.org/curated/en/710771543609067500/pdf/132610-REVISED-00-COUNTRY-PROFILES-dig.pdf (p-147,148).

⁹⁸ Sunstein, Cass, et al., (2018). Behavioral Economics and Public Opinion, Intereconomics, 53 (1) 5-7. Available at https://www.econstor.eu/bitstream/10419/177419/1/005-007-Forum-Sunstein Reisch.pdf. Also, see, U.S. Department of Labor. Office of the Assistant Secretary for Policy. Behavioral Insights and DOL. Retrieved from https://www.irs.gov/pub/irs-soi/17rpirsbehavioralinsights.pdf. Behavioral Insights Toolkit. (2017). Retrieved from https://www.irs.gov/pub/irs-soi/17rpirsbehavioralinsights.pdf.

⁹⁹ Pre-Legislative Consultation Policy (PLCP). Para 2. (February 2014). Ministry of Law & Justice, Government of India.

¹⁰⁰ See, MoEF, supra note, 91.

¹⁰¹ NITI. (2022). Thematic Report: Behaviour Change. Behavioural Insights Unit of India. DMEO. Retrieved from https://dmeo.gov.in/sites/default/files/2022-05/behavior%20change%20report%2017%20Mav.pdf.

| Best practices/ Recommendations | Prevalence in the United States | Prevalence in India |
|--|--|--|
| An integrated Regulatory impact assessment (RIA) in all stages of regulatory process | Conducting ex-ante assessments is institutionalized but not the ex-post assessments # | RIA is not a mandatory requirement of law/policymaking process* |
| Policies with clearly defined problem and objectives | In general, policy documents are elaborate on providing problem context and outlining policy objectives* | In general, policy documents are less elaborate on providing problem context and outlining policy objectives* |
| 'Full' impact analysis | Requirement of multiple Executive Orders* | Pre-legislative consultation policy of 2014 requires impact assessment (though not binding)* |
| | National Environmental Policy Act (NEPA) requires federal agencies to assess environmental impacts of their proposed actions | Federal statutory requirement to conduct environmental impact assessment for a list of identified activities # |
| Simple and flexible methodology | Several Executive Orders specify different methodologies* | Examples of agencies adopting less structured/qualitative CBA Ψ |
| RIA proportional to the significance of regulation | RIA required for economically significant regulatory actions* | RIA is not a mandatory requirement of law/policymaking process* |
| Applying Behavioral | Social and Behavioral Sciences Team | Behavioral Insights Unit (NITI) |
| insights (BI) in policymaking | (NSTC) Prevalence of using behavioural insights in policymaking in several federal agencies | Prevalence of using behavioural insights in policymaking in several sectors |
| Stakeholder engagement and communication of assessment results | Inadequate Information | Inadequate Information |
| An oversight body serving 'whole of government' policy | Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget* | National Institute for Transforming India (NITI) (non- regulatory) * |
| Enabling legislation requiring RIA | Requirement of multiple Executive Orders* | Pre-legislative consultation policy of 2014 requires impact assessment but it is not |
| *Documentary Analysis | Ψ Interview Analysis | mandatory* #Secondary Literature Review |
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3. Monitoring and evaluation

Most of the recommended M&E practices show high prevalence in the US and moderate prevalence in India. However, a few practices show high prevalence in India as well, such as the M&E institutional framework and the established evaluation criteria.

In the US, multiple administrations have focused on performance monitoring and evaluation for over three decades, such as the Government Performance and Results Act

(1993), the Program Assessment Rating Tool (2002), the Accountable Government Initiative (2010), the GPRA Modernization Act (2010), and the Foundations of Evidence-Based Policymaking Act (2019). However, recent literature suggests that the federal agencies focus more on evaluating the programs than policies/regulations. Several agencies could be considered a part of the M&E institutional mechanism such as the Office of Management and Budget (OMB), Government Accountability Office (GAO), and the Performance Improvement Council (PIC). Multiple administrations have focused on transparency and public engagement in their initiatives and legislations on performance monitoring and evaluation. Most of the federal agencies have performance indicators and values on their official websites. 103

In India, since 1950s, the federal government has focused on evaluation. The Programme Evaluation Organization (PEO) was established in erstwhile Planning Commission in 1952, the Performance Management and Evaluation System (PMES) 104 was developed in 2009 and the Data Monitoring and Evaluation Office (DMEO) in NITI was established in 2015. DMEO is the apex monitoring and evaluation office in the country. It uses the output-outcome monitoring framework developed in collaboration with concerned departments/Ministries to monitor and evaluate approximately 500 schemes of the government of India.¹⁰⁵ DMEO has also developed a 'Data Governance Quality Index' based on six parameters to assess data preparedness of the federal ministries/ departments. 106 Further, the Development Evaluation Advisory Committee (DEAC) at the federal level is constituted with the objectives of building an evaluation culture, institutionalizing the evaluation of government schemes, conducting evaluation studies, and capacity building of evaluation in the states. 107 Regarding transparency and public engagement, there are mixed trends. The interview analysis suggests limited availability of information in public domain whereas, the information available on the agencies' official websites suggests that many agencies have recently developed public- facing dashboards

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¹⁰² Bennear et al., (2022) (forthcoming). Agency Action under the Foundations for Evidence Based Policymaking Act (FEBPA).

¹⁰³ Mark, Katherine and Pfeiffer John R. (2011). Monitoring and Evaluation in the United States Government- An Overview. (2011). Independent Evaluation Group, The World Bank Group.

¹⁰⁴ For details, *see*, World Bank (2018), *supra* note, 85 at 178 ("By 2014, this system, which was located in the Cabinet Secretariat, covered 80 departments within GOI and 800 Responsibility Centers (which included subordinate offices, autonomous bodies, and the like").

¹⁰⁵ NITI Aayog. (2021). Annual Report 2021-2022, at 30.

 $^{^{106}}$ NITI Aayog. Data Monitoring and Evaluation Office (DMEO). Overview: Data Governance Quality Index. Retrieved from https://dmeo.gov.in/content/dgqi-overview.

¹⁰⁷ See, NITI (2021), supra note, 105 at 32.

displaying key performance indicators.¹⁰⁸ However, it is difficult to comment on the effectiveness and usefulness of the information displayed.

Table 41. Comparing the monitoring and evaluation practices in the US and India

| Best practices/ Recommendations | Prevalence in the United States | Prevalence in India |
|--|---|---|
| M&E as an integrated part of policy cycle | M&E is more program-based than policy-based # | M&E is more program-based than policy-based Ψ |
| Institutional framework for M&E | OMB, GAO, PIC # | PEO in erstwhile Planning Commission, PMES, NITI and DMEO* |
| Identifying data and indicators absolutely necessary for monitoring policy performance | More focus on programs than policies/regulations # | Output- outcome monitoring framework (though more focus on programs than policies/regulations)* |
| Established criterion of evaluation | Rule relevance, cost of the rule # | REESI+E framework- relevance, efficiency, effectiveness, sustainability, and impact with an additional 'Equity' * |
| A culture of M&E and learning | Inadequate information | Monitoring and stakeholder feedback inform policy changes Ψ Development Evaluation Advisory Committee at the federal level # |
| M&E information readily available to the public | Transparency encouraged in all initiatives/ legislations on performance monitoring and evaluation # Most federal agencies display performance indicators on their official websites# | M&E information limitedly available in public domain Ψ Federal agencies' dashboards of key performance indicators # |
| *Documentary Analysis | Ψ Interview Analysis | #Secondary Literature Review |

4. Iterative decision-making

In iterative decision-making and ex-post reviews, the actual regulatory practices suggests a mixed trend in the US and India. In the US, an agency could review and revise the rule in several ways, including based on the agency's experience of implementing a rule; requirement by law or Presidential directive; petition from the public; and review by experts. 109 Regarding multiple rule reviews, the secondary literature suggests that the agencies focus on assessing one rule at a time with limited emphasis on assessing the effect

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 $^{^{108}}$ For example, <u>http://nhp.mowr.gov.in/home/nhp_dashboard.aspx</u>. Also, see, http://nwm.gov.in/?q=nwm-dashboard

¹⁰⁹ The Office of Federal Register. A Guide to the Rulemaking Process. Available at https://www.federalregister.gov/uploads/2011/01/the-rulemaking-process.pdf.

of multiple rules.¹¹⁰ Regarding resources, the literature suggests that such resources are limitedly allocated for conducting ex-post reviews. For example, the recent Federal Evidence-based Policymaking Act requires federal agencies to prepared iterative learning agendas and annual evaluation plans, however, the Act does not allocate specific resources for these activities.¹¹¹ Regarding public participation in policy evaluation, literature suggests that academic research centers play an important role in retrospective analysis, such as by validating the agency results.¹¹² However, literature also suggests that much of the retrospective review analyses are not published or archived in ways that are accessible.¹¹³

In India, there is evidence of adaptability of laws and policies such as through amendments and revisions over time. Various factors result in law/policy revisions including stakeholder feedback, post-implementation challenges, new developments, court rulings, etc.¹¹⁴ Thus, the laws and policies are changing over time but most of the revisions are not based on formal evaluation of the law/policy performance. Additionally, there are examples of the Parliamentary standing committees evaluating the performance of laws and policies.¹¹⁵ However, such evaluations are not done for every law and policy. Similarly, from time to time, the government of India also sets up commissions focusing on reforms in a particular sector. Such commissions review the relevant laws and engage the stakeholders in preparing their reports. For example, the government of India constituted the Second Administrative Reforms Commission (2005) which reviewed several laws related to public administration and consulted stakeholders while submitting 15 reports on

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¹¹⁰ See, Bennear and Wiener, 2021a, supra note, 71.

¹¹¹ See, Bennear et al., supra note, 102.

¹¹² See, Aldy, supra note, 71 at 17.

¹¹³ Wiener, Jonathan B., and Ribeiro, Daniel L. 2016b. "Impact Assessment: Diffusion and Integration." In Bignami, Francesca and David Zaring (Eds.) Comparative Law and Regulation. Cheltenham: Edward Elgar.

¹¹⁴ This is similar to Wendy Wagner's observations of dynamic rulemaking in the US agencies. For details, see, Wagner, et al., (2017). Dynamic Rulemaking. 92 New York University Law Review 183. (Agencies revise rules for error correction, incremental policy development, policy clarification, and changes in the physical, technical, or institutional environments. The agencies were generally quite responsive to changing conditions and to the input of those who were most directly affected by their rules).

¹¹⁵ Parliament of India. Rajya Sabha. (July 2020). The Law Making Process. (The standing committees have scrutinized and presented reports to the Parliament on prominent national long-term policies including the draft Agriculture Policy Resolution (1992), National Agriculture Policy, New Telecom Policy (1999), National Drug Policy, and National Housing Policy.) Also, see, Lok Sabha Secretariat. An Introductory Guide. Departmentally Related Standing Committees at 7,8. May 2019. Retrieved from http://loksabhaph.nic.in/Committee/INTRODUCTORY GUIDE(ENGLISH).pdf

the key issues. 116 Similarly, in 2011, the Ministry of Finance constituted the Financial Sector Legislative Reforms Commission to review the Indian financial laws. 117

Table 42. Comparing the Iterative decision-making in the US and India

| Best practices/ Recommendations | Prevalence in the United States | Prevalence in India |
|--|--|---|
| Built-in provision of ex-post review | Several examples in the analyzed laws/ policies* | Several examples in the analyzed laws/ policies* |
| Independent institutional mechanism of conducting/reviewing ex-post reviews | OIRA partially fulfils this requirement with its oversight responsibility for ex-post reviews* # | No such mechanism exists* |
| Established criteria to identify regulation/policy for ex-post review | Multiple criteria established through Executive Orders (e.g. E.O. 12044, E.O. 12498, E.O.12866) # | No established criteria. However, examples of policy revisions and legal amendments suggest focus on rule relevance and rule improvement* |
| Assessment of cumulative regulatory burden- the effect of multiple rules | Limited/no such assessments # | Inadequate information |
| Allocated resources for expost reviews | Limited allocation of resources e.g. FEBPA 2019 # | Inadequate information |
| Public participation and dissemination of results | Important role played by academic research centers # Limited publication and archiving of retrospective reviews # | Monitoring and stakeholder feedback inform policy changes Ψ Limited publication of the |
| Guidance on conducting retrospective reviews by an independent regulatory oversight body | OIRA in the Office of Management and Budget* | rationale of policy revisions Ψ No such mechanism exists* |
| *Documentary Analysis | Ψ Interview Analysis | #Secondary Literature Review |

5. Public Participation in law/policymaking

Comparing the actual regulatory practices in public participation suggests that of the three rights provided in the Aarhus convention, the first right — 'Access to information' is recognized equally in both the US and India. In US, the Freedom of Information Act provides the right to public to access information or records from federal agencies. ¹¹⁸

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¹¹⁶ Kalra, Harsimran. (2011). PRS Legislative Research. Public Engagement with the Legislative Process. Also, *see*, Department of Administrative Reforms & Public Grievances, Government of India. Government Decision with regard to Second Administrative Reforms Commission, Reports available at https://darpg.gov.in/en/government-decisions-on-2nd-arc?page=1

 ¹¹⁷ Resolution No. 18/1/2011-RE dated March 24, 2011, Ministry of Finance, Government of India.
 118 Office of Information Policy. U.S. Department of Justice. Freedom of Information Act. Retrieved from https://www.foia.gov/about.html.

Similarly, in India, the Right to Information Act is a federal Act which provides the right to citizens to access information from the government.¹¹⁹

The second right relates to 'participating in decision-making' through public notice and comment i.e. public notice of proposed agency action or decision-making including relevant details such as potential impacts of the decision, efforts to reduce any negative impacts, non-technical summary of proposed action, and specifying the time period of providing feedback or comments. The US Administrative Procedure Act mandates public notice and comment in federal rulemaking process. Whereas in India, though agencies generally adopt public notice and comment, the process remains discretionary as it is not mandated by a federal law/statute. However, the analyzed law and policy documents e.g. groundwater sector have provisions of notice and comment.

The third right is regarding the 'access to review' in case the above two rights are violated. In the US, the first two rights are statutorily recognized, therefore, the public can go to the court of law in case of any violation by the public agencies. In India, the public can go to the court of law/ recognized appellate structure provided in the Act for the access to information. Regarding the public notice and comment, at a federal level, there is no specific remedy, however, the analyzed law and policy documents e.g. groundwater sector provides for dispute resolution.

Table 43. Comparing the rights related to public participation in the US and India

| Rights | Prevalence in the United States | Prevalence in India |
|-------------------|--|--|
| Access to | The Freedom of Information Act | The Right to Information Act |
| Information | | |
| | Draft regulations displayed through | Draft law/policies published on the |
| | website, press release, Federal Register | department's websites, official gazette* |
| | notice* | |
| Participation in | Public notice and comment is mandatory | Public notice and comment is not a |
| decision- | (Administrative Procedure Act)* | federal statutory requirement.* |
| making | | |
| | | However, analyzed law and policy |
| | | documents e.g. groundwater, have |
| | | provisions of notice and comment.* |
| | | |
| Access to justice | Both the Acts provide for remedies in case | The Right to Information Act provides |
| | of violation of the laid down procedure # | for remedies in case of violation of the |
| | | laid down procedure. |
| | | |

¹¹⁹ Department of Personnel & Training. Government of India. About Right to Information Act 2005. Retrieved from https://rti.gov.in/.

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¹²⁰ Section 553. Administrative Procedure Act.

| | | Public notice and comment is not a federal statutory requirement. However, analyzed law and policy documents e.g. groundwater, have provisions of dispute resolution.* |
|--------------------------|----------------------|--|
| *Documentary Analysis | Ψ Interview Analysis | # Secondary Literature Review |

6. Inter-agency coordination

The actual practices regarding inter-agency coordination suggests high prevalence in India than the US. This could partially be attributed to limited information available in the US context on a few practices. In the US, the agencies take independent decisions and also consult and communicate when required. Additionally, there are examples of legislations such as the GPRA Modernization Act requiring the OMB to coordinate with agencies in developing cross-agency priority goals.¹²¹ Other initiatives also encourage inter-agency coordination such as the President's Management Agenda.¹²²

In India, the agencies take independent decisions and also consult and communicate when required. Further, the Government of India (Transaction of Business) Rules, 1961 mandate inter-ministerial consultations on all matters impacting more than one department.¹²³ Similarly, these rules mention the Cabinet to resolve the inter-ministerial divergences.¹²⁴ NITT's National Development Agenda is an example of governmental prioritization. It focuses on cooperative federalism, indigenous manufacturing (Make in India), financial inclusion, labor reforms, skill development, digital India among others.¹²⁵ Further, the government of India and UN's Sustainable Development Cooperation framework 2023-27 is an example of the overall government strategy. It is a results framework with six outcomes for the entire country including all states. The six outcomes relate to the

¹²¹ U.S. Government Accountability Office (GAO). (2021). Government Performance Management: Key Considerations for Implementing Cross-Agency Priority Goals and Progress Addressing GAO Recommendations. Retrieved from https://www.gao.gov/products/gao-21-104704.

¹²² U.S. Chief Information Officers Council (CIO). President's Management Agenda. Policies & Initiatives. Retrieved from https://www.cio.gov/handbook/policies-initiatives/pma/.

¹²³ Rule 4 (a). The Government of India (Transaction of Business) Rules, 1961. Available at https://cabsec.gov.in/transactionofbusiness/transactionofbusinessrules/.

¹²⁵ National Institute for Transforming India (NITI). Overview: National Development Agenda, Fourteenth Finance Commission and the Union Budget 2015-16. Retrieved from https://www.niti.gov.in/sites/default/files/2019-07/NITI%20Brief1.pdf. Also, see, PM India. NITI Aayog: Transforming India's Development Agenda. Retrieved from https://www.pmindia.gov.in/en/major_initiatives/niti-aayog-transforming-indias-development-agenda/

following sectors: (i) health, (ii) food and nutrition, (iii) quality learning, (iv) economic activities, (v) environment and ecology, and (vi) human rights and social justice. 126

Table 44. Comparing the Inter-agency coordination practices in the US and India

| Levels of coordination | Prevalence in the United States | Prevalence in India |
|---|--|--|
| Agencies take independent decisions | Agencies act independently in their public policy domain* | Departments/ Ministries act independently in their public policy domain* |
| Agencies communicate with other agencies | General information exchange takes place between the agencies | General information exchange takes place between the agencies |
| Agencies consult with other agencies | Sector-specific examples identified in analyzed law/policy documents* | Sector-specific examples identified in analyzed law/policy documents* |
| Avoid differences between agencies | Inadequate information | e.g. Inter-departmental consultations are mandatory for all matters impacting more than one department # |
| Finding inter-agency agreement | Inadequate information | e.g. Committee of Secretaries at the cabinet level # |
| Judging the divergences between agencies/actors | Inadequate information | Inter-ministerial divergences resolved by the Cabinet* |
| Setting the parameters for organizations | GPRA Modernization Act requires OMB to coordinate with agencies in developing cross-agency priority goals # | Inadequate information |
| Governmental prioritization | President's Management Agenda with cross-agency priority (CAP) goals # | National Institute for Transforming India's (NITI) National Development Agenda # |
| Overall government strategy | Inadequate information | Government of India-UN Sustainable Cooperation Framework (UNSDCF) 2023- 27 # |
| *Documentary Analysis | **Interview Analysis | #Secondary Literature Review |

D. Conclusion

1. Recommendations for India

Based on the descriptive and comparative analysis, and the best practices recommended by international bodies and academic researchers, following are the recommendations for India:

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 ¹²⁶ Government of India-UN Sustainable Development Cooperation Framework 2023-27 Results
 Framework. Retrieved from https://unsdg.un.org/sites/default/files/2022-06/India Cooperation Framework Results Framework 2023-2027.pdf

a. Policies with clearly defined problem and objectives

To successfully assess the effectiveness of the law/policies, it is important to clearly define the policy context and objectives. In India, law/policy documents are less elaborate on providing problem context and outlining the policy objectives. Therefore, it is recommended that at the design stage, policies should clearly articulate the underlying cause(s) of the identified policy problem and outline the policy objectives.

b. Structured decision-making processes

Adaptive regulations in essence emphasize on 'learning' based on new information and developments. Structured decision-making processes are excellent ways to optimize learning based on planned processes to collect, assess, and use information. Assessing risks and uncertainties and assessing impacts of policies, etc. are the tools of structured decision-making. If introduced, such processes would serve the goal of informed and rational decision-making.

- In India, there is limited emphasis on assessing risks in law/policymaking and the evidence suggests that existing agency practices are ad hoc, less formal, or based on subjective assessments which are often not documented. Therefore, it is recommended that India should consider both objective and subjective evidence on risk in law/policymaking processes, such as considering data and statistics, as well as knowledge in terms of justified beliefs based on observations, reasoning, dialogue, etc.
- Similarly, India may consider introducing impact assessment of policy/ regulatory action by using simplified and flexible methodologies which are commensurate with existing resources and agency capacities. These could be on the lines of the quick assessment studies being conducted by the DMEO.

c. Pre-legislative consultation

Pre-legislative consultation increases the legitimacy of the proposed rule/regulation. It provides the scope of deliberating the proposal with the public and interested stakeholders. India's pre-legislative consultation policy 2014 has several provisions to improve transparency of legislative proposals and strengthen public participation such as requiring the department/ ministry to publish draft legislation for at least 30 days, publishing an explanatory note with details of key legal provisions in a simple language, publishing a summary of public feedback and comments on its official website, and holding additional

stakeholder consultations when required. Evidence suggests that the agencies follow public notice and comment and engage public (stakeholders) in law/policymaking, however, the processes remain discretionary. Therefore, India may consider legislating on public consultation and make it a mandatory requirement in law/policymaking.

d. Monitoring & Evaluation an integrated part of policy cycle

Evidence suggests that monitoring and evaluation (M&E) is mostly an afterthought phenomenon in India's law and policymaking process. M&E mechanisms are not in place when a law/policy is rolled out. This results in a lag and contributes to the ineffectiveness of M&E. Therefore, it is recommended that there should be prospective planning of relevant data collection and identification of key performance indictors at the policy design stage. In implementation stage, these identified data and indicators should be monitored and in the post-implementation stage, this information should feed back into the system to evaluate policy performance and inform or update the law/policies.

e. A culture of M&E and learning

Evidence suggests that the agencies limitedly use the available M&E data to inform or update the law/policies and the M&E information is generally not available in public domain. Therefore, it is recommended that steps should be taken to foster a culture of M&E among the public officials and the stakeholders, such as by promoting the quality of M&E, emphasizing the use of data and results of evaluation across government, building capacities of government officials, and establishing stakeholder engagement mechanisms such as researchers and industry validating the policy evaluation results/reports published by the government agencies.

f. Retrospective reviews- single agency multi-policy reviews

Regulatory learning implies learning from the multiple past rules and using their analyses to improve future rules and assessments. It helps in comparative analyses of the performance of alternative policy designs/instruments and the accuracy of methods employed in assessments to understand what worked and what did not. In India, though the policies and laws have been revised/amended several times, the processes have been largely unplanned and less structured. The agencies have not focused on reviewing the impact of earlier policies on the given subject before making a new policy. Therefore, India

would benefit from introducing multi-policy reviews where the agencies review the impact of earlier policies on the subject before formulating a new policy.

g. Inter-agency coordination- multi-agency multi-policy reviews

India's federal structure provides a robust foundation for the flourishing adaptive governance structures. However evidence from the interviews suggests the need to improve inter-agency coordination. One potential way is by introducing multi agency, multi rule reviews. Evidence suggests that there is no formal evaluation of the policies/laws which impact more than one agency. Therefore, India could benefit from introducing multi-agency multi-policy reviews to analyze the collective impact of policies which are formulated by different agencies. The learnings could be useful for multiple agencies and save resources (cost-effectiveness due to combined use of resources). India's groundwater sector is a classic example of the negative interactive effect of the policies of multiple agencies.

The key recommendations for India are depicted in the adaptive regulatory cycle by embedding these recommendations at various stages of the regulatory cycle.

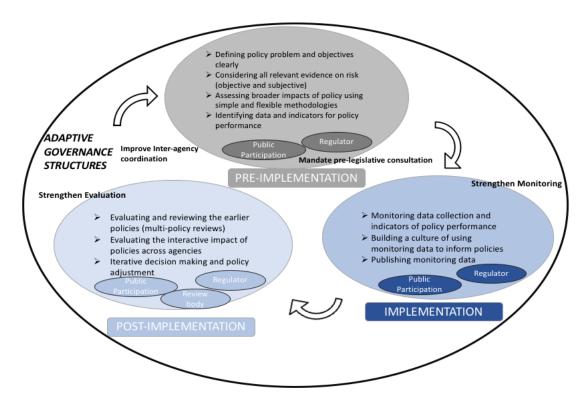


Figure. 5 Adaptive Regulatory Cycle for India

2. Towards Behavioral Insights in Adaptive Regulation

Factoring behavioural insights in adaptive regulatory framework could benefit in its better adoption and implementation. International organizations and academic researchers have recognized the importance of behavioral insights to improve policymaking.¹²⁷ The following behavioural insights could improve the adoption and implementation of the recommendations for India.

- i. Overcoming heuristics and biases (through structured decision-making)- In complex situations, individuals often resort to heuristics (i.e. mental shortcuts or intuitive judgements) to expedite decision-making. However, these shortcuts result in sub-optimal decisions.¹²⁸ This tendency could be overcome by providing structured decision-making processes.¹²⁹
- ii. Overcoming attention biases (through built-in provisions)- People have limited attention and evidence suggests that attention biases could influence policy choices. Built-in features could be a behavioral design strategy to increase their salience for the decision-makers. Such built-in features could seize the decision-makers' attention in advance and help by incorporating these into the agency decision-making processes. 132
- iii. Leveraging 'Messenger effect' (to increase implementation and compliance of adaptive processes)- The source of information ('messenger') influences how people process the information and make decisions. This is called the messenger effect.¹³³ A process required by law or authorized by the executive order (e.g.

¹²⁷ See, OECD Toolkit, supra note 53.

¹²⁸ Tversky, A., & Kahneman, D. (1974). Judgment under uncertainty: Heuristics and biases. *Science*, *185*, 1124-1131; Also *see*, Sunstein, C.R. (2003). Terrorism and probability neglect. Journal of Risk and Uncertainty, 26(283), 121-136; Also *see*, Gifford, R. et al. (2009). Temporal pessimism and spatial optimism in environmental assessments: An 18-nation study. Journal of Environmental Psychology, 29, 1–12.

¹²⁹ See, IRS Toolkit, supra note 98, at 16. Also, see, Milkman, K. L. et al., (2009). How Can Decision Making Be Improved? Perspectives on Psychological Science, 4 (4), 379-383.

¹³⁰ Thaler, R.H. and Benartzi, S. (2004). Save more tomorrow: Using behavioral economics to increase employee saving. Journal of Political Economy, 112(1), University of Chicago. Also, *see*, OECD Toolkit, *supra* note 53, at 21.

¹³¹ See, IRS Toolkit, supra note 98, at 23. Also, see, Behavioural Exchange. (2018). Behavioural Insights for Public Policy- Case Studies from around Australia. Retrieved from

https://behaviouraleconomics.pmc.gov.au/sites/default/files/resources/behavioural-insights-public-policy.pdf.

¹³² See, OECD Toolkit, supra note 53.

¹³³ Maclean, J. C. et al (2019). Information Source and Cigarettes: Experimental Evidence on the Messenger Effect. National Bureau of Economic Research. Working Paper No. 25632. Also, *see*, Behavioural Exchange, supra note, 131, at 22.

- President's Executive Order or an Order from the Prime Minister Office) is likely to be implemented than if it's a non-binding agency office order.
- iv. Overcoming complexity (through simplified and flexible methodologies of impact assessments)-Complexity of processes cause people to ignore/ eliminate some information and use mental shortcuts to simplify decision-making.¹³⁴ And making things 'easy' and 'simple' increase the likelihood of people accepting the task than what seems challenging and complex.¹³⁵
- v. Discouraging the use of heuristics and biases (through Guidance documents on conducting policy reviews) Clear guidance on how to go about in structured decision-making could discourage the use of heuristics and biases.¹³⁶
- vi. Overcoming missed attention (through system-generated reminders and feedback to use information resulting from M&E)- Evidence suggests that feedback and reminders increase the chances of people acting on the given information and introduce required changes.¹³⁷
- vii. Leveraging goal-setting behaviors (through specific periodicity reviews)Periodicity adds specificity to the process of review. It is akin to goal-setting behavior where people with specific goals perform better than without.¹³⁸
- viii. Appealing to the agency's brand image (through framing e.g. learning from the past policy actions)- People are very receptive to the messages which appeal to their positive self-image. Similarly, entities also have identities to protect. Behavioral strategy of 'framing' could be used to introduce regulatory learning by identifying it with the agency's brand image and as a rational choice for an agency to consider.
- ix. Using principles of choice architecture (through designing inter-agency consultation process as a default option). 141 This is akin to nudging the agencies to

¹³⁴ Simon, H. (1972). Theories of bounded rationality. Decision and Organization, 1, 161–176. Also, *see*, Tversky, A. (1972). Elimination by aspects: A theory of choice. Psychological Review. 79, 281–299.

¹³⁵ Behavioural Insights Team. (2014). EAST: Four simple ways to apply behavioural insights, BIT, London. Also, *see*, IRS Toolkit, *supra* note 98, at 12,35.

¹³⁶ See, IRS Toolkit, supra note 98, at 16.

¹³⁷ Id. at 28. Also, see, IRS Toolkit, supra note 98, at 22.

¹³⁸ Gollwitzer, P. (1999). Implementation intentions: Strong effects of simple plans. American Psychologist. 54, 493–503. (Implementation intentions help people make a concrete plan to achieve a goal by specifying when, where and how they will achieve the goal and by listing any obstacles to the goal). Also, *see*, Behavioural Exchange, *supra* note, 131, at 6.

¹³⁹See, IRS Toolkit, supra note 98, at 14.

¹⁴⁰ *Id.* at 35. (The identity of an organization might include its "brand" (in the outward-facing sense of how others perceive it) or its self-concept (in the inward-facing sense of how it defines itself). In both cases, entities exhibit behavior that shows that they care about their identities.)

¹⁴¹ See, OECD Toolkit, supra note 53, at 23, 28.

- make the preferred choice as a default option. For opting-out, the agency needs to seek exemption and explain its rationale for the same.
- x. Leveraging the 'collective impact' (through multi agency rule reviews)- Behavioral insights emphasize on 'collective impact' through cross-sector coordination.¹⁴²
 Regulatory learning through multi agency rule reviews¹⁴³ could be an excellent way to create such collective impact.

3. Contribution to the advancement of knowledge

This research makes three contributions to the advancement of knowledge. First is the development of an adaptive regulatory cycle with six broad features of adaptive regulation. The six features are informed by the literature review and are embedded in different stages of the regulatory cycle. Four of these features are essential from the perspective of a learning-oriented adaptive decision-making process, and the remaining two are overarching. These overarching features emphasize on the importance of participatory processes and an enabling ecosystem to implement adaptive regulation. This regulatory cycle could be used as an analytic tool to study the presence of adaptive decision-making processes in law/policy making at the country, state, or agency level.

The second contribution of this research is the investigation of the prevalence of adaptive regulation in India, which is an under-studied area in law/policy research. The directed content analysis approach is used to analyze the law/policy documents of three sectors in India and to analyze the interview transcripts of 33 key stakeholders across three sectors. No previous study to the best of the author's knowledge has explored the prevalence of adaptive regulation in India using the combined methodology of document and interview analysis based on the directed content analysis approach.

The third contribution of this research is the development of an adaptive regulatory cycle for India. It has key recommendations informed by the best practices recommended by international bodies and academic researchers. The recommendations are embedded in

¹⁴² Foster, Lori. (2018). Applying Behavioural Insights to Organizations: Theoretical Underpinnings, at 22. EC-OECD Seminar Series on Designing better economic development policies for regions and cities. Available at https://www.oecd.org/cfe/regionaldevelopment/Foster_Applying-Behavioural-Insights-to-Organisations.pdf. Also, *see*, Kania, John and Kramer, Mark (2011). Collective Impact. Stanford Social Innovation Review. Retrieved from https://ssir.org/articles/entry/collective_impact. ¹⁴³ *See*, Bennear and Wiener, 2021a, *supra* note, 71.

different stages of the adaptive regulatory cycle, are specific to India's context, and address the gaps identified by the findings of the document and interview analysis. A key recommendation is that India should strengthen its systems of monitoring and evaluation, to support better iterative decision making. Further, these recommendations could be relevant for other emerging economies to improve their regulatory processes and overall advance regulatory learning.

Appendix I

Interview Questions

- 1. Opening question(s) would be individual oriented and would be place/ situation specific. (e.g. How long have you been working in this position/ sector?)
- 2. Did you have a chance of participating in a law/ policy-making process?
 - a. If yes, in what capacity did you participate? (e.g. as a stakeholder, as a citizen, etc.)
 - i. How was your experience?
 - (a) What did you like about the process?
 - (b) What was most challenging?
- 3. In general, many factors could determine law and policy-making as well as their revisions. These could be political interests, stakeholders' interests, or factors like cost-benefit analysis.
 - a. In your opinion, which factors dominate the law and policy making in this subsector?
 - How does the department/ regulatory body consider the best available science in law and policy making? (Could you share some recent examples?)
 - b. Is there a practice of considering policy alternatives while making policies?
 - i. How does the regulatory body consider broader impacts of policy alternatives?
- 4. What do you think are the ways in which the department/ regulatory bodies respond to risks and uncertainties?
 - a. Is there a practice of assessing the risks and uncertainties of policy alternatives?
 - i. What is typically the process adopted?
 - 1. Are experts consulted in this process?
 - b. If circumstances change after policy making, how does the department respond to that?
- 5. Could you suggest one or two legal provisions that enable revisiting the laws and policies in this sector? (or in general) (e.g. sunset clause, periodic review, retrospective review)
- 6. Could you suggest one or two examples of regulatory learning in this sector? (or in general) (e.g. pilot programs, phased roll-outs, policy variance over time and space, experimental rules)
 - a. Are there legal provisions in support of such regulatory learning practices?
- 7. What are the ways in which the department/ regulatory bodies monitor and evaluate the policy? (e.g. identifying key performance indicators, feedback mechanisms)
 - a. Is monitoring & evaluation (M&E) carried out internally or by independent bodies?

- i. Is there planning on the kind of data that should be collected and monitored?
- ii. How well-equipped do you think are the M&E personnel? (e.g. skills as well as infrastructure)
- b. Do you think the M&E actually informs the future law and policy-making?
 - i. Would you like to share information on some good practices and/or concerns?
- 8. In your view, what is the level of public participation in law and policy-making in this sector/sub-sector?
 - a. What mechanisms are used by the department/ agency to reach out to the stakeholders? (e.g. public notice on website, public notice in newspapers, email communication, telephonic messages, etc.)
 - b. Are there specific for for conflict resolution/ grievance redressal in case the public face difficulties in the comment/ feedback process?
- 9. What are the public platforms for providing comments/feedback in the law and policy-making process?
 - a. Are these platforms accessible and user-friendly?
 - b. Are the documents/reports related to the law and policymaking subject available in public domain?
 - c. Could you share the broad categories of stakeholders who you think participate the most and the least in law and policy-making process?
- 10. Considering this sub-sector has interconnections across multiple departments/ regulatory bodies, how do you think they collaborate and coordinate in law and policy making?
 - a. What are the best practices and/challenges observed?
 - i. Is there a lead /nodal agency to guide the policy-making in this subsector?
 - 1. What are your views on its role?
 - b. In your view, which level(s) of government (federal, state, local) are best situated to regulate this sub-sector and what are the reasons for your choice?
- 11. In general, do you see value in adapting the laws and policies to new information and changing circumstances?
 - a. Do you think such regulations could garner support of political leadership and policy-makers?
 - i. What do you think could be the challenges?
 - b. What are your views on the need of adaptive regulation in this sub-sector?
 - c. Based on your experience and expertise, is there anything else you would like to add regarding the interview topic? (e.g. a question you think should have been there in the interview guide or any question that did not make sense to you, etc.)

Appendix II

Interview Analysis of Political leaders of India (Regulatory stage-wise)

1. Pre-implementation stage

The pre-implementation stage comprises of three broad features: assessing the risks and uncertainties, conducting broader and fuller impact assessments, and engaging public in the law/policymaking process.

Assessing risks and uncertainties

Of the six participants, three shared that no risk assessment is done in law/policy-making, two shared that it is done in an informal way such as through discussions, and one participant did not respond to this question.

Less formal/ explicit acknowledgment or assessment of risks

Participant A- The participant shared that the policymakers do not assess the potential risks in a systematic manner.

Participant A said — ["they (policymakers) don't formally do it or they don't think it's (risk assessment) very relevant.."]

Participant B- The participant shared that when the proposed bills are discussed in the legislative assembly, discussion on risks also takes place. However, over time, the debates in the legislative assembly have reduced which has impacted the overall discussion.

Participant B said — ["Where the discussion takes place, there discussion on the risks and uncertainties also happens and where no discussion takes place, then there is no point of these being discussed. Slowly and slowly all these things are getting centralized over time, which is not a good sign"].

No risk assessment

Participant C- The participant shared that no risk assessment takes place while making laws or policies.

Participant C said — ["Unfortunately, when the policy is framed, (it) is mostly a one man's brain child. So generally, there is no in-depth discussion from people of various expertise.."]

Participant D- Echoing a similar view, the participant shared that risk assessment is necessary, however, the law/policymaking process lacks it.

Participant E- The participant shared that in lawmaking, no one asks the question if a law is needed or not.

Participant E said — ["when you set out to do a law, I don't think that the basic question of do we need this law or not (is asked), it doesn't matter. I think one tends to assume that you need a legislation. And then you look at alternatives, what's the best form of legislation?"].

Broader and fuller impact assessment

The interview analysis suggests that the formal impact assessments are limitedly conducted in the law/policy space. Of the six participants, three shared that broader impact assessments take place while making laws and policies, such as through discussions and studies. Two participants shared mixed views and one participant shared that no impact assessments happen.

i. Broader assessment

Participant A- The participant shared that there is a practice of inter-departmental discussion, discussion with experts, and thorough study of potential policy impacts.

Participant D - The participant shared that depending on the policy context, the government engages experts including international experts. He gave the example of the state government consulting experts from Israel on developing water management policies.

Participant F- The participant shared that policies are discussed threadbare. Mostly the committees take the view of department officials as well as the stakeholders and present it as a report to the government for consideration.

ii. Skewed assessment

Participant E- The participant shared that such broader discussions depends on the bill and may or may not be discussed or analyzed in detail. There are examples of bills passed in a hurry as well as examples of thought-through legislations.

Participant E said — ["very often what happens is that legislation is in response to a short-term crisis. And governments sometimes are in a hurry to get these laws passed.... you can't generalize, there are bills that have been passed, you know, within a matter of a few weeks, there are bills that have, for example, the bill to reorganize the state of Jammu and Kashmir was introduced the 12 o'clock of August 2019, and was passed at 7:00 without undergoing any scrutiny, any debate, any examination of the bill"].

Participant C- The participant shared that there are hardly such detailed impact assessments. Inputs from people with expertise are missing and most legislations are passed without any debate or discussion.

Participant C said — ["although we are the lawmakers, but we get the copy of the draft bill when it is just about to pass in the state (legislative) assembly... Because the ruling party just wants to finish with the business of the Legislative Assembly in the least possible time"].

Participant B- The participant shared that in the Parliament, the debates happen thoroughly. The bills are referred to the legislative committees where all aspects of proposed law are examined in detailed. However, such elaborate discussions do not take place at the state level.

Participant B said — ["I'm not saying that it doesn't happen at all at the state level, but it is not that impactful the way it should be"].

iii. Science and policy

Participant E- The participant shared that consideration of science in lawmaking depends on the nature of the bill. For example, regarding a bill on the use of DNA technology in the criminal justice delivery system, the Parliament's committee took widespread inputs from the scientific community.

iv. Cost-benefit

Participant C- The participant shared that there is hardly any cost-benefit analysis taking place in law/policymaking.

Participant E- Echoing a similar perspective, the participant shared that no formal costbenefit analysis is done.

Participant E said — ["You're giving more rationality to law making, than it exists. No, I don't think that anybody looks at. I mean, we have a broad discussion, of how the law will affect different sections, but not a formal cost benefit analysis. I've seen in the US, you know, studies on the costs of legislation that I have not seen here"].

Public Participation

Of the six participants, four shared that public participation in lawmaking process is not adequate and should be improved. Whereas, two participants shared that the existing mechanisms of public participation are adequate.

i. Low public participation and scope to improve

Participant A- The participant shared that the public participation in law/policy-making process is negligible. He shared that the citizenry is educated and aware but there are no platforms where they could be engaged.

Participant A said — ["it (public participation) is very minuscule, and you can say it is non-existent"].

Participant C- The participant shared that there is no in-depth public participation when laws and policies are made.

Participant C said — ["For the formality sake, the draft is put on the website for receiving suggestions and feedback, but I don't think so there is any wider participation happening from people"].

Participant D- Similarly, the participant shared that public participation is low and there is a need to involve more people in law/policymaking process.

Participant D said — ["we have not been able to reach out to the people so that they can react, they can put in a comment, they can put their thoughts on that"].

Participant E- The participant shared that it is important to consult people before a law is made. He shared the example of England where before formally legislating, there is a practice of preparing a green paper followed by a white paper.

Participant E said — ["I think what is very important is to, put out a law for wider consultations before government makes up its mind. So, what do you call the prelegislative debate and discussion. So, it's not always done"].

ii. Adequate public participation

Participant F- The participant shared that the existing way of public participation is through elected representatives, which in her opinion is the correct way. The participant shared that people give them memorandums which as elected representatives they take to the lawmaking bodies.

Participant B- Echoing a similar view, the participant shared that for such a big and populous country, there could not be direct participation of people. It will always be indirect, through the representatives and we have elected public representatives in the form of political people. However, the participant shared that with the passage of Anti-Defection Law, the intra-party democracy has reduced which in a way has impacted participation in lawmaking.

Participant B said — ["The Parliament in its wisdom has passed the law that is the antidefection law, though it has advantages of its own, but it has also led to the different members of legislative assembly to toe the lines made by the party. So, in this, the representation and voice of different groups of the society, their impact has weakened, as compared to the influence or the impact that they had before the passage of the Act"].

Key points:

- Formal risk assessment and impact assessment are not part of the law/policy-making. These processes could be subjective, based on the policymaker's discretion, or be completely absent.
- Participants views range from the government conducting less formal risk assessment to no-risk assessment.
- There are mixed views on the government agencies' conducting impact
 assessments or in-depth deliberating on legislative proposals. There are
 examples of the bills passed without any discussion or scrutiny as well as wellthought out legislations.
- More participants expressed concern on the inadequacy of public participation in law/policymaking.

2. Implementation

In the implementation stage, the adaptive regulatory cycle emphasizes the need for relevant data collection and effective monitoring and evaluation (M&E) mechanisms to gauge regulatory performance. The interview analysis suggests that the monitoring and evaluation largely takes place through informal channels and mechanisms. Most participants shared that such monitoring processes are inadequate and where policy provides for M&E, it is not translated into action.

Monitoring and evaluation

Participant A- The participant shared that the monitoring is inadequate, not systemic, and varies from person to person working in the system.

Participant C- The participant shared that there is no monitoring and evaluation of policies. He shared people in the (state) government are hardly doing their work properly, monitoring is the next step.

Participant C said — ["First and foremost, I think we are not even doing our regular work effectively. So, I think for monitoring, there should be an analytical wing"].

Participant E- The participant shared that there are no systematic structures for monitoring a law post-implementation. However, feedback from the stakeholders, from agencies, as well as tribunals highlight the infirmities in the law and accordingly changes are incorporated in the law. He gave the example of the Insolvency and Bankruptcy Code, wherein post-implementation, many amendments were made.

Participant E said — ["So, without a formal institutional structure, it's not true to think that laws don't get or are not subject to a constant process of review.... In a functioning democracy, which is based on laws, these laws are automatically going to be subject to constant review"].

Participant B- The participant shared that there are ample mechanisms for monitoring but there is a gap in implementation.

Participant B said — ["What I'm trying to say is that mechanisms are there, regulations are there, there is no dearth of anything, if there is any dearth of something, then this is that is in the implementation, it is in the will."].

Key points:

- Participants shared that there is no systematic M&E, the existing practices could range from stakeholder feedback, discretionary agency action, to no monitoring and evaluation.
- However, one participant shared that despite not having structured M&E, stakeholder feedback gets translated into changes in the laws and policies.

3. Post-Implementation

This stage comprises of ex-post reviews and iterative decision-making. Interview analysis suggests that the participants have mixed views on post-implementation changes in the laws and policies.

Iterative Decision-making and Policy adjustment

i. Review

Participant E – The participant shared that the review provisions are not politically feasible. It is a self-destructing mechanism in a law, thus, akin to the poison-pill.

Participant E said — ["There's too much for the Parliament to explain, you know. We are bringing a law and also putting a provision that after 10 years the law will not be applicable. It won't fly, politically, it won't fly"].

Participant A and C – The participants shared that they have not seen many examples of such review provisions in practice.

ii. Pilot programs and Phased-implementation

Participant D - The participant shared that the government is generally open to the idea of trying new things on a pilot basis before the full-scale roll-out.

Participant D said — ["before making a law, before introducing into the whole system, or to whole state, so what they do is they go in for a pilot project"].

Participant B – Similarly, the participant shared that rolling out pilots happens many times in the government. He shared that the 'green revolution' was also a pilot which was implemented in the state of Punjab by the federal government before introducing in other parts of the country.

Participant C - The participant shared that many times there are timelines mentioned in the law (phased implementation). But when the law is implemented, you do not see such things happening, such timelines are not followed.

iii. Policy response to change

Participant E – The participant shared that there are hardly any laws in the independent India which have not been amended. He shared several examples of federal laws which have been amended over time. These changes could be due to stakeholder feedback such as industry associations or even the court judgements.

Participant E said — ["the functioning of government, democracy is based on laws. It's not true to say that laws don't get through a process of review. There have been committees set up to examine laws, they've been committees set up to review the functioning of laws. So, it's not right to say that laws are not amended"].

Participant F- The participant shared that changes in laws and policies have been happening. As elected representatives, we bring such issues in the Parliament as well as in the state assemblies. The laws have been changed through ordinances as well.

Participant B- The participant shared that there are legislative committees whose task is to look after the law's implementation, and see what is relevant and what changes are required in practice. However, there are gaps in implementation of such provisions.

Participant A- The participant shared that it takes time to bring changes in the law and these changes could be caught up in the procedural rigmarole.

Participant C- Echoing a similar view, the participant shared the changes in the law are time-consuming and do not happen quickly. For example, he shared that most amendments (at the state level) took around two or two and a half years. Thus, amendments happened when the government was in the middle of its tenure.

Participant D- The participant shared that changes in the laws do not happen often. Many times, the political interests or the constituent interests prevent such changes from taking place.

Participant D said — ["..they are looking at the people that they might not get annoyed. Or I think, basically, they have lots of personal interests, I would say political interests"].

Key points:

- Participants shared that despite limited planned provisions, the laws and policies at the federal level are reviewed and changed based on multiple factors including stakeholder feedback as well as court judgments.
- Most participants shared that changing laws/policies at the state level are time-taking processes and not undertaken frequently. They also emphasized the role of political interests in stalling such processes.
- Participants shared limited examples of pilot programs and phasedimplementation of policies.

4. India's regulatory cycle and Adaptive governance structures

Regarding the adaptive governance structures, of the six participants, two consider such coordination is effective in law/policymaking whereas, four participants consider that there are coordination challenges.

Inter-agency coordination

i. Effective coordination

Participant B - The participant shared that lawmaking is a well-coordinated exercise where inter-departmental consultations are done and are working effectively.

Participant E- The participant shared that every law follows through the cabinet process in which all departments/ministries share their feedback. However, ultimately it is the administrative ministry and the Ministry of Legal Affairs which take the legislation forward. He further shared that within these two, generally the Ministry of Legal Affairs vets everything, thus, the legal experts give their final seal of approval.

ii. Gaps in coordination

Participant A - The participant shared that when laws and policies are made, there are inter-ministerial discussions at the state level. However, such discussions do not involve the local functionaries which results in gaps in implementing such laws and policies.

Participant C - The participant shared the inter-agency coordination is generally missing in the state government.

Participant D - The participant shared that the departments do not interact with each other. Giving example of water sector, he shared that there are multiple departments whose work impacts water but not much coordination is seen. There should be a nodal agency for dealing with common sectoral interests.

Participant F – Echoing a similar view, the participant shared that there is not much coordination between the state agencies and the departments. She gave an example of how

while developing the real estate colonies, many times the Public Works Department (PWD) lays down the roads and then the departments dealing with sewerage or cables come into the picture and have to dig up the roads to complete their works. She said this is a minor example but indicates the lack of coordination in different agencies including at the district level.

Need of Adaptive Regulations

The interview participants were asked their views on the need for adaptive regulation in India. Four of the six participants acknowledged the importance of adaptive regulations and a few of them shared certain requirements to be fulfilled for their effective implementation such as public education, research, and public support. However, two participants shared mixed views on the need to have written review provisions.

i. For

Participant A- The participant shared that adaptive laws are very much needed and could be a game changer, particularly in places where people are demanding change in governance practices. And if such laws (and their reviews) are kept objective and not linked to parochial interests, such as caste, religion, then their implementation could be smooth.

Participant C and D - Both participants shared that there is definitely a need to review the laws over time because the things are changing at a faster pace than was imagined a couple of decades ago. However, there is a need to improve people's education as well as to understand the societal patterns where such laws need to be implemented.

Participant C said — ["the variation in our society is a big challenge, reaching out to everyone is quite a difficult thing. One, I think we need to bring up the level of education...And I feel that we are not developing the research the way we should. Till the time we do not understand and try and analyze the behavior patterns of the society because every society has a different behavior, and different culture, (there will be challenges)"].

Participant E - The participant shared that the changes such as climate change or the groundwater situation, were not anticipated by the national leaders 50 years back. However, these changes are now forcing us to adapt our laws and policies. For effective implementation of such laws, you will need public support.

Participant E said — ["you cannot do it unless you have the cooperation of the people... In this adaptive thing, to my mind is the need to educate and explain to the people what the future for them and their children is going to be. That's the only way because at the moment the situation is I don't care what happens tomorrow, I'm dying today, my stomach has to be filled today. So, it's a very difficult situation. But it's getting out of hand, you have to have this adaptive mode"].

ii. Mixed views

Two participants shared mixed views on the need for adaptive regulation. One emphasized that India does not need written review provisions as the laws have been changing over time even without such written provisions. Another shared that adaptive law per se is not the need of hour, what is needed is the implementation of existing legal provisions, which in his view are adequate.

Participant B- The participant shared that the it does not matter whether the laws are adaptive or not, the key thing is implementation.

Participant B said — ["If there is a provision of adaptive law, but you do not follow, then it makes no difference whether there's provision or not. Alternatively, there is no provision of adaptive law, but you are proactive and you do it, then the problem is solved. So, the need is not of adaptive regulation. The need is of proactive legislators who can spend a lot of time in detailed discussions in the year. So, these shrunk sessions are not good for lawmaking"].

Participant F- The participant shared that there is no doubt that the laws should be adaptable but he said that for the most part, Indian laws cannot be accused for the lack of adaptability.

Participant F said — ["Our laws also, you know, reflect societal values. So, we are not a country that likes U-turns, we are not a society that likes complete transformations. We adapt, things change, we adapt. I can't think of any law passed in independent India just not been adapted, you know, to changing circumstances"].

However, regarding the specific reviews provisions in law, the participant shared —["how do we know? How do we define? (when the laws needs to be revisited).. You don't need to (mention it). I mean, whenever an executive feels the need for doing away with a piece of legislation, the executive has the powers... It makes sense when governments are not amending laws, when governments are reluctant to amend laws, or passing laws. The Constitution is a classic example 120 amendments in 71 years. So, I don't see any value to it (in India's context)"].

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