Regulatory review of new product innovation: Routine-practice perspective

By

Derrick Antwi Donkor Boakye

A thesis submitted to the Brunel Business School, Brunel University London, in partial fulfilment for the award of degree of Doctor of Philosophy (PhD)

Abstract

Regulatory agencies have come to represent non-market actors whose safety evaluations of products determine the market access and commercial success of new products. Yet, the extant discourse on regulatory agencies and their review of new product innovations (NPIs) has only offered an understanding of the phase-gate product review process, strategies used by innovating firms to navigate regulatory constraints, and a (re)conceptualization of the role of regulatory agencies as innovation intermediaries — all within stable and well-defined contexts. This has led to limited insights into the internal dynamics of regulatory activities and processes: specifically, their ongoing coping and adaptive responses to innovation landscapes, market conditions, and the organizing contingencies at the interface of socio-cultural and material contexts that establish their local rationale for conducting product reviews. Drawing on the contemporary turn to practice and routines in social theory as a lens, this thesis explores regulatory review of NPIs by examining how the local coping practices of product evaluators at the coalface of NPI evaluation coalesce to define the adaptive character of regulatory agencies and their responses to context-specific conditions that combine to form and shape regulatory review of NPI process. Developing the study's contribution based on the organizing routines of a regulatory agency operating in a context marked by underdeveloped markets and institutions, the Ghana Food and Drug Agency (FDA) served as the empirical research site. Elucidating how practices and routines underpinning the review of NPIs cohere in the form of exaptive strategies to parry the disruptive and evolving innovation landscape, emphasis was placed on the product evaluators' situated practices, dispositions, and organizing relations to theorise the product review process and adaptive tendencies of the agency. Adopting interpretive research approach and attuning to an exploratory research design, data for the empirical inquiry was chiefly collected through ethnographic semi-structured interviews with thirty-one (31) regulatory officers, supervisors and laboratory analysts working across four loosely coupled departments within the FDA. This was supplemented with three hundred and fifty (350) hours of non-participant observation, and twenty-five (25) publicly available data sources in the form of archival documents on the work of the regulatory agency.

The main findings from the study are captured in threefold. First, in delineating how the regulatory review of NPIs may play out in practice in contexts marked by underdeveloped markets and institutions, the study identified salient interactive patterns of routines that are coded in artefactual materials to inform situated practices and skilled adaptive actions of product evaluators, which cumulatively constitute cognitive and noncognitive routines that give life to the regulatory review process. Second, a continuous (re)creation of established patterns of product evaluation yields a set of tacit knowledge and innovative practices that underline the adaptive qualities needed to both sustain the intention of the product evaluation framework and respond to the fluxing innovation landscape

and contextual dynamics. Third, ongoing adjustments and navigation of sediment patterns of action that provide stable orders in the regulatory review process come to define the regulators' sensitivity to local circumstances as a way-finder to achieve a responsive regulatory review framework.

Four primary contributions emerge from the thesis. First, by examining the connections between structures and agency underpinning regulatory processes and decisions from a routines-practice perspective, the thesis offers theoretical specifications of how the mutually enabling bundles of codified stable patterns in the form of organizing structures, and the actual situated accomplishment of product evaluators, interact to co-constitutively define the shared organizing practices that portray what, and how, regulatory reviews are conducted. Second, explicating beyond the contents and sequence of aggregated patterns that define regulatory review processes, the thesis extends our understanding of regulatory reviews by unveiling how the situated enactment of regulatory evaluations possesses a great deal of socio-cultural contingency, such that the navigation of organizing boundaries to define new evaluation *paths* is construed in interactions within webs of competing and complementary logics, socio-cultural repertoires and persuasions, and a duality of stability and agility-seeking. Third, the thesis offers deeper insights into the dynamics of micro situated practices of the atomistic individual who engages in the day-to-day evaluation of new products, the interactive web of mutually enabling relationship between organizing structures, clusters of evaluation routines and their co-evolving patterns to define both stability and change in regulatory review processes. Fourth, contributing to the burgeoning discourse on the relational ties between innovating firms and regulatory agencies as a form of non-market strategy that yields competitive advantage, the thesis underlines the collaborative efforts between innovating firms and regulatory agencies as a pragmatic approach to developing expertise and narrowing the knowledge gaps that have long underpinned the enduring concerns about regulatory uncertainty.

Declaration

I hereby declare that the thesis is based on my original work, except for quotations and citations which have been duly acknowledged. I also declare that it has not been previously or concurrently submitted for any other degree at Brunel University or other institutions.

Derrick Boakye

Derrick Boakye

23/04/2023

Acknowledgement

The writing of thesis was undoubtedly shaped by all sorts of intellectual inputs from my supervisory team, colleagues, friends, and family. I am really grateful to them for the many hours spent to engaging in extensive thinking, debating, and critiquing; it has indeed come a long way to widen the scope and clarity of the ideas imprinted in this work. On the long list of all deserving credit for their contribution, however, I would like to single out a few. First, my principal supervisor Professor David Sarpong, who has been the all-important motivation to my embarking on this scholarly journey, and a compass guiding my navigation through the intellectual wilds. His disposition to sharing all he has ever learned, nurturing in me a zeal for excellence, his endless sacrifices, of time and even pecuniary, has helped carve out of me a *scholarly character* and uprightness. I cannot hurl all credits at David without acknowledging that his efforts were equally made possible by sacrifices of his loving family who understand and continue to support him. I am also grateful to my loving aunt Cynthia 'Maafio' Antwi, whom I call "mum", for all her kindness, and for giving me the opportunity to pursuit this academic endeavour. To my mother Adwoa Foriwah for teaching me how to read, and my father Eric Boakye whose affectionate description of me as the *primus inter pares* has been a source of motivation. And to the very person who has made my life as a PhD student a little less boring, Philomina 'Stone' Sarpong, and her family, for all the delicious homecooked meals. I also wish to acknowledge the Brunel Business School and the Ghana Scholarships Secretariat for funding and supporting this research. Many thanks to the CEO of Ghana Food and Drugs Authority, Delese Mimi Darko, for granting my access to the agency to conduct this study, to Percy Adomako Agyekum for guiding me through various departments and units of the FDA, and to all respondents who willingly and eloquently shared their insights to constitute the rich data set in this thesis. Finally, I am grateful to all scholars whose intellectual works have served as the bedrock on which this thesis has been designed to contribute to knowledge. I end by borrowing from the reported quotes of Kwame Nkrumah, that; in all things I have held myself to but one ambition and that is to pursue higher education so I may be better prepared to contribute to humanity.

Table of contents

List of tables

List of figures

Dedication

I dedicate this thesis to Great One who designed and created the universe and all its glory, through whom our gifted traits and talents are unleashed. And to all those before, those today, and those after.

CHAPTER ONE

Introduction

It is a practical truism that new product innovations (NPIs) are critical to organizational renewal and underpin competitiveness and survival in today's high-velocity business environment (Danneels, 2002; Miller, 2021). The quest to create and capture sustainable competitive advantage through value propositions that satisfy the ever-changing needs and demands of society is therefore very much rooted in the innovative capacity of the contemporary organization. Thus, for most of today's firms, developing and commercialising innovative products is the lifeblood of their very existence (Heidenreich & Kraemer, 2016; Slater et al., 2014). In this regard, the concept of innovation has since captured the core interest of scholars, who have sought to answer pertinent questions about forms of innovation and their implications for business organizations and industries. Such efforts have led to the conceptualisation of product innovations as being radical, on one extreme end of the conceptual pole, and incremental, on the other (Alexander & Van Knippenberg, 2014). Offering insights into the degree and magnitude of change in the core working principles and design of new products, as well as their continuous improvement as products hybridize with market conditions, these foundational concepts of product innovation and their turbulent effect on market dynamics have seeded several variant abstractions of product innovation, including architectural and modular innovations, *inter alia* (Fixson & Park, 2008). However, the extant literature further underlines that the concept of innovation finds its absolute meaning through the adoption and diffusion of the new product into the market (Datta et al., 2015; Slater & Mohr, 2006). In other words, innovation comprises technological development of a product combined with the market introduction of that product to end users (Prieger, 2007). As Garcia and Calantone (2002, p. 122) explained, innovation is an "iterative process initiated by the perception of a new market and/or new service opportunity for a technology-based invention which leads to development, production, and marketing tasks striving for the commercial success of the invention".

Yet, the process of commercialising product innovations on the market, and ensuring their success, is melded in a complex web of interactions with several nonmarket actors and stakeholders, particularly regulatory agencies whose standards, rules, and requirements have to be satisfied in order for new products to receive legitimacy and support in the market (Kessler & Chakrabarti, 1996; Foucart & Li, 2021; Guidi et al., 2020). Preoccupied with their mandate to protect public health and safety, regulatory agencies primarily conduct technical evaluations of NPIs to mitigate public health risks and deception (Gao & McDonald, 2022; Rindova et al., 2005; Wiegmann & Roca, 2021). Thus, an NPI is adjudged fit for commercialisation based on the outcome of regulatory reviews that are guided by rigorous scientific testing rules and safety principles (Polidoro, 2020; Sherman et al., 2017). Nonetheless, there are existing (and emerging) concerns about regulatory review processes having somewhat inhibiting influence on innovation efforts. Specifically, some scholars have argued that prolonged and complex regulatory review processes slows down the pace of achieving widespread commercial application of critical innovation outputs, and even lead to loss in profits or competitive advantage that may be accruable to the innovating firm (Carpenter, 2002; Hargadon & Douglas, 2001; Polidoro, 2020). Also, the regulatory review process may entrap innovators in a web of uncertainty about the commercial tendency of their outputs, widening the valley of death in innovation and thereby distorting investor confidence as the predictability of returns on investment becomes practically impossible (Gao & McDonald, 2022; Kwon et al., 2022; Roca & O'Sullivan, 2020). This concern is further intensified in the context of nascent industries, where regulatory agencies often lack appropriate frameworks for evaluating products that are developed from such domains (Gao & McDonald, 2022; Kuzma & Besley, 2008). Of particular concern is the inability to define comprehensive regulatory standards for emerging sustainable NPIs that seem to cause technological discontinuities and emerge from these nascent industrial fields (Bergek et al., 2013; Yuan & Zhang, 2020).

Against this background, prior research has sought to understand the contents of the regulatory review process, what influences decisions to approve or reject products, and how innovating firms could navigate existing barriers. Several studies have thus drawn attention to the scientific rigour

through which the regulatory review process, as executed by experts who are perceived to be well-informed about the different technologies driving the NPI landscape (Hargadon & Douglas, 2001; Rindova et al., 2005), develops it contents of product testing techniques, standards, rules-setting, monitoring, and reinforcing of safety requirements post-commercialisation (Guidi et al., 2020; Polidoro, 2020; Sherman et al., 2017). Furthermore, regulatory agencies are often found to set up their robust product evaluation criteria by situating their evaluation standards within broader regulatory arrangements in order to enhance their influence on the legitimacy of products and to facilitate commercial penetration into other geographical markets (Manders et al., 2016). Yet, regardless of these organizing logics underpinning the regulatory review process, some prior studies have identified several 'non-scientific' elements that tend to influence or shape regulatory decisions and processes. For instance, Dranove and Meltzer (1994) argued that the 'importance' ascribed to products, in terms of the social importance of the new product, has the potential to influence the speed of regulatory review. Also, other studies suggest that regulatory agencies often rely on prior decisions on a product, usually in other collaborating regulatory jurisdictions, to assuage risk and safety uncertainty, thereby enabling rapid product reviews (Ishibashi et al, 2012; Kaitin & Cairns, 2003). Also, the size and characteristics of the innovating firms has been found to enable them to invest in intensive research and development to limit product risk and enhance efficacy, build reputation within the regulatory landscape, and muster socio-political influence on the regulatory agencies (Carpenter, 2004, 2002; Olson, 1997). An emerging consensus also draws attention to how the social and institutional environments within which the NPIs are developed determine the outcomes and dynamics of regulatory reviews (Hargadon & Douglas, 2001; Ishibashi et al., 2012), the cognitive effects of routines in diffracting experiences of regulatory speed and decisions as evaluators come to understand the underlying technologies on which new products are built (Polidoro, 2020), and the intensity of collaborative efforts to address regulatory voids (Downer, 2010; Gao & McDonald, 2022; Prieger, 2008).

Cumulatively, these insights on the organizing practices of regulatory agencies have come to inform trends in strategies adopted by innovating firms to navigate the complexities and impediments

posed by regulatory review processes. A dominant approach has been the adoption of well-coordinated policy-influencing strategies to influence and direct the politically sensitive regulatory agency (Carpenter, 2004) to favour products from a focal firm— what has come be known as 'non-market' strategies (Bonardi et al., 2006). Such approaches may include indirect influence through peer agencies and powerful stakeholders who tend to frame the legitimacy of regulatory agencies (Hiatt & Park, 2013), instigating public and media pressure, political connections, lobbying, and the use of market reputation as a preconditioning mechanism to influence interdependency and co-optation (Carpenter, 2004, 2002; Dranove & Meltzer, 1994; Ozcan & Gurses, 2018). Ultimately, these strategies are designed to overcome regulatory uncertainty in gaining access to the market in order to accrue competitive advantage (Gao & McDonald, 2022). However, given that this endeavour is challenging and costly to execute, and that the existing regulatory manoeuvring tools remain in boxes that are the prerogative of large, established firms (Gao & McDonald, 2022; Carpenter, 2004), definitions of informed steps towards building interactive structures that offer wider opportunity for innovating firms to adaptively respond to regulatory activities are lacking. This has ignited further research on how regulatory agencies could reconceive their role as non-market intermediaries whose activities contribute to a web of stakeholder relationships which are geared towards fostering innovation (Foucart & Li, 2021; Kivimaa et al., 2019; Roca & O'Sullivan, 2022). A burgeoning literature also draws attention to the cognitive effects of routines as the underlying delays in regulatory reviews, providing insights into the dynamics of regulatory activities and how their influence on innovating firms could be redressed (Polidoro, 2020).

Despite the prevalence of scholarly efforts to understand the regulatory review process, strategies to allow innovating firms to navigate regulatory constraints, and re-conceptualization of the role of regulatory agencies as innovation intermediaries (Kivimaa et al., 2019), insights into the degree to which local rationale for evaluating and categorising new products in distinct contexts remain sparse. In addition, little research has examined the internal organizing dynamics of the regulatory agencies and how their sets of embedded situated activities come to shape (or be shaped by) the innovation

landscape. Prior attempts to address this pertinent issue have only managed, in part, to provide insights into the causal logics between factors that determine the dynamics of regulatory review process within an empirically skewed pharmaceutical industry (Hiatt & Park, 2013; Kwon et al., 2022; Polidoro, 2020). Furthermore, the existing contributions are often developed within stable contexts where regulatory standards and guidelines are clear and fully fledged. As a result, the extant insights are limited in terms of their ability to offer a holistic understanding of dynamics of regulatory reviews in agile contexts. Attention to this gap is particular important, as the innovation landscape is one that is characterised by a high-velocity environment where important new products may emerge without a predetermined regulatory evaluation standard or guidelines (Gao & McDonald, 2022; Grandy & Hiatt, 2020; Kuzma & Besley, 2008; Lee et al., 2017). Consequently, knowledge gaps are created between reviewers and innovators about the technologies underpinning NPIs, thereby impeding the ability for regulatory agencies to quickly adapt the evaluation framework to respond to the ever-changing innovation landscape to provide bespoke evaluation criteria (Gao & McDonald, 2022; Liberti et al., 2013). Meanwhile, research on the regulatory reviews/agencies to date has offered little insight into the adaptive qualities of regulatory agencies, since they responsively become dynamic in their everyday execution of product evaluations, as they accumulate, develop, and assimilate new knowledge. Hence, insights into how regulatory agencies create fit between their organizing schemas, rules, standards, guidelines, and the emerging needs and trends in the innovation landscape and the market selection environment remain scant. As Guidi and colleagues (2020, p. 8) argued, there is a need for scholarship on regulation to revert 'back to their roots' and make the question of what influences regulatory choices more central in their studies, examining the connections between the structures and agency influencing regulatory decision-making. This call raises key questions on how to unpack the substrate organizing structures and practices, and the pairings of socio-cultural schemas, cognition, and material artefacts that sustain regulatory review processes and allow product evaluators to imagine new paths for executing product evaluations.

A critical reflection on these concerns brings into view the need to extend the empirical setting beyond the already-defined stable regulatory contexts, and to narrow the analytical focus to the emic. Embarking on such scholarly endeavour thus requires consideration of a more agile regulatory review context, coupled with sensitivity to a theoretical construct that has the potential to zoom in and shed light on situated actions, and the socio-cultural and cognitive constructions that cumulatively influence and shape the regulatory review process and decisions. In this respect, insights from existing works on the cognitive underpinnings of routines in regulatory review processes provide some important theoretical leads. According to Polidoro (2020), although the cognitive effects of regulatory evaluation routines may lead to delays in the commercialisation of NPIs, this phenomenon may also signal opportunities for regulators to adopt 'metistic knowledge' (Sarpong et al., 2018), which is needed to inform and realign the regulatory review framework to match and respond to the complexities of emerging technologies. Therefore, given that routines provide fundamental insights into an organization (Tsoukas, 2021) and "represent an invaluable resource to capture organisational change" (D'Adderio, 2008, p. 769), the theoretical concepts of routines become extremely important in addressing questions on how regulatory agencies (re)organize their day-to-day activities and adapt their product evaluation processes. Specifically, drawing on a practice perspective of routines (Parmigiani and Howard-Grenville, 2011), which is rooted in the sociological thoughts on the recursive relationship between structure and agency as mutually enabling (Geiger, 2022; Feldman & Orlikowski, 2011; Feldman & Rafaeli, 2002), opens the opportunity to explore how abstracted or patterned processes that guide specific modes of situated actions, undertaken within time and space, may come to shape the dynamics of change and adaptation in organizing (Danner-Schröder, 2021; Feldman, 2000; Feldman & Pentland 2003)— and in this study, the organizing of regulatory reviews. Furthermore, this practice perspective not only recognizes that routines are the building blocks of the organization but also emphasizes routines as much more complex adaptive systems (Feldman & Pentland, 2022, p. 6), which when keenly observed would be able to provide a fine-grained understanding of how contextual

contingencies may diffract product evaluation routines as they encounter varying contexts and conditions.

The routines-practice perspective (which is often captured as Routine Dynamics Theory in the extant discourse on routines) thus becomes relevant to addressing the existing gaps in the literature on regulatory reviews. Particularly, this perspective allows for the rendering of prominence to the context-specificity of situated enactment and the socio-material artifacts through which logical adaptations in the regulatory review processes can be conceived. In this respect, a regulatory review process is abstracted in this thesis as a pattern of actions and practices that are bounded by both scientific testing rules and social, organizational, and cognitive factors (Cohen, 2007; Feldman, 2000; Pentland & Rueter, 1994). Product evaluations are thus a set of routines that are 'enacted' into life by multiple and situated performative accomplishments of product evaluators, which are in constant flux and deeply entrenched in the dispositional realm of the emotional, cognitive, as well as the material and social world (Pentland & Feldman, 2005; Reckwitz, 2002). The complex interrelation between these contextual contingencies allows for cumulative development of useful shared understanding of the product review processes as well as the dynamic interactions of regulatory agencies with the innovation landscape. This implies that the ways in which product evaluators make use of what they have learned in their situated practices to shape both individual and collective action, and that of the regulatory agency as a whole, and in turn learn from the results of what specific actions have been undertaken (Cohen, 2007, p. 775), is perceived to underlie the adaptive responses of regulatory agencies to changes in the innovation landscape. On this basis, ontological commitment is rendered to the Heraclitan philosophy that 'everything changes, and nothing abides', in order to conceptualising the regulatory review process as being in continuous change so as to inform delineations on how regulatory agencies respond and adapt to the equally inevitable change in the technological landscape. Effort to verse an account of the infinitesimal patterns through which this adaptation of regulatory evaluation routines unfolds would therefore serve the theoretical impetus to providing fine-grained explication of the

mechanism through which socio-organizational and cognitive constructs emerge and fall out of use in the regulatory review of NPI processes.

Situating an empirical response to how regulatory agencies and their product evaluation processes evolve within routines-as-practice, however, begins by drawing on the foundational argument within this perspective, which highlights that routines are constitutive of both abstract patterns that are formally espoused and often codified, or *ostensive routines*, and the specific actions taken, within which the tacitly conceived patterns are expressed enacted, or *performative routines* (Cohen et al., 1996; Feldman & Pentland, 2003; Pentland & Feldman, 2005; Rerup & Feldman, 2011). This metaphysics of routine is critically important because in the context of regulatory reviews there are explicitly stored, formal guidelines and standards that represent the explicit knowledge of the product evaluations processes (Chorniy et al., 2021; Sherman et al., 2017), and which are transmissible in the formal systematic language of the regulatory agency. Furthermore, given that "not all knowledge is codifiable" (Hodgson and Knudsen, 2004, p. 7), there is a clear distinction between 'knowing how' and 'knowing that' in the regulatory review process. This thus brings into view how the specific performative actions of the regulatory officers and the organizing practices of the regulatory agency are shaped and executed, as they go forth to enact the espoused patterns of product evaluation. In addition, the enactment of product evaluation routines is initiated with predefined intentionality and meaning, which are achieved through nurtured competences and their materiality (D'Adderio, 2011; Dittrich & Seidl, 2018; Orlikowski, 2007; Shove et al., 2012). This implies that all material elements – such as standard operating procedures, product review application forms, evaluation guidelines and parameters or standards, laboratory equipment and chemical solutions or solvents, and computer systems, among others – become central to the accomplishment of the product evaluation routines. Also, the ability to conduct laboratory testing, use material artifacts, and understand and interpret evaluation standards, as well as the capacity to perceive the prevailing technological knowledge in the innovation landscape, further constitute the competences of the product evaluator. Finally, meanings associated with the regulatory review process are relayed in the form of *power* wielded by regulatory

agencies to protect public health and ensure safety, influencing decisions that are elicited on the selection environment, restricting or approving products to commercialise, and in shaping the trajectory of future innovation.

Against this background, the primary aim of this thesis is to draw on these theoretical insights to embark on a scholarly endeavour to provide empirical characterisation of how the everyday adaptive practices of product evaluators— which are socio-cognitively defined within the boundaries of their contextual materiality— contribute to efforts to (re)define the regulatory review process and adjust the regulatory frameworks in response to new markets, production processes and the changing market contexts within which the technologies underpinning products are developed. Therefore, the situated practices of the product evaluators which define the regulatory review process are understood not merely as events or complementary actions, but as mutually recursive and constitutive of the cognitive, corporeal, and social world (Feldman & Orlikowski, 2011). In accounting for the mechanism through which situated actions can inform the regulatory review process, attention is directed towards understanding the (un)conscious thoughts, reflections, tacit knowledge, and discernible patterns of relational actions that are not easily codifiable but tend to define the process of producing and reproducing the patterns of the regulatory review process. However, in theorising the evolution of regulatory reviews, the thesis first presents a set of conceptual vocabulary which further strengthens and situates the enactment of product evaluations in a much more succinct dialectical expression of those routines as effortful accomplishments that are cognitively bound. An emphasis on the distinction between organizational cognition (Secchi & Cowley, 2021) and the cognitive or motor activities that encompass situated actions of routine enactors (Nayak et al., 2020) constitutes what is termed in this thesis as *cognitive* and *noncognitive routines*. Thus, on the one hand, cognitive routines represent the well-known aspects of organizational life within the broader organizational cognition, and which constitute the commonly known patterns of action or shared cognition within the organization (Cannon-Bowers & Salas, 2001; Secchi & Cowley, 2021). Moreover, the explicit characterisation of an

organization's processes is referred to as the cognitive representation of the organization (Lazaric, 2021; Gavetti & Levinthal, 2000; Zuzul, 2019), and hence, that of regulatory agencies.

On the other hand, noncognitive routines capture the tacit nature of specific performatives of routines, which eventually transform into knowledge that is deeply rooted in the enactor's mind, such that it is difficult to codify and communicate (Pentland & Feldman, 2005). It can be expressed only through action and involvement in a specific context, and acquired through experience, observation, imitation, and practice (Kim, 1998). Thus, although "abstract understandings of routines are distributed across a complex web of people and everyday artefacts" (D'Adderio, 2011, p. 777), the situated enactments reserve a pragmatic development of routines that define the variation between agents' actions and the espoused patterns (Dittrich & Seidl, 2018; Feldman, 2000; Teece, 2012). The core argument here is that what underpins situated actions is an embodiment of capacity of the actor's skills, know-how, tacit knowledge and presuppositions. As Dosi et al. (2000, p. 5) argue, "some of the non-modular knowledge required is skill-like, regardless of what it is called—but these are skills that can be learned only through experience in the specific organization". This also draws to attention an incisive definition of implicit/tacit knowledge, captured by Cohen et al. (1996, p. 668):

> …implicit knowledge is knowledge about covariations in the environment, learned by exposure to stimuli exhibiting the covariations, obtainable without attention or awareness, demonstrated by improved performance, but not fully verbalizable, and not fully manipulable, in the sense that it cannot be re-represented explicitly to serve as input to other procedures.

This form of tacit knowledge therefore describes agents' ability to execute an action, but it is difficult to fully explain why they perceive things as they do (Cohen et al., 1996; Collins, 2005). Thus, the knowledge which is acquired through the performatives is linguistically captured in cognitivist terms as noncognitive routines (Nayak et al., 2020). As such, the use of the term 'noncognitive' here does not imply that the routine is mindless or does not require cognitive efforts; rather, it is used to contrast the

organization's cognitive representation/routines with the tacit knowledge that is acquired in the arena of actions.

Rooted in these theoretical arrestations, this thesis conceives the enactment of espoused patterns of product evaluation (cognitive routines) to survive on the substrate of the tacit knowledge honed from practical experience and exposure to the socio-material context, which seeds the enactment of noncognitive routines. In other words, the enactment of noncognitive routines forms the backdrop against which the cognitive routines come to life. They therefore constitute the organizing practices of the regulatory agency that are transmitted into the formal and explicit artifacts of the regulatory agency's cognitive routines to define the adaptivity and change in regulatory review processes. As Nelson and Winter (1982, p. 134) noted, "much of the knowledge that underlies the effective performance is tacit knowledge of the organization, not consciously known or articulable to anyone in particular". In this respect, the objective here is to build a convincing account of how the mechanism through the dynamic interplay between cognitive and noncognitive routines comes to be implicated in the negotiation of stability and change of regulatory review processes. More importantly, the thesis seeks to provide a theoretical explication of how stability in coordination and change in improvised forms of routines may come to characterise regulatory reviews and decisions. Thus, a fine balance is established between the organizational cognitive routines that are captured in artefactual materials and the socio-cultural practices and individual cognitions that yield the enactment of noncognitive routines to underpin the content, sequences, and processes of the regulatory review of NPI. The empirical focus, therefore, is to map out how new evaluation routines emerge and become normalised or naturalised within the contingencies of socio-organizational and cognitive elements. This journey through the empirical wilds is guided by three interrelated research questions:

1. How do cognitive and noncognitive routines come to be identified and labelled in the discourse of regulatory review?

2. How and when do noncognitive routines lead to the identification of opportunities for innovation in the regulatory review process?

3. What are the organizing practices that enable (or impede) noncognitive routines in regulatory review of new product innovation?

These questions are considered in the context of the Food and Drugs Authority (FDA) of Ghana: the official regulatory agency that is mandated to scientifically evaluate and approve new products for commercialisation in Ghana (Dowuona-Hammond, 2018). The FDA represents a rarely explored context of an agile regulatory agency that is responsive to industry dynamics and whose operation is embedded in an underdeveloped context where socio-cultural artifacts and practices, and dispositional mindsets of product evaluators about the nature of the products under review, serially combine to extend regulatory decision-making beyond the putatively rooted scientific logics. In this regard, the execution of noncognitive routines in this context is considered to yield variations that may be assimilated into the cognitive routines, thereby helping to account for the mechanism of change and adaption of regulatory review frameworks (D'Adderio, 2008; Pentland & Rueter, 1994). Furthermore, this empirical context affords the opportunity to observe multiple processes within the FDA's product review framework, which is composed of rich and complex routines that satisfy the overriding interest of this study. In approaching this empirical site, the study draws insight from recent studies adopting inductive theory-building through observation and analyses of single exceptional cases (e.g., Aversa et al., 2021; Vaccaro & Palazzo, 2021) to focus on the FDA's review of New Alcoholic Beverage Applications (NABA). This is significant, as it presents an important departure from the empirically dominant pharmaceutical drug, medical devices and genetics industries in the extant body of literature (see, for example, Gao & McDonald, 2022; Olson, 2008; Polidoro, 2020). In this regard, the focus on NABA offers an opportunity to provide a more holistic characterisation of the regulatory review landscape, thereby extending the stock of knowledge beyond the existing boundaries of thought. Furthermore, the general evaluations of NABA – including details on the products' labelling, and the decision to approve, defer, or reject a product – in the context of the FDA, is not solely based on the scientific analysis of the 'technological' constituents of the product. Rather, social practices and the

dispositional mindsets of the product evaluators about alcohol consumption cumulatively influence the evaluation routines and decisions. This implies that the scientifically bounded logics of the FDA's regulatory evaluation routines and decisions may be fraught with the influences of discretion, improvisation, cognitive constraints, and socio-religious values (Garud & Rappa, 1994; Winter & Szulanski, 2001). As such, the embeddedness of the FDA's evaluation of NABA in this context helps to bring into clearer view the ways in which product evaluators establish a viable and comprehensive shared understanding of their situated practices, not only in terms of the general representations of the regulatory agency's cognitive routines, but also in terms of the sociocultural persuasions of the individual product evaluator, and that of the context.

Data for this empirical enquiry is gathered through thirty (30) semi-structured interviews with informants at the FDA, spanning product reviewers, who are at the coalface of the review of the new product applications; laboratory analysts, who engage in the biological and physiochemical testing of products; heads of units and departments, who act as supervisors in the NPI review process and engage in the deliberations leading to the final regulatory decision; and field officers, who ensure continued evaluations after products have gained authorisation to be commercialised through post-market surveillance. In addition, 375 pages of FDA documents, which capture the key tasks, activities, behavioural and ethical codes, and rules that constitute the cognitive routines are sourced and analysed. Furthermore, as Pentland and Feldman (2008, p. 344) noted, "we cannot discern the significance of an artifact by inspecting it from our own (etic) point of view". On this basis, the study is designed to render priority to observing regulatory officers at the FDA in their effortful accomplishment of routines in their situated roles, which are guided by documented procedures and codified processes, but which present evidence of enacted variations in practice. Hence, the interview and documentary data are bolstered with 350 hours of observation, which render insights into the situated practices and enactments of the product evaluators at the FDA. The data analysis takes an inductive approach to emerge a comprehensive account of the mechanism through which the

emergence of these 'non-scientific' constructs in the regulatory review processes may come to be implicated in the dynamic interplay between the artifact-embedded (non)cognitive routines.

In this vein, the thesis offers four main contributions to the discourse on regulatory reviews. First, it provides a theoretical understanding of how the mutually enabling set of codified patterns in the form of organizing structures, and the actual accomplishment of product evaluators, interactively define the organizing practices that portray what, and how, regulatory reviews are conducted. In this respect, the thesis responds to calls to examine the connections between structures and agency influencing regulatory decision-making (Guidi et al., 2020) by explicating beyond the contents and sequence of aggregated patterns that define regulatory review processes to include the dynamics of micro situated practices of the atomised individual who engages in the day-to-day evaluation of new products. Second, the thesis unveils how specific contexts present varying frames for enacting regulatory reviews and the performative processes through which evaluation standards are adopted and assimilated into the socio-cultural context, as well as emerging cues from the innovation landscape. Thus, context-specific dynamics inflict distinctive practices that define a local rationale for evaluating products, but innovatively strive to remain in conformance with the established standards and rules within the broader regulatory landscape. Third, offering new insights on how a dynamic configuring change and redefinition of the existing coherent sequence of product evaluations helps to address concerns about how regulatory cost, uncertainty, and delay come to be reposed in the interactive web of mutually enabling relationships between organizing structures, clusters of routines and their co-evolving patterns to define both stability and change in the regulatory review processes. This brings into illumination how the learning regulators (Carpenter, 2004), within the contingencies of organizing, come to refine their evaluation processes through a constitutive mode of knowledge conversion which exists between the acquired tacit knowledge of the regulatory officers and the scientific-bounded schemas for evaluating products. Fourth, the thesis presents an important point of departure from the enduring notion on the use of non-market strategies to influence regulatory decision-making by providing insights on how direct *regulator–innovator* interactions effectuate shared reasoning to

influence regulatory review processes, standards, and decisions. Thus, the thesis draws attention to collaborative efforts between innovating firms and regulatory agencies toward bridging knowledge gaps to ensure that regulatory review frameworks are responsive to the dynamics of the innovation landscape. Consequently, a regulator-innovator nexus is drawn to the centre-stage, labelling it as a pragmatic approach to developing expertise and limiting knowledge gaps affecting regulatory review processes.

1.1 Structure of thesis

Following this introduction chapter (**Chapter One**)— which captures the background arguments within which this study is situated, highlights the existing lacunae in the literature, outlines the study's aims and objectives of the study, delineates the research questions and how they are addressed, and presents a snapshot of the contributions of the study— the remainder of the thesis is structured into six chapters:

Chapter Two presents a critical review of the extant literature on the regulatory review of new product innovation. In doing this, the chapter begins by exploring the literature on new product innovation and its various typologies, after which it critically examines the current body of knowledge on regulatory reviews, thereby creating a connection between these two streams of scholarly engagement. In conducting an in-depth critical analysis of the discourse on regulatory reviews, a systematic approach to mining, selecting, and synthesising the relevant literature for reviews is delineated. In this effort, conceptual models and tables are presented to unpack the existing arguments on specific regulatory concerns that influence product evaluation processes and decisions into four main themes: *speed and delays*, *safety and efficacy*, *cost and uncertainty*, and *routines*. Following this, the empirical gaps are highlighted to emphasise the need for immediate scholarly attention. Next, the chapter extends the analysis of the literature and its gaps by identifying important theoretical leads to address the identified shortcomings in the literature. Specifically, the chapter provides a situated

exploration of the areas that have received empirically modest attention within the recent burgeoning theoretical arguments on organizational routines. After exploring the core foundational insights that underpin the extant discourse on organizational routines and highlighting the differing ontological perceptions and conceptual specifications that have come to shape the argument on what routines *are* and how their enactment defines and shapes organizational reality, the chapter abstracts in cognitivist terms the conceptual vocabulary for aspects through the practice perspective on organizational routines. After establishing that routines and practices are inextricable, as we cannot make sense of or assume the existence of one without the other, the chapter goes on to situate the discourse on regulatory review within the routines–practice perspective. Following the presentation of a conceptual model that captures these important theoretical constructs, the chapter concludes by highlighting the significance of the routines–practice perspective as a metatheoretical lens to unpack the web of socio-cognitive and organizational relations in which change, adaptation and inertial qualities of regulatory agencies and their evaluation frameworks may come to be identified and labelled.

Chapter Three offer insights into the methodological tools and strategy adopted to garner and analyse the empirical data for the study. The chapter begins by presenting a detailed description of the research setting – FDA Ghana – along with the historical background of the regulatory agency, its organizing structures, and the unstable and underdeveloped context within which its product evaluations are conducted. The chapter renders prominence to socio-cultural practices in the interpretation and enactment of product evaluation routines to shed light on context-specific dynamics that define a local rationale for executing regulatory reviews of NPI. In addition, it defines the case study approach adopted to set the focus for the dynamics of situated enactments to observe, and which serves as a springboard to attract insights from other related products, in order to offer a distinct nature of products as a counterplay to the conventional focus on the pharmaceutical drugs and genetics industry. In this regard, the chapter provides a detailed discussion of alcohol consumption, market trends and policies which place the FDA at the centre of national efforts to control the use of such products. Here, the chapter draws attention to how such social concerns and polices come to hold the

potential to extend regulatory review processes and decisions beyond the scientific analysis of the 'technological' constituents of the product to include influences from social practices, including socio-religious persuasions and the dispositional mindsets of the product evaluators about alcohol consumption. Following this, fine details of the research design are presented, while at the same time capturing arguments that problematise the existing methodological approach and the abstractions that limit the ability to achieve immersion into the interplay of socio-cognitive dynamics in regulatory review processes. In addition, the chapter highlights how the paucity of research on these core subjects in the discourse on regulatory reviews, and the nature of the theoretical underpinnings of the study, create the impetus to adopt inductive qualitative traditions for the study. It then provides details on the sampling strategy, including the selection criteria, access negotiation and research ethics approval, and the participant recruitment procedure. In addition, conditions imposed by the Covid-19 pandemic and the safety procedures put in place prior to and during the data collection process are discussed. Next, a detailed explanation of the data collection process is presented, highlighting each of the data collection tools employed and presenting in detail the contents and purposes of each. The subsequent section presents the details of the analytical procedure, the data coding strategy for generating theoretical insights from the data, and qualitative measures for ensuring validity and accuracy of theorising. The penultimate section of the chapter presents some reflections on the methodological limitations, after which the chapter is concluded by way of a summary.

Chapter Four provides the first set of empirical findings in response to the foremost research question. Specifically, it presents both a theoretical understanding and an empirical characterisation of how the (non)cognitive routines constructed come to be identified and labelled in the discourse of regulatory reviews. The chapter begins by providing an overview of the repetitive patterns of action (or routines) that define the process of evaluating products at the FDA. Following this, the logical underpinnings of the organizing routines that constitute the regulatory review process are unpacked. In this vein, the espoused routines of the FDA and the situated enactments of the product reviewers are delineated along four lines of attention. The first theoretical theme, *differing cognitive demands*, draws

attention to how the regulatory officers at the FDA strike a distinction between the enactments of cognitive and noncognitive routines in the situated practices. It therefore underlines that while the cognitive routines embody the specific procedures, configurations, intentions, and meanings of the regulatory review framework, the noncognitive routines sustain the practically honed tacit knowledge that is expressed in situated actions within the boundaries defined by the cognitive routines. The next theme, which is captured as *frequency conceives mastery*, delineates how the repetitive nature of patterns of action sustains the core operational identity of the FDA. Furthermore, this theme elaborates on how frequent and prolonged involvement in these patterns yields in-depth understanding of when and how the cognitive patterns of activities are triggered, the materials/artefacts and competences required to enact the routines, and the symbolic meanings that the routines must accomplish, thereby defining the co-constitution of (non)cognitive routines in the regulatory review process. Also, the *knowledge-gathering power* theme captures how the effective elements of the noncognitive routines transcend into the codified processes to constitute the bundles of routines that underpin what organizing reality at the FDA is negotiated and how. The final theme, *decaying patterns of action*, empirically demonstrates how the 'learning to unlearn' characteristic of routines at the FDA leads to the elimination of some existing cognitive patterns, thereby becoming consequential in the bid to (re)design efficient structures of collective action.

Chapter Five submits empirical characterisation of *when* and *how* noncognitive routines in new product evaluation lead to the identification of opportunities for innovation in the regulatory review process. The chapter focuses on explicating the underlying socio-cultural practices which determine the context-specific dynamics that yield variations in the replication of established regulatory guidelines and evaluation standards within global regulatory discourse. It therefore makes apparent how imperfect organizing conditions, both within the FDA and in the local context, are navigated to yield new forms of organizing repertoires that come to define how the situated role-routines of product evaluators are enacted to initiate change in the cognitive routines of the FDA. In doing this, the chapter first delineates the pragmatic paradoxes of the ways through which socio-cultural persuasions come to

ignite variant forms of organizing routines relevant to prevailing conditions. The chapter goes on to provide a detailed analysis of this phenomenon through four theoretical frames. It begins with an analysis of how the contingencies of meaning, practice, and cultural repertories enable social structures to define the broader cultural norms at the FDA to establish a set of contextual knowledge that informs the situated logics for enacting the regulatory evaluation routines. Playing out as an imperfect organizing system, the chapter underlines the FDA's understanding of the need to be agile and adapt its regulatory framework to the perceived or preferred regulatory standards across the regulatory landscape. Next, it delineates how these cultural practices spell out the institutional configuration, which defines ways of adopting and enacting cognitive regulatory evaluation routines. Hence, it unveils how the cultural tools used to assign meaning and interpret the activities of the FDA are mobilised to frame the regulatory framework around a perception of complex scientific analysis and rigour in order to secure their legitimate role in the market selection environment. Following this, the chapter presents the power of *reflexive monitoring* of organizing routines in shaping tacit knowledge to navigate the complexities of the regulatory and innovation landscapes. Specifically, it provides a detailed analysis of how the regulatory officers create and enact change-triggering conversational spaces that facilitate 'collective reflection' to imagine new, robust patterns for evaluating products. The final theme in this chapter provides insights into how the situated practices of product evaluators inform emergent forms of organizing in the event of jolts to the established routines, as well as the role of technology in ensuring the stability and sustainability of such adaptive outcomes.

Chapter Six offers an empirically grounded explication of the organizing routines that enable or impede change and adaption in regulatory review processes. The chapter begins by demonstrating how the duality of inertia and flexibility that characterises the dynamics of routines is exhibited in the context of the FDA. It defines how situated actions underlying product evaluation routines (re)create the organizing structures of the FDA, which constrain and/or enable adaptive responses that are reposed in noncognitive routine enactments. Following this, four main theoretical categories are expanded to capture the underlying mechanism through which this phenomenon is exhibited. First,

the dynamics of organizing the organizing structure that recognizes that, regardless of the product evaluator's intellectual grasp of their situated practice to facilitate the enactment of noncognitive routines towards productive ends, the ability to accomplish such actions in their entirety is limited by the authoritative orders that they assume. This analysis is followed by an explication of the distributed nature of the evaluation routines across subunits of enactments that provide partial or continuous contributions to accomplish the regulatory review process. In this respect, the analysis explores how the complex web of interacting routines is caught up within multiple situated practices that are actioned by professionals or experts who have distinct orientation to, or understanding of, the intentions of the regulatory review framework. It therefore draws attention to how multiple specialised blocks of closely interacting routines operate in combination to cumulatively shape and adapt the regulatory review process of the FDA. The chapter then provides a fine analysis of how change in the content of a focal routine or its enactors constrains the ability to enact noncognitive routines in order to ensure stability in patterns. This phenomenon is further explored to reveal how the ability to facilitate redistribution of knowledge that finely interacts with one another to yield an informed set of changes in order to align the patterns of change come to be, nonetheless, rooted in these *switches and shifts* in routines. The final theoretical category explored in this chapter expands on how change in the patterns of action becomes both relational and processual as co-opting mechanisms are established between the distinct blocks of product evaluation routines. Finally, a co-creation dynamic is unveiled to demonstrate the scope of possible conceptions of agility from which the FDA can construct and legitimise patterns of change that emerges from the industry in an effort to bridge knowledge gaps.

Chapter Seven presents the final discussion and conclusion to the thesis. It begins by presenting an overview of the study and its findings, after which the findings are further discussed in the context of the literature. Following this, the core contribution of the thesis is extensively elaborated. Next, the implications of the thesis for theory, innovation management and policy are delineated in detail. The penultimate section in this chapter captures the limitations of the study and the potential

avenues for future research to explore. Finally, the chapter concludes with a reflection on how the research questions have been answered, reiterating the contribution offered by the study.

CHAPTER TWO

Regulatory review of new product innovation

This chapter of the thesis presents a critical review of the extant literature on the regulatory review of NPIs. The structure of the chapter follows a chronological path from exploring the literature on NPIs and their various typologies to critically examining the current body of knowledge on regulatory reviews. In conducting an in-depth critical analysis of the discourse on regulatory reviews, the approach to mining, selecting, and synthesising the relevant literature for review is delineated. Conceptual models and tables are presented to unpack the extant literature's contributions on regulatory reviews into themes. Following this, empirical gaps are highlighted, after which the theory of routine is explored as a potential lead to address those gaps. In the penultimate section, the chapter situates regulatory reviews within the routines-as-practice perspective. The final section summarises and concludes the chapter.

2.1 New Product Innovation

NPI remains critical to organizational renewal and survival in today's high-velocity business environment, as it underpins performance, competitiveness, growth, and profitability (Hofman et al., 2016; Jacobides, 2005; Park et al., 2018). According to Miller (2021), continuous innovation is required to respond quickly to changing market conditions and industry evolution, and therefore remains "the lifeblood of firms competing in dynamic environments" (Slater et al., 2014, p. 552). The ability to manage NPIs and the resulting market and technological change thus underpins the core competence of a firm to gain competitive advantage (Park et al., 2018, p. 326). Therefore, it follows that some innovating firms may come to dominate the market or industry with their product design concepts and innovation outputs, while others may simply follow (Kessler et al., 2000). Such dominant firms may establish product designs that embody the common requirements of component features that characterize the set of core design concepts which correspond to the major functions performed by

products in the industry (Henderson & Clark, 1990). As a result, a dominant firm may define the ways in which product components are integrated and thus provide general acceptance of a particular product architecture and its characteristics of technological evolution. Nonetheless, the innovation literature brings into sharp contrast the relationship between product innovation and industry or market dominance when innovations are refined to extend the established design, and when a new dominant design is established through new combination of a set of core design concepts to form a new product innovation (Fixson & Park, 2008; Leifer et al., 2001). This also brings into view the various scholarly discussions on what has been a longstanding conception of the practical distinction between radical and incremental innovations (Ali, 1994; Ettlie et al., 1984).

Radical Innovation. Radical innovations (RI) combine a new set of core design concepts to establish a new dominant design (Leifer et al., 2001; Slatter et al., 2014). Thus, RIs are technological breakthroughs that produce landmark new products to create a distinctively new market, and potentially a new industry (Leifer et al., 2001; McDermott & O'Connor, 2002). Such innovations draw heavily on the complex skill sets, capabilities, and resources of the innovating firm to generate entirely new sets of product features that offer more positive performance outcomes (Atuahene-Gima et.al, 2005; Slatter et al., 2014; Wang et al., 2021). As such, "radical innovations represent dramatic departure from existing products…and provide substantially greater benefits for customers" (Rubera & Kirca, 2012, p. 135). More importantly, the technological principles, architecture, or components of such NPIs differ significantly from existing knowledge (Henderson & Clark, 1990; Slatter et al., 2014). However, in situations where RIs offer features that are familiar to an existing product, the innovating firm can gain competitive advantage and dominate the market, as it renders the existing knowledge or product obsolete (Lettl et al., 2006; Rubera & Kirca, 2012; Yu et al., 2010). Therefore, RIs may introduce new competitors, define the competitive landscape, and redefine the dynamics of an industry (Christensen et al., 2008; Henderson & Clark, 1990). This disruptive power of such innovations is emboldened by their ability to "satisfy unmet market needs, thereby resulting in a quantum leap in customer value" (Lettl et al., 2006, p. 252). Henderson and Clark (1990, p. 12), elaborating on this type of innovation,

illustrated that a move from a ceiling air fan to central air conditioning, for example, is an RI which is "designed from new components associated with compressors, refrigerants, and their associated controls, and add whole new technical disciplines and new interrelationships". In this regard, the central air conditioning as an RI produces a new dominant design concept, satisfies an under-served market, improves customer value, and poses a potential threat to the established product design. Thus, the literature makes a succinct description of what forms RI could take, suggesting that such innovations present major technological development and competence which may disrupt, dominate, or replace an established product category or market, or create a distinct market (Abernathy & Clark, 1985; Bower & Christensen, 1995; Henderson & Clark, 1990; Tripsas, 1997).

Incremental Innovation. Incremental innovation, or what Rothwell and Gardiner (1985) simply call 'reinnovation', is perceived as a continuous innovation that provides an extension to a product line or modification to the existing technology. It involves the development of improvements to an established product design that provide better functional benefits to the market (Oerlemans et al., 2013; Rubera & Kirca, 2012). In most cases, incremental innovations are initiated by the innovating firm through its internal R&D initiatives to enhance the firm's competence and competitiveness (Abernathy & Clark, 1985; Banbury & Mitchell, 1995). According to Garcia and Calantone (2002), an existing product innovation could, at the point of market diffusion, be rendered radical in nature, but would be conceived to be incremental at the advanced stage of the product life cycle where newer versions are introduced as improvements to the existing technology. Thus, as Henderson and Clark (1990, p. 11) also explained, such innovations present "improvement in individual components of an existing product but the underlying core design concepts, and the links between them, remain the same". Yet, incremental innovations that are internally developed by the innovating firm may cannibalise the firm's existing set of products or create a new market niche (Abernathy & Clark, 1985). They may, nonetheless, not necessarily pose a threat to the survival of an established firm when introduced by a competitor, but could equally be disruptive, as they present a core competence that satisfies changing market need (Bower & Christensen, 1995). Again, in Henderson and Clark's (1990, p. 12) illustration of an air fan,

they clarify that "improvements in blade design or in the power of the motor would be [an] incremental innovation", as they offer modifications to the established product. Incremental innovations therefore do not only reinforce core concepts but also leave linkages between concepts and components unchanged (Chou et al., 2016).

2.1.1 Other typologies of product innovation

Several scholars have long argued that the characterisation of product innovations at the polar extremes of radical and incremental is a categorisation that subsumes several other forms of innovation (Abernathy & Clark, 1985; Henderson & Clark, 1990). This important stream of the innovation literature provides a distinctive categorisation of various forms of innovations in terms of their combination of components and their linkages between components. Such scholarly efforts have become critically important, as the ability to initiate and manage this form of innovation, in practice, is a strategic means for delivering both reliable and variable innovations to achieve high performance leading to operational advantage, and hence explains intra-industry heterogeneity across firms (Baldwin & Clark, 2006; Fixson & Park, 2008; Ulrich, 1995). In this regard, Fixson and Park (2008) argued that higher degrees of specialisation have led to a new form of product innovation labelled modular innovation and architectural innovation (AI). In this technological categorisation of product innovation, the scheme by which a product is allocated its physical components and combination of the product's components becomes the underlying distinction (Aspelund et al., 2005; Habib et al., 2020). Henderson and Clark (1990, p. 12), in their seminal work on the reconfiguration of existing product technologies, also explained that an innovation could be characterised as architectural if it changes a product's architecture but leaves the components, and the core design concepts that they embody, unchanged. As was illustrated by Abernathy and Clark (1985), the switch from right hand to left hand steering vehicles and the front mounted engines in automobile layout are some forms of AI. Thus, a reconfiguration and redefinition of an established system is introduced to link together existing components in a new way, but the core design concept behind each component and the associated scientific and engineering knowledge remains the same (Baldwin & Clark, 2000; Henderson & Clark,

1990; Hofman et al., 2016). In this regard, Henderson and Clark added that AI "destroys the usefulness of a firm's architectural knowledge but preserves the usefulness of its knowledge about the product's components" (Henderson and Clark, 1990, p. 10).

Ulrich (1995, p. 3) also provided an elaborate definition of AI as "the arrangement and mapping of functional elements of a product to its physical components and the specification of the interfaces between physical components". This brings an engineering perspective in defining the architecture of a product as a mapping of a product's functional elements to its physical components, and hence introduces the typologies labelled *modular* and *integral* architecture (Habib et al., 2020). According to Ulrich (1995, p. 4), modular architecture is "a one-to-one mapping from functional elements in the function structure to the physical components of the product, [which] specifies decoupled interfaces between components", while integral architecture would take the form of "a complex (non-one-to-one) mapping from functional elements to physical components and/or coupled interfaces between components". Ulrich further argued that this distinction in product architecture is dependent on "the level of detail at which the components and functional elements are considered" (1995, p. 5). Thus "product architecture is a technical system that allows the constituents of a product to interact and correlate with each other" (Chen & Liu, 2005, p. 772). Against this background, Schilling (2000, p. 312) defined product modularity as "a continuum describing the degree to which a system's components can be separated and recombined, and it refers both to the tightness or coupling between components and the degree to which the 'rules' of the system architecture enable (or prohibit) the mixing and matching of components". As such, innovation in modular architecture may offer a flexible integration of a product's functional components or may be tightly coupled to prevent the scheme of arrangement and mapping of its core components to be disintegrated. Schilling illustrated this with the example of personal computers, which "originally were introduced as all-in-one packages but rapidly evolved into modular systems enabling the mixing and matching of components from different vendors" (2000, p. 312). However, a more integrated form of product architecture like bicycle componentry, such as brakes, gear sets and cranks, which were typically sold as individual components and flexibly matched

every vendor's design, are now sold predominantly in integrated component bundles that may not be flexibly compatible with those from different manufacturers (Fixson & Park, 2008; Park et al., 2018; Schilling, 2000). As such, the underlying distinction between these two forms of AI is the introduction of flexibility or compatibility of the core components which constitute a product's architecture.

Henderson and Clark (1990, p. 12), however, contrasted the architectural typology of product innovation with those that change only the core design concepts of a technology but leave the products architecture unchanged. The argument they put forward here is that the core design concept of a product is embodied within the components which perform a well-defined function (Henderson & Clark, 1990, p. 11). Further drawing on the motor component of the ceiling fan illustration, Henderson and Clark argued that "a particular motor is a component of the design that delivers power to turn the fan. [However] there are several design concepts one could use to deliver power [and] the choice of one of them-the decision to use an electric motor, for example, establishes a core concept of the design". In this regard, modular innovation overturns the core design concepts underlying the operation of components; however, the mapping between the design and components remains the same. As such, innovation takes place in "isolated modules within the broader product design" (Habib et al., 2020, p. 3). Henderson and Clark (1990, p. 12) further illustrated that the degree to which an analogue dialling device can be simply replaced with a digital one suggests that digital innovation is a modular innovation. As such, modular innovations take effect in the technologies embedded in the components that represent a product's architecture (Habib et al., 2020; Magnusson et al., 2003). The innovation takes effect in the form of a change in the core concept of one or more of a system's components, without changing the architecture (Aspelund et al., 2005).

2.2 Regulatory reviews and new product innovation

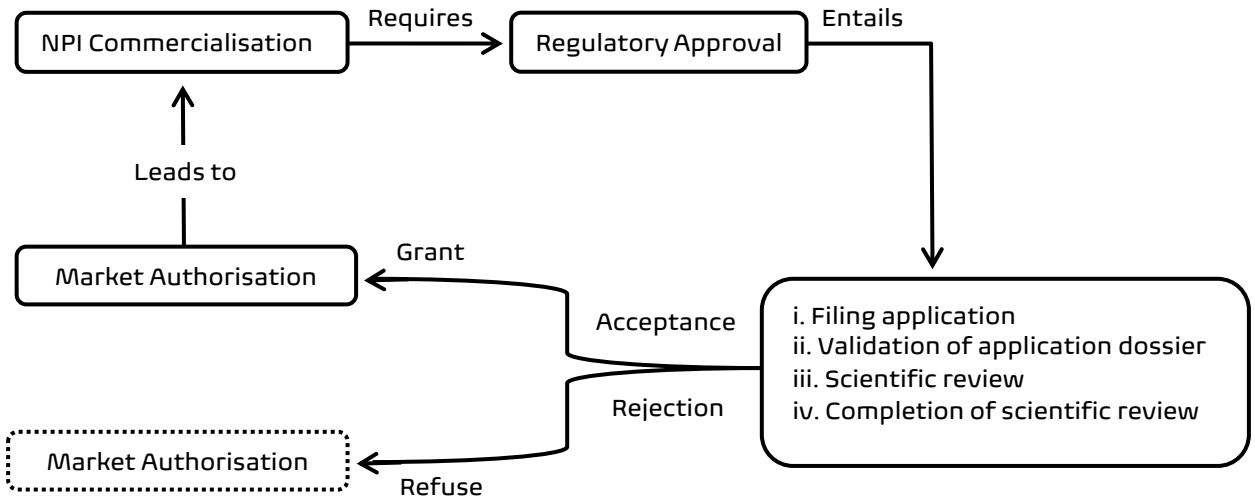
Regardless of the in-depth discussion on the significance of product innovations and the various typologies which have varying implication on the innovating firm, there is an aspect of the new product innovation process which the existing literature acknowledges as critical. For instance, Garcia and

Calantone (2002, p. 122), while explicating the concept of innovation, drew on the Organization for Economic Cooperation and Development (OECD) definition of innovation as the "iterative process initiated by the perception of a new market and/or new service opportunity for a technology-base invention which leads to development, production, and marketing task striving for the commercial success of the invention". Based on this definition, they argued that innovation as a process comprises the technological development of an invention combined with market introduction of the invention to end users. Also, Prieger (2007, p. 220) defined innovation as "the commercialization and introduction of new products to consumers". As such, it is argued that the concept of innovation finds absolute meaning through the adoption and diffusion of the new product into the market (Datta et al., 2015; Slater & Mohr, 2006; Jolly, 1997). However, according to Lettl et al. (2006), the introduction of an innovation to the market, among other consequences, triggers a regulatory response. In this regard, the transition of these innovations from the laboratory to the market would require that products meet strict regulatory standards and requirements (Foucart & Li, 2021; Garber et al., 2014; Shen, 2013). As Kessler and Chakrabarti (1996) argued, the ability of the innovating firm to bring new products to market requires conformity to standards, rules, and requirements in order to receive legitimacy and support.

Regulatory agencies are thus nonmarket stakeholders who are tasked with the responsibility of effectively conducting such technical evaluations to ensure that NPIs conform with approved standards (Olson, 2008; Rindova et al., 2005; Wiegmann & Roca, 2021). Amongst these standards are the efficacy and safety concerns that need to be mitigated to protect public health and prevent deception (Downer, 2011; Prieger, 2002). In this regard, an NPI is adjudged fit for commercialisation based on the outcome of regulatory reviews that are guided by scientific testing rules and principles (Polidoro, 2020; Sherman et al., 2017). The regulatory review process can therefore be defined as the sequence of evaluations conducted by regulatory agencies before NPIs are allowed onto the market. In the pharmaceutical industry, for example, the review of a new drug application entails various phases (Phases I, II, and III) of clinical trials before products are granted approval for market commercialisation

(Chorniy et al., 2021; Polidoro, 2020). Generally, as depicted in Figure 2.1, the commercialisation of NPIs that require regulatory approval entails a series of stages, including the submission and verification of application documents and conducting scientific evaluations to inform the decision to approve or reject the product. Ultimately, the innovation is either refused or granted market authorisation to commercialise the NPI. However, in order to understand the dynamics that underpin this espoused regulatory review process, this chapter now takes a systematic approach to access and critically review the extant literature on regulatory agencies and their product review processes.

Figure 2.1 New product innovation and the regulatory review process



2.2.1 Literature search method

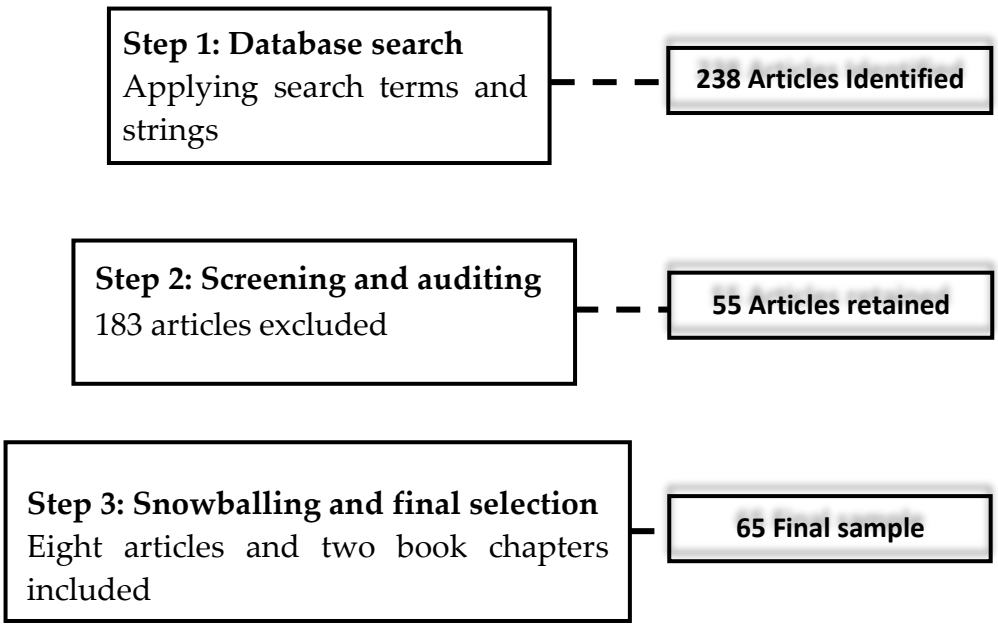
A systematic, inclusive, and methodologically transparent approach is adopted to review and identify the homologies and disparities in the wide range of literature on regulatory reviews (Denyer & Tranfield, 2009; Tranfield et al., 2003). This method assumes prime importance in this effort as does not only provides a rigorous process to identify, synthesise and critically analyse prior contributions in a scholarly domain, but also allows for the articulation of theoretical mechanisms that are inherent or relevant to the research interest (Denyer et al., 2008; Ellwood et al., 2017). Against this backdrop, three main steps (summarised in Figure 2.2) were followed to identify, select, and review the existing relevant

literature on regulatory reviews; including a database search, screening and auditing of the literature sample, and snowballing, final selection, and analysis.

2.2.2 Database search

The first step towards identifying relevant literature for this review was to conduct a comprehensive search through online academic databases comprising Web of Science, Scopus, JSTOR, Science Direct, and Business Source Complete. The search was structured to maximise the inclusion of different research streams in peer reviewed journals across multiple disciplines. The following keywords were applied to the academic databases: "review" or "evaluation", "regulatory*", "innovation", "regulatory delay*", "product*"; the process yielded 263 articles. However, the search terms were progressively refined, which then led to a thesaurus of search strings— including "regulatory review", "regulatory evaluation", "product innovation", "new product", and "product review". The new terms were reapplied to all the databases to generate a set of 253 articles. Duplicates were removed and the remaining output was subsequently merged to generate 238 articles.

Figure 2.2: Flow Chart of Search Strategy



2.2.3 Screening and auditing

Bibliographic data of the initial set of 238 promising articles were copied onto a project spreadsheet. To ensure that the article sample was relevant to the topic of interest, a narrow definition of regulatory reviews was adopted: a sequence of evaluations conducted by regulatory agencies NPIs are allowed onto the market. Drawing on this definition, two basic criteria were introduced for inclusion and exclusion. First, the article must explicitly use regulatory reviews and/or innovation as the main thesis of its research. Second, the selected articles must have set product innovation as the focus of their research, thus excluding processes innovation. In this regard, the titles and abstracts of the articles were thoroughly screened, leading to the exclusion of 143 articles from the initial sample. To ensure that the selection process served as a mechanism to prioritise quality, the remaining 95 articles were audited and analysed. A short note section was created on the project spreadsheet which contained detailed descriptive data and content summaries of the articles. Criteria such as the source of the journal or conference proceedings in which an article was published were then used to appraise the quality of the literature sample. For the journal publications, the *Chartered Association of Business Schools* list (CABS list), the *Financial Times* (FT 50) and *Scientific Journal Ranking* (SJR) were used to evaluate their sources. With regard to the conference papers, which are also referred to as "articles", they included those that were presented at high-quality conferences such as the proceedings of the *Centre for Innovation in Regulatory Science*. This procedure led to a further cull in the literature sample by 40 articles, leaving only 55 articles in the final sample.

2.2.4 Snowballing, final selection and analysis

In the quest to ensure completeness and validity of the selected literature sample (Tranfield et al., 2003), a final phase was conducted which involved backward and forward searching via cross-references of the various articles. This snowballing strategy led to the discovery of eight additional articles and two book chapters which were extensively referenced in the existing article sample and in the broader literature. The additional literature was subjected to the content screening and quality auditing procedures described above before qualifying for inclusion. This brought the final list to 65 literature

samples from which data was extracted for in-depth analysis and critical review. The data analysis began by scanning through the main texts of all selected literature to identify the conceptual distinctions and similarities, and the academic discipline in which each study was published. From the analysis, it was identified that although the articles were distributed among management, economics, medicine, politics and law journal outlets. Interestingly, majority of the studies were empirically skewed towards the pharmaceutical drug industry. Furthermore, an emerging consensus in the literature emphasised regulatory agencies' reliance on scientific testing rules and processes to generate the evidence required to evaluate NPIs. Several studies argued that the testing standards and techniques that underpin the perceptual exploration for selecting the criteria for granting market authorisation to an NPI are defined solely by the scientific frames within which products are evaluated. The analysis progressed to identify some common arguments from the literature, which were then classified based on specific themes (see Table 2.1). This technique was important to enhance the identification research gaps, and to synthesise the extant knowledge into a comprehensive framework relating to regulatory reviews.

Table 2.1: Thematic classification of literature sample

Literature	Speed and delays	Routines	Cost and uncertainty	Safety and efficacy
1. Abraham (2002)				x
2. Alleman and Rappoport (2002)			x	
3. Arora and Tosti (2017)				x
4. Berndt et al. (2005)	x			x
5. Breckenridge et al. (2011)				x
6. Carpenter (2002)	x	x	x	
7. Carpenter et al. (2003)	x			
8. Carpenter (2004)	x			x
9. Carpenter (2008)	x			x
10. Carpenter et al. (2012)	x			
11. Chorniy (2021)			x	x
12. DiMasi et al. (1991)			x	
13. DiMasi and Manocchia (1997)	x			
14. DiMasi (2002)				x
15. DiMasi et al. (2003)			x	
16. DiMasi and Faden (2009)	x			
17. Dimitri (2010)			x	
18. Downer (2010)				x

19. Downer (2011)				x
20. Downing et al. (2012)	x			
21. Downing et al. (2017)	x			
22. Dranove and Meltzer (1994)	x		x	
23. Finkel (1980)	x			
24. Fleming (2015)			x	
25. Friedman et al. (1999)	x			x
26. Gans and Ridley (2013)	x			x
27. Garber et al. (2014)			x	
28. Gieringer (1985).			x	x
29. Grabowski et al. (1978)	x			
30. Grabowski and Wang (2008)				x
31. Haines (2017)				x
32. Hirai et al. (2010)			x	
33. Hoerr (2011)			x	
34. Ichimaru et al. (2010)	x			
35. Ishibashi et al. (2012)	x	x		
36. Jones (2015)			x	
37. Kaitin et al. (1991)	x			
38. Kaitin et al. (1994)	x			
39. Kesselheim et al. (2015)	x			
40. Kessler and Chakrabarti (1996)	x			
41. Klonoff (2020)		x		
42. Kuzma and Besley (2008)	x			x
43. McNamee et al. (2017)	x			
44. Olson (1995)				x
45. Olson (1997)	x			
46. Olson (2000)	x			
47. Olson (2004)	x			
48. Olson (2008)				x
49. Ono et al. (2005)	x			x
50. Polidoro (2020)		x		
51. Prieger (2002)	x			
52. Prieger (2007)	x			
53. Prieger (2008)	x		x	
54. Ranchordás (2015)	x		x	
55. Regnstrom et al. (2010)	x			
56. Reichert et al. (2001)	x			
57. Ridley et al. (2006)	x			
58. Roca and O'Sullivan (2020)			x	
59. Rosenblatt et al. (2016)	x		x	
60. Sherman et al. (2017)				x
61. Thomas (1990)			x	
62. Tyner and Sadrieh (2011)			x	x
63. Vernon et al. (2009)			x	
64. Vogel (1990)	x			x
65. Wrubel et al. (1997)	x	x	x	

2.3 Regulatory review concerns

This section describes the compendium of findings from the readings of the selected literature on regulatory reviews. Despite the consensus in the literature conceiving regulatory reviews as a process that is driven by evidence and knowledge derived from the scientific testing rules, there are some concerns or issues that were identified to cumulatively enable (or impede) the sequence of evaluations conducted by regulatory agencies before new products are allowed onto the market. Some studies have pointed to the "importance" ascribed to products (Dranove & Meltzer, 1994), the size and characteristics of the innovating firm (Olson, 1997), and the social and institutional environment within which the NPIs are induced (Hargadon & Douglas, 2001; Ishibashi et al., 2012) as the consequential factors in regulatory review processes and decisions. A thematic analysis of the literature led to establishing that these factors underlie four fundamental concerns that not only shape the organizing practices of regulators, but also give form to firms' perception of regulators' power to influence their ability to create and capture value from their innovations (Blind, 2016; Blind et al., 2017; Polidoro, 2020). Against this background, the chapter now unpacks the specific regulatory review concerns (see the conceptual model in Figure 2.3), organized along the following emerging themes: speed and delays, safety and efficacy, cost and uncertainty, and routines.

2.3.1 Speed and delays

The literature draws attention to the significance of the time elapsed between the initial submission of a product for review and the granting of regulatory approval for commercialisation to both innovators and consumers (Prieger, 2007, 2008). The extant arguments stress on the ability of pioneering firms to capture first-mover advantage by delivering innovative products to market quickly (Papachristos & van de Kaa, 2020; Zhao et al., 2012). Thus, for the innovating firm, accelerating all intermediate activities, processes, and decisions in the regulatory evaluation process to enable swift transition of NPI from the laboratory to the market is a critical success factor and a priority (Jones, 2003; Kessler & Chakrabarti, 1996; Vesey, 1991). However, several other studies also suggest that this objective is

usually not realised, as regulatory processes usually tend to take longer than anticipated (Carpenter, 2004; Prieger, 2002, 2007). Prolonged regulatory review process leads to a reduction in the present value of the NPI, diminishes the competitive advantage that may be accrued to the innovating firm, constrains the pace of innovation, and even distorts the incentive to innovate (Kessler & Chakrabarti, 1996; Prieger, 2007; Ranchordás, 2014). Nonetheless, some of the literature encountered argued that knowledge gaps between innovators and product evaluators account for the protraction in time NPI evaluators need to assess and understand the technology underpinning the development of NPIs (Carpenter, 2004; Rosenblatt et al., 2016). Thus, in reviewing the literature, it was apparent that the pace at which technologies evolve, coupled with the complexity and sophistication they entail, presents dramatic leaps in terms of regulators' familiarity with the emerging technologies as well as the absorptive capacity to learn, adapt and provide timely reviews for the NPIs under review (Downer, 2010, 2011). Some scholars associate this cognitive gap, which makes it difficult for product reviewers to make rational decisions with acceptable levels of certainty, to the depletion of the benefits in the nexus between academia and regulatory agencies due to the absence of credible scientific research or lags in the publication of academic research findings (Abraham, 2002; Carpenter, 2004; Sherman et al., 2017).

Regardless of the predominance of studies on the challenges in reviewing and authorising the commercialisation of NPIs on the market, several studies have drawn attention to some significant efforts made by regulatory agencies to narrow, or even eliminate, delays in regulatory review processes. Notable among these undertakings is the United States FDA's strategic effort to assign ratings to new medical products that are developed to fight neglected diseases (Gans & Ridley, 2013; Kaitin et al., 1994; Ridley et al., 2006). According to Gans and Ridley (2013), the humanitarian value attached to such products is a key driver of the keen interest in expediting regulatory review processes. Dranove and Meltzer (1994) also argued that the social importance attached to products tends to influence reviewers to expedite the review process. Elsewhere, although fees charged for the application of regulatory reviews are regarded as a nuisance cost imposed on innovating firms, scholars advocate the continuous implementation of these fees, as they help to provide the finance needed to improve infrastructure and

hire additional staff to review large clinical data and to clear application backlogs (Kaitin & Cairns, 2003; Olson, 2000; Ono et al., 2005; Reichert et al., 2001). In this regard, several studies have found that these strategies have been pivotal in improving administrative procedures and have in turn corresponded to drastic reductions in regulatory review times (Downing et al., 2012; DiMasi & Faden, 2009; Ichimaru et al., 2010; Olson, 2004). Yet, throughout the analysis of the literature it was also observed that there are lingering concerns about incongruities and biases in the review time across different products. Some scholars point to the degree of discretion that product reviewers have in deciding whether to grant approval for NPIs under review, the social importance attached to products, and the size and characteristics of the innovating firms (Carpenter, 2004; Dranove & Meltzer, 1994; Olson, 1997; Regnstrom et al., 2010).

Turning to firm characteristics, it has been well argued in the literature that relatively large and multinational firms tend to experience shorter review times and expect favourable decisions due to the readiness and availability of data from previously reviewed and approved products by regulatory agencies in other collaborating jurisdictions (Ishibashi et al., 2012; Olson, 1997). This is the case because regulatory agencies often rely on data from other regions where the focal products under review had already been reviewed to bolster their decision to reject or approve a product for commercialisation (Gieringer, 1985; Kaitin & Cairns, 2003). Thus, as the literature suggests, earlier submissions of similar products tend to reduce the number of issues through which subsequent submissions need to sift for regulatory approval (Carpenter, 2004; Downing et al., 2017; Wrubel et al., 1997). In addition, some studies contend that large firms often have enough capital to invest in intensive research and development (R&D) to specialise and produce products that meet regulatory requirements, thereby building good reputation with regulators (Carpenter, 2012; Kaitin & Cairns, 2003). This reputational value tends to assuage uncertainties and precondition regulators to view NPI from such firms as safe and of some appreciable level of efficacy, and thus helps to expedite the review process (Kaitin & Cairns, 2003; Rindova et al., 2005). Other studies also suggest that well-established firms are able to muster their experience with the complex review process, and with their huge resource outlay, provide

all relevant information to regulators to help speed up the review process (Hirai et al., 2010; Regnstrom et al., 2010). Furthermore, most of the innovating firms that grant reviewers access to core technological information to bridge knowledge gaps and gain clarity on regulatory requirements can signal the cost of delays to regulators, and thereby experience an expedited review process (DiMasi & Manocchia, 1997; Prieger, 2008).

However, some scholars caution that these efforts to expedite regulatory review processes and decisions may hold far-reaching inimical consequences for consumers, as this could result in adverse effects or lead to a rise in the number of post-market withdrawals (Berndt et al., 2005; Friedman et al., 1999; Grabowski and Wang, 2008).

2.3.2 Safety and efficacy

It was stressed throughout the literature that the establishment of regulatory institutions makes apparent the importance of safeguarding public health and safety, thus creating the impetus for regulatory review processes to ensure that safety and efficacy are guaranteed before NPIs are commercialised on the market (Breckenridge et al., 2011; Haines, 2017). As a result, although this effort to guarantee safety and efficacy from clinical data is perhaps the most complicated and time-consuming phase in the review process, several studies have found that regulatory agencies subject NPIs to rigorous safety and quality evaluations in order to accumulate compelling evidence to inform the decision to approve or restrict products from entering the market (Carpenter, 2002; Downer, 2010; Olson, 1995). More importantly, the literature hints that the asymmetrically distributed nature of information between producers and consumers in the markets, which then makes regulatory reviews the only means of averting the risk of commercialising and consuming potentially harmful products (Carpenter, 2004; Olson, 2008; Polidoro, 2020). This is in accord with the observation made by Polidoro (2013) that regulatory agencies keep the public *on the qui vive* by conferring approval stamps, which signal safety and quality guarantees, on products. In this regard, other scholars hold the view that enshrouded in the ability of regulatory agencies to influence consumers' evaluation of a product is an

indirect control of a non-market decision-maker on decisions that are elicited on the market-based selection environment (Nelson & Winter, 1982; Polidoro, 2020).

Meanwhile, Wrubel et al. (1997) had lamented that a keen focus on averting safety concerns poses a protracted increase in challenges facing innovating firms in the NPI commercialisation process. Product reviewers adopt stringent regulatory frameworks and tortuous evaluation criteria, which underscore the rising rejection and attrition rates in NPI reviews (DiMasi et al., 2010; Kuzma & Besley, 2008). Also, there are general concerns about the dearth in knowledge on the underlying technology on which NPIs are developed, hence rendering regulatory decisions a subjective value judgement that lacks the acuity of scientific rigour (Gieringer, 1985; Prieger, 2007). Some studies have observed that regulators often lack clear and specific evaluation frameworks for reviewing products that are built on novel technologies, and thus rely on other related technologies as a proxy for determining whether a focal innovation would be granted approval or not (Kuzma & Besley, 2008; Tyner & Sadrieh, 2011). This long-standing concern had long cautioned by Gieringer (1985) who argued that regulatory evaluations are often fraught with uncertainties about safety and potentially damaging consequences of NPI in the long term. Also discussing this concern in the context of the US airline industry, Downer (2010) underlined that the Federal Aviation Administration (FAA) – the regulatory agency which is charged with the responsibility to assess the reliability and safety of passenger aircraft – sometimes delegates technical evaluations to the innovators who have more tacit knowledge on the prevailing technology. Also, as observed by Berndt et al. (2005) in their analysis of approval times and withdrawal rates in the US pharmaceutical industry, drug failure and market withdrawals are rather common despite the high regulatory standards. Consequently, this has led to some level of consumer uncertainty about the quality of products that are commercialised on the market (Arora & Tosti, 2017). Against this background, several scholars tend to advocate the adoption of informed choice systems, which derive their rigour in allowing innovators to provide adequate information on products for consumers to make a rational choice without regulatory influence (Gans & Ridley, 2013; Gieringer, 1985).

On the contrary, other scholars have argued that the thoroughness of regulatory review processes in ensuring that NPI approval does not bypass any safety checks, as well as the informational value they offer, remain crucial in providing quality assurance to consumers (Olson, 1997; Ono et al., 2005). It is, however, worth noting that due to the regulatory agencies' sensitivity to political institutions, this legitimate call on regulators as gatekeepers of public safety is often constrained by the need to satisfy consumers' demands and respond to political pressures (Carpenter, 2004; Olson, 1995). As regulatory agencies become entangled in the juggle between politics, public interest, and scientific evidence, they are challenged with a conundrum on how to assure the safety and efficacy of products while at the same time providing timely public access to products (Chorniy et al., 2020). The literature also highlights several cases where well-structured and politically organized consumer groups, with the support of media coverage, precipitate pressure on regulators to expedite reviews (Epstein, 1996; Keidan, 2007; Vogel 1990). In this regard, Carpenter (2002) pointed to the regulator's reliance on legislative support to secure continuous legitimacy to operate as a burgeoning influence that disrupts the work of regulatory agencies.

2.3.3 Cost and uncertainty

A fundamental concern in the literature is the inimical influence that regulatory reviews tend to have on both consumers and innovating firms. With regard to consumers, it has long been argued that regulatory delay may hold over or even deprive consumers' access to potentially valuable products that might be of utmost importance in pre-empting health crises (Gieringer, 1985). For the innovating firms, the ever-increasing complexity, and the stringent and laggard nature of the regulatory review process, lumber these firms with tremendous cost and uncertainties in NPI development initiative (Dimasi et al., 2003; Rosenblatt et al., 2016; Thomas, 1990). It is also well argued in the literature that prolonged reviews trap innovating firms in a temporal uncertainty, thereby limiting innovating firms' ability to obtain time-based advantages and to forecast returns on their investments (Garber et al., 2014; Hirai et al., 2010). In fairly recent times, several scholars have observed that in addition to loss in early

entrant profit and competitive advantage (Carpenter, 2002; Prieger, 2008), the review process and its associated delays wreak high opportunity cost of investment, research and development, and NPI development time (DiMasi, 2002; DiMasi et al., 2010; Dimitri, 2010; Vernon et al., 2009).

Yet, a major concern that lingers amongst innovation scholars is that NPI development requires huge financial outlay and innovating firms often resort to venture capital institutions and other financial investors to provide the financial brace to transform their mock-ups into viable products (Burger-Helmchen et al., 2020; Lerner & Nanda, 2020). However, some scholars have observed that as these investors place high value on the ability to mitigate losses and on the predictability of returns on investment, prolonged reviews fuel the perception of risk and market failure for the 'non-tested' product (Merrill, 1984; Prieger, 2007). This is because revenues that could potentially be accrued from commercialising NPIs might be delayed, while the cost of resources employed for the development of products may continue to accumulate: hence, investor confidence might be distorted, leading to failure to secure investment and rendering NPI had to commercialise (Hoerr, 2011; Ranchordás, 2015; Roca and O'Sullivan, 2020). On this concern, Hoerr (2011) provides a hypothetical illustration to show the impact of regulatory delay on investment and concludes that the longer the review time the more the Internal Rate of Return (IRR) and Net Present Value (NPV) of the innovating firms' investments continues to plummet. This implies that although it is well emphasised in the literature that regulators seek to be attuned to delaying the review process to ensure that the public are consuming safe products, their processes also impose crushing financial burdens on innovating firms and distort new product development initiatives (DiMasi & Faden, 2009; Prieger, 2007).

2.3.4 Routines as regulatory concern

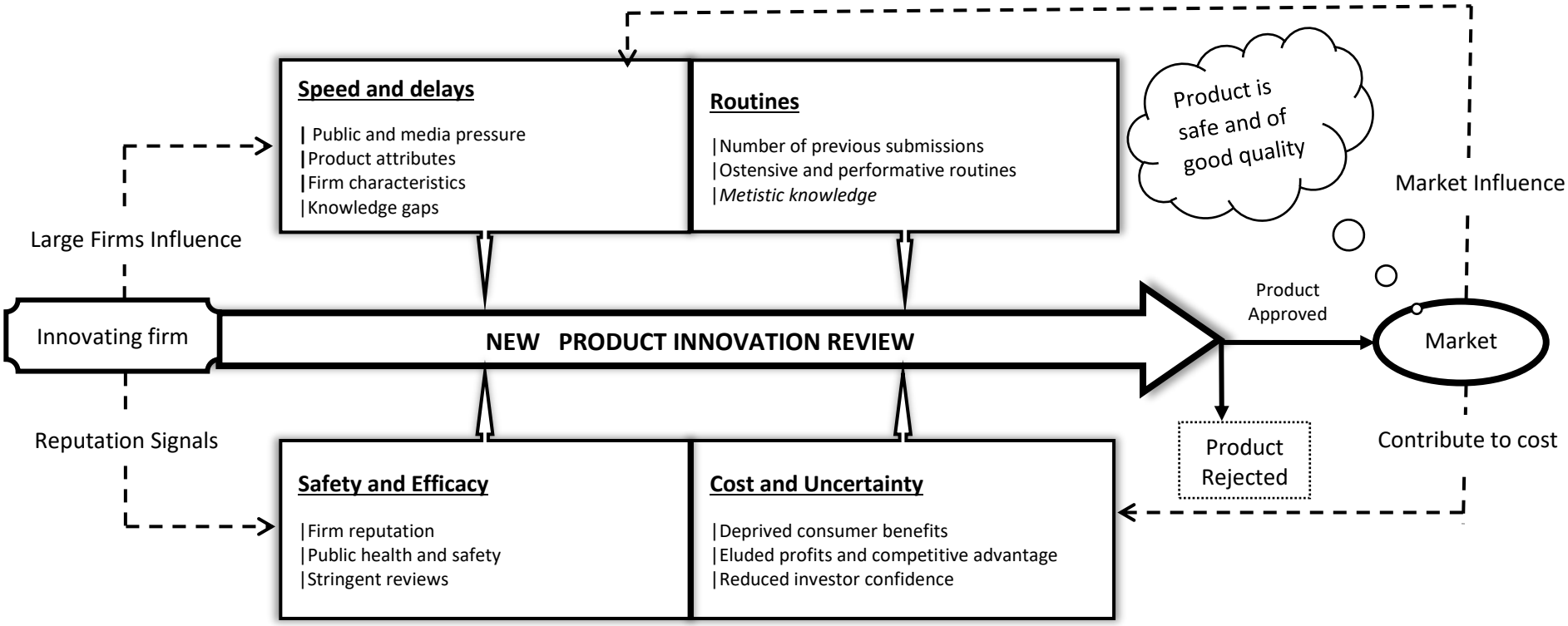
In an exhaustive empirical study of the US FDA's review of new drug applications, Polidoro (2020, p. 2402) strongly argued that the routine evaluation of innovations with similar operational concepts leads to the accumulation of knowledge about technologies underpinning NPIs, which, in turn, increases the tendency for regulators to include other issues that are "not necessarily applicable to the review,

thereby extending the review time". In other words, regulatory evaluation takes place in a context where product reviewers are routinely confronted with new technologies, thus enriching their knowledge stock on different technologies that exist in a particular domain of innovation. This phenomenon then creates the situation where product reviewers become susceptible to their accumulated knowledge, hence leading to the adoption of evaluation criteria that are incommensurable with the focal innovation under review. In this regard, Polidoro (2020) emphasised that the cognitive effects of routines undergird the apparent incongruities in regulatory decisions and delays in the review time. This assertion about routines fuelling delays in regulatory review processes provides some insights, in part at least, to explain what Carpenter (2002, p. 494) called the "order-of-entry effects". Carpenter (2002) argued for this order-of-entry phenomenon against the background that the importance reviewers attach to NPI is entirely dependent on the product's potential to provide benefits that outweigh existing alternatives and hence the relative speed of the review process for the new product. Meanwhile, the extant conceptualisation of routines in the literature also directs attention to the effects of the repetitive review of products with similar technologies on the cognitive frames that form the substrate of regulatory decisions. This implies that as reviewers deepen their knowledge base of existing technologies over time, there is a likelihood that the initial set of applications will experience shorter review times as issues such as the existence of alternative product are excluded from the evaluation process. However, because routines have an inclusion effect on regulatory agencies (Polidoro, 2020), subsequent reviews are rather likely to be delayed as reviewers become acquainted with the underlying technology on which the emerging innovations are developed.

Nonetheless, Polidoro (2020) also found that routines and their cognitive underpinnings are important conceptual building blocks that shape the context in which regulatory review processes take place. Put starkly, the continuous review of innovations with similar operational concepts enriches the regulators' cognitive understanding of emerging technology and helps them to adapt the scientific constructs that define the evaluation framework accordingly. Polidoro (2020, p. 2406) explained that the repeated evaluation of innovations that are built on different technologies, in turn, creates the ability

for reviewers to be "mindful of limitations" in applying their knowledge about similar technologies to the review of subsequent innovations. Therefore, routines can also help to eliminate the delays that are caused by the inclusion of inapplicable evaluation criteria in the review of subsequent innovations. This implies that routines provide a context for reviewers to engage in a learning process; hence, regulatory agencies rely on evaluation routines to bridge the persistent knowledge gap between reviewers and innovators as they continuously enrich their knowledge base of the emerging technologies (Carpenter, 2004; Rosenblatt et al., 2016). Against this backdrop, it is observed that incremental innovations, rather than radical or discontinuous innovations (Adams et al., 2006; Veryzer, 1998), tend to experience prolonged regulatory review processes. Highlighting the potential of new technologies to avert this concern, Polidoro (2020, p. 2407) hypothesised that "the recent introduction of new technologies in the same domain of an innovation attenuates the extent to which knowledge about other technologies increases that innovation's regulatory review time".

Figure 2.3: Conceptual model of regulatory review concerns



2.4 What remains unanswered

The discussion in the literature so far raises an interesting set of empirical and theoretical gaps that offer opportunity to build and expand the existing knowledge on the regulatory review of NPIs. First, the mainstream research on regulatory reviews is largely skewed towards the pharmaceutical drug industry and is heavily burdened with quantitative inferential, which only go far enough to provide causal logics of factors that determine the dynamics of the regulatory review process. In addition, these contributions are developed in empirical settings that are characterised by stable and well-developed institutions. As such, the relevance and insights of prior contributions are limited in providing a holistic overview on the discourse regulatory review of NPI, as they may not apply in other institutional and social contexts. Second, the depth of the knowledge gap between reviewers and innovators about the technologies underpinning NPIs has been identified to account for the constraints of speedy reviews, incongruities in regulatory decisions, and the social and economic costs that the regulatory review process enfolds. Specifically, the persistent lack of ability, on the part of regulatory agencies, to quickly adapt the evaluation framework to respond to the ever-changing innovation landscape has largely remained a conundrum. Meanwhile, the extant literature has paid little or no attention to explaining how regulatory agencies are able to accumulate knowledge and initiate change in response to changing conditions in the innovation landscape. In this regard, there is little understating of how regulatory agencies are able to build adaptive qualities to match with industry dynamics. Third, it is well-emphasised in the literature that regulatory agencies indirectly shape the trajectory of future innovations, as they wield the power to select out products from transitioning from the laboratory to the market. Nonetheless, it is also observed that there are several social, institutional, and cognitive factors that may determine or constrain the regulator's ability to influence the evolving trajectories in the innovation landscape (Polidoro, 2020; Garud & Rappa, 1994). However, there is a paucity of empirical research to qualitatively provide insights into how these factors emerge, fall out of use, and shape the regulatory review process.

It follows from these observations that the best way to fill the context lacuna in the literature is to provide an alternative agile empirical setting worth observing, and more importantly, to provide some theoretical constructs that could address the series of socio-cultural concerns that cumulatively influence and shape the regulatory review process. In this respect, key insights from existing works on the cognitive underpinnings of routines in regulatory review processes provides a theoretical lead. In his recent work, Polidoro (2020), after advocating empirical enquiry into other research domains, argued that cognitive effects of regulatory evaluation *routines* may not only lead to delays, but also help to develop sensitivity to what could be described as '*metistic knowledge'* (Sarpong et al., 2018), which is needed to inform and realign the regulatory review framework to match and respond to the complexities of emerging technologies. Thus, given that routines provide fundamental insights into organizations (Tsoukas, 2021) and "represent an invaluable resource to capture organisational change" (D'Adderio, 2008), the theoretical concepts of routines become extremely important in addressing questions on how regulatory agencies (re)organize their day-to-day activities, as well as adaptations to regulatory review processes. More importantly, the concept of routines offers prominence to the context specificity of enactment and the socio-material artifacts to provide a fine-grained understanding of how contextual contingencies may diffract routines in varying contexts and conditions (Wright, 2019). As such, a regulatory review process can be abstracted as a *pattern* of actions and *practices* that are bounded by both scientific testing rules and social, organizational, and cognitive factors (Cohen, 2007; Feldman, 2000; Pentland and Rueter, 1994). This complex interrelation allows for the cumulative development of useful shared understanding of the product review processes, as well as the dynamics of the interaction of regulatory agencies with the innovation landscape. Therefore, by rendering ontological commitment to the Heraclitan philosophy that 'everything changes, and nothing abides' (Chia & Tsoukas, 2003), the regulatory review process is conceived to be in continuous change in order to respond and adapt to the inevitable changes in the technological landscape that underpins NPIs. Against this background, an effort to build informed account of the mechanism through which this adaption of regulatory evaluation routines unfold would also serve as a theoretical impetus to provide a fine-grained

explication of the mechanism though which these socio-organizational and cognitive constructs emerge and fall out of use in regulatory review processes. On this basis, the next section examines the various concepts and salient arguments in the literature on organizational routines to fully situate the operations of regulatory agencies and to allow for further theoretical scrutiny.

2.5 Exploring the concept of routine

The term 'routine' is common in everyday parlance and remains a foundational concept in organizational research. However, the scholarly discourse on routines is rendered a domain of differing ontological perceptions and conceptual specifications on what routine *is* and how their enactment defines and shape organizational reality. Therefore, delving into the various conceptualisations of routine is a vital precondition for providing a clear understanding of how change or inertia and adaption of organizational processes may unfold. A critical stroll through the literature identifies 'habits' occupying analogous intellectual space with the concept of routine. Hodgson (2008, p.16) aptly defined habits as "submerged repertoires of potential behaviour [that] can be triggered or reinforced by an appropriate stimulus or context". This implies that habits are established in terms of the proclivity to behave in a particular way in a particular class of situations (Hodgson, 2008). Hodgson further argued that although habits may disappear in a status of automaticity, they are "the necessary means of avoiding full reflection over every detail" of an action (2008, p. 17). Also, Cohen (2007), in his reflection on the work of the American pragmatic philosopher John Dewey, extended the delineations on habits to emphasize that habits are inextricably intertwined with cognition and emotion. In his view, the interplay between the cognitive processes that underlie an action and the emotions which help to determine the value of what that action may accomplish occurs in a system in which habit is integral. Through ongoing interaction and replication, habits provide what Hodgson (2008, p. 16) affectionately described as the "normative power of custom established in human society". In consequence of these views, habits can be described as the building blocks of behavioural patterns which are reproduced when triggered in similar material conditions or contexts (Cohen, 2007; Knudsen, 2008).

Similarly, routine, as defined by Hodgson (2008, p. 21), are "organisational dispositions to energise conditional patterns of behaviour within an organized group of individuals, involving sequential responses to cues". Thus, "individual skills are among the building blocks of organizational routines" (Dosi et al., 2000, p. 4), and like habits, routine exist and survive on the substrate of replication through organizational learning and knowledge transfer (Becker, 2008; Winter & Szulanski, 2001). This definition draws attention to established consensus amongst scholars illuminating understanding on the analogy between habit and routine, which points to a distinction between what is habitual and what is routine (Cohen, 2007; Hodgson & Knudsen, 2004; Knudsen, 2008). The former emphasises the disposition and skills of individuals, while the latter relates to the collective, groups, or organizations (Cohen et al., 1996; Dosi et al., 2000; Hodgson, 2008). Therefore, routines are not, in themselves, habits, but rather an ontological layer above habits (Hodgson, 2008)— which constitutes "a coordinated, repetitive set of organisational activities or sustained shared cognitive bundle" (Miner et al., 2008, p. 153). According to Becker (2004), it is the interaction between multiple actors that establishes the core distinction between individual habits and organizational routines. This sense-making of routine fits well with the collective definition that was proposed by a group of scholars who met at the Santa Fe Institute in 1996. At the conference which established the groundwork for the field, routine was defined as "an executable capability for repeated performance in some context that has been learned by an organization in response to selective pressures (Cohen et al., 1996, p. 683). This definition, however, seizes three distinct but conceptually inseparable intellectual spaces for routine. As Cohen et al. (1996) elaborated, this general definition for routine emphasises the *capability* to generate actions and direct sequences of *unfolding action*; the *context* within which the execution of action accomplishes some transformation in the organization; and the characteristic of routine as a *learned system* that yields tacit knowledge that is consequential for altering its enactments in response to changing contexts.

Accordingly, this synoptic definition of routine rebuts the notion that routines are mindless and mundane actions that are not cognitively grounded, and thereby lack conscious deliberation, reflection, and effort to accomplish (Becker, 2004; Cohen, 2007; Parmigiani and Howard-Grenville,

2011). On the issue of mindlessness, the discourse on routine has long been plagued with some disparate conceptions, as some scholars have argued that what is termed as 'routines' are mere heuristic actions or automated processes that do not require substantial cognitive commitment to carry through (Ashforth and Fried, 1988; Dosi et al., 2000; Gersick and Hackman, 1990; Louis and Sutton, 1991). In other words, to borrow from Cohen's (2007, p. 774) apt exposition on the notion of routine as mindless and mundane, "routine actions are not tightly integrated with deliberation, reflection, or feelings". Cohen further explains that taking routines as mundane action implies that "the actions we refer to as routine are likely not to be of major importance" (2007, p. 774). Thus, in common everyday usage, the phrase "'merely routine' or 'it's a routine matter' is often a way of indicating that not much attention or skill is required" to perform an action (Cohen, 2007, p. 774). However, in his metaphorical explanation of this conception of routine, Cohen (2007, p. 777) argued that: "the learning behind our embodied capabilities for an action, such as eating our cake, can disappear into the taken-for-granted status of normal functioning until an arm is disconcerted, say by an injury or a stroke, and must learn anew". This implies that there are learning capabilities embedded in routines which are often sealed in a status of automaticity. This evocative explanation thus suggests that the accomplishment of routine requires conscious efforts, as it draws on cognitive resources, particularly when shocks are encountered (Becker, 2004; Cohen et al., 1996; Gersick & Hackman, 1990; Louis & Sutton, 1991). Also, Pentland and Rueter (1994), drawing on grammatical models to counter this conflicting perspective on mindlessness, argued that each routinised process results from effortful accomplishment, which is enabled by the cognitive structure of participants.

Having clearly established the cognitive underpinnings of routine, attention is now drawn to the issue of what properties or characteristics routines might possess. Turning to Nelson and Winters's *Evolutionary Theory of Economic Change* – the seminal book which seeded most of the arguments in the burgeoning literature on organizational routines – the authors defined routines as the "regular and predictable behaviour *patterns* of firms" (1982, p. 14), and provided an apt conceptualisation of routines as biological genes that are heritable and selectable by the environment, and thus contribute to radically

"new combinations of existing routines" (1982, p. 130). Although the assumption of 'routines as genes' has been a bone of contention among scholars (Hodgson, 2008; Vromen, 2006), this analogy reserves a core set of general principles that has been applied to a range of social and organizational phenomena, including routine studies (Hodgson & Knudsen, 2004). Particularly, the ability of genes to mutate to provide variation (Nelson & Winter, 1982) has helped in providing a fine argument for defining routines as generative structures that involve rules, replication, and selection. Also, this ontological analogy has helped to fully render an explanation to the inertial qualities of organizational structure (Becker, 2005; Pentland & Rueter, 1994; Winter & Szulanski, 2001). Against this backdrop, scholars have continuously emphasised that routines are not only espoused as standard operating procedures (Cyert & March, 1963) or "recurrent action patterns" (Cohen, 2007, p. 773) that conceive replication (Winter & Szulanski, 2001), but also serve as a "repository of organisational memory" (Parmigiani & Howard-Grenville, 2011, p. 4) from which organizational actors reflect, learn, and generate a repertoire of reasonably effective patterns of action that are suitable for conditions in the imminent moment and the long run. Again, Nelson and Winter (1982, p. 99) underlined that routines are "the most important form of storage of the organization's specific operational knowledge". Also, Cohen and Bacdayan (1994, p. 555) asserted that routines are established patterns of organizational action that store organizational experience in a form that allows transferability of that experience to new situations. Likewise, Feldman and Rafaeli (2002), employing ballroom dance as a metaphor to analyse the adaptive property of routines, posited that the perpetual interaction with routines creates a connection that contributes to organizations' ability to maintain stability and adapt to changing circumstances. Thus, routines both represent the inertial qualities of an organizational structure and serve as a memory for organizational learning and adaptation (see Pentland & Rueter, 1994).

In an effort to understand the core conceptual spaces that the concept of routine seeks to grasp, Becker (2004) provided an extensive delineation of some core characteristics of routines. In his review of the literature on organizational routines, Becker (2004, p. 645) identified patterns in routines as a form of regularity represented by actions, activities, behaviours, and interactions. Here, clarity is made

in relation to organizational routines as behaviour that survives on the substrate of actions involving multiple actors which are observable and responsive to stimuli. This explication, however, complements the longstanding conceptualisation that routine assumes the character of collective activity patterns or patterns of interaction (Gersick & Hackman, 1990). Also, it reveals another characteristic of routines which points to their recurrent nature. In this regard, Becker underlines that it would be practically challenging to refer to something happening only once as a routine (2004, p. 645). Therefore, there must be an element of repetition to identify an action as a routine (Parmigiani & Howard-Grenville, 2011). In addition, such understanding foregrounds the collective character of routines, which constitutes the nexuses of actions and actors across temporal and spatial domains (Cohen et al., 1996). Thus, a routine is a collective phenomenon that can be interrupted and unveiled by the tensions of individual action rules and heedful accomplishments (Becker, 2004; Weick, 1993). Furthermore, despite the patterned and recurrent nature of routines, which suggests some form of stability, routines are conceived as processual in nature, as they are ongoing accomplishments which are mutually constitutive of the generative aspect of organizational life (Feldman, 2016; Howard-Grenville, 2005; Howard-Grenville & Lodge, 2021). This implies that routines exhibit some characteristics of temporality, may decay, switch, or shift among their organizing contents, respond to environmental change and the tensions of interacting routines, and incrementally adapt to experiences (Beker, 2004). As such, routines hold the potential to contribute to organizational change and adaptation, as they are embedded in the organizing structures of the organization, exhibiting unfolding and dynamic sequences of constructing and reconstructing organizational reality. Against this background, it is important to highlight that the characterisation of routines would only be fruitful by acknowledging the relationship between routines and the material, organizational, and social contexts within which they are triggered. Again, Becker (2004) argued that routines and context are so intimately related that when observed in the absence of context, they become meaningless and lose their generative nature. Thus, the context specificity of routines in historical, local, and relational forms are

essentially inextricable, as the constellation of socio-organizational and cultural factors, as well as interpretative mindset, enable or limit their existence.

On this note, several streams of studies in organizational research that share in these characterisations of routine have provided an extensive analysis of the role of routines in accomplishing work, gaining capabilities and competitive advantage, and their importance for firm performance (Aime et al., 2010; Dutta et al., 2003; Mitchell & Shaver, 2003; Peng et al., 2008). The attention so far is directed towards explaining how routines are built to form capabilities that lead to differential performance in creating and capturing value. In this regard, organizational routines are conceived as repetitive and context-dependent entities that form the building blocks of organizational capabilities (Becker, 2004; Dosi et al., 2008). Dosi et al. (2000, p. 5) proclaimed organizational routines as usurping "the major function of coordinating the skills of the organization […] by turning that collectivity of skills to useful effect". Therefore, routines are characterised by a complex interaction between environmental factors and interpretive mindsets which, given the level of impediment in the transfer of knowledge, provides the potential to gain competitive advantage (Becker, 2004; Szulanski, 1996). Collis (1994, p. 145), in his explication on the value of organizational capabilities, defined capabilities as "socially complex routines that determine the efficiency with which firms physically transform inputs into outputs". Thus, according to Collis, an organization's capabilities are embedded in its set of routines (1994, p. 146). Recent works adopting a dynamic approach to capabilities also suggest that the underpinnings of micro-foundations of capabilities stem from high level routines (Helfat & Winter, 2011; Teece, 2012; Winter, 2003). Thus, routines are vital to creating and capturing value, as a routine "governs the ability of an organization to learn, adapt, change and renew over time" (Collis, 1994, p. 145). Moreover, Cohen and Levinthal (1990, p. 135), in their seminal work on absorptive capacity, argued that "to integrate certain classes of complex and sophisticated technological knowledge successfully into the firm's activities, the firm requires an existing internal staff of technologists and scientists who are both competent in their fields and are familiar with the firm's […] organisational processes [and] routines". On this note, Lewin et al. (2011, p. 81) also underlined that "the ability of

organisations to discover and implement complementarities between absorptive capacity routines explains why some firms are successful early adopters…, [as] this capability depends on the extent to which the firm evolves, adapts and implements the configuration of its internal and external absorptive capacity routines". As noted by Parmigiani and Howard-Grenville (2011), these arguments on routines emphasise the ontological analogy of routines as a whole or a 'black box' which forms the micro-foundations of capabilities and informs arguments for routines as the repository of organizational memory.

Elsewhere, a stream of research anchored in practice theory conceptualises routines as the everyday activity of organizing which defines the dynamics of stability in coordination and change in improvised forms (Feldman, 2000; Feldman & Orlikowski, 2011; Feldman & Rafaeli, 2002). Scholars adopting this perspective attempt to open the 'black box' of routines to identify and study its internal structures and constituents (Feldman & Pentland, 2008; Parmigiani & Howard-Grenville, 2011; Pentland & Feldman, 2005). In this regard, a critical emphasis is placed on the everyday situated actions of actors in creating the building blocks of organizational reality. Feldman and Orlikowski (2011, p. 1245), for example, argued that "the consequentiality of action means not just that routines are created through action and do not exist without action, but also that the development of the routine occurs through the enactment of it". This implies that routines are created and developed through the performance of actors and provides the potential for organizational flexibility (Howard-Grenville, 2005). These scholars, drawing on practice ontology to theorise organizational routines, have also attempted to explain the extent to which the "repetitive, recognizable patterns of interdependent action, carried out by multiple actors" (Feldman & Pentland, 2003, p. 95) offer the potential for change or stability in the way organizations accomplish work (Feldman, 2000). An often-relied-upon analogy in this stream of routine research is that which was proposed by Pentland and Rueter (1994), who argued that like grammars, which define the sets of constructive possibilities for the syntactic constituent of a language, "organisational routines are a set of possible patterns – enabled and constrained by a variety of organizational, social, physical, and cognitive structures – from which organizational members enact

particular performances" (Pentland & Rueter, 1994, p. 491). In this regard, practices are carried out against a background of rules and expectations; however, these rules become apparent only through enactment of the repertoire of actions available to organizational participants (Feldman, 2000; Feldman & Pentland, 2003). This argument then seeded a conceptualisation of organizational routines as embodying the duality of structure and agency, as proposed by Giddens in the theory of structuration, in order to capture a subtle difference between routine in principle and routine in practice (Feldman, 2000; Feldman & Orlikowski, 2011).

Against this background, Feldman and Pentland (2003), in their reconceptualization of organizational routines, argued that the abstract idea of the routine is representative of *structure,* while the actual performance of the routine by specific people, at specific times, in specific places, represents agency. These aspects thus constitute the two intimately connected parts of organizational routines. The authors then adopted the terms *ostensive* and *performative* as a conceptual vocabulary to refer to these aspects of routines. Analogously describing the ostensive aspect as a musical score that contain the various components which make up an orchestral piece while the performative aspect assumes the actual performance of the music (Feldman & Pentland, 2003, p. 102-103), a neat and clear-cut distinction was established between the 'know what' and 'know how' of routines. Thus, the ostensive aspect was argued to shape the perception of routines, while the performative aspect entailed the specific actions taken by specific people at specific times when they are engaged in an organizational routine (Feldman & Pentland, 2003, p. 102). In this regard, the ostensive aspect serves as a generative resource from which participants draw their understandings of a routine to account for their actions and reproduce the routine (Feldman & Pentland, 2003). Furthermore, Feldman (2003), drawing attention to the performative aspect of routine, argued that the mechanism that guides the production of legitimate variations on performance to modify a routine serves the same purpose to ensure the stability of the routine. Thus, the process of creating, recreating, and maintaining how an organization operates is implicated in the performative aspect of routine. Also, Pentland and Feldman (2005), in their explication of routine as a unit of analysis, extended the discussions on the ostensive and performative aspects to

include the role of physical artifacts in the conceptualisation of routines as a generative system. The introduction of artifacts in the study of change and stability in routines was important for explaining the representation of the ostensive and performative aspects in practical situations. Here, "artifacts such as rules, checklists, and written procedures serve as a proxy for the ostensive aspect of routine [while] artifacts such as work logs and databases serve as a convenient archival trace for the performative aspect of routine" (Pentland & Feldman, 2005, p. 796). Furthermore, Pentland and Feldman (2007) identified the use of ICT tools in the purchase of airline tickets, for example, as an artifact in the routine of flight booking. Also, Pentland and Feldman (2008, p. 248) emphasised that artifacts not only reflect the ostensive and performative aspects but also have instrumental, aesthetic, and symbolic dimensions, which may have effects on related tasks and goals, trigger sensory reactions, and provide interpretation for the impact elicited by the artifact.

2.5.1 Recasting routine in cognitivist terms

In examining and complementing the extant emphasis in the literature on the centrality of cognition in the enactment and accomplishment of routines, this chapter now revisits the ostensive and performative aspects of routine to establish a foundational argument for defining routines in cognitivist terms. This has become rather important to this research, as the varying scholarly debates so far concur that routines are not mere heuristics or mundane actions but are bound by cognitive efforts (Cohen, 2007; Pentland & Rueter, 1994). Also, it is worth noting that Becker (2004, p. 645) in his extensive review of the various scholarly works on organizational routines conceptualised and asserted that "routines can be understood as cognitive regularities or cognitive patterns". On this basis, the use of the term 'cognitive' here can simply refer to the organized knowledge that defines the framework for understanding information and executing repetitive patterns of actions in organizations (Garud & Rappa, 1994; Gioia, 1992). Secchi and Cowley (2021), in their model of cognition in organizations, identified routines as a constituent of the well-known aspects of organizational life within the macro level of organizational cognition. And as routines involve the coordination of multiple organizational participants (Feldman & Pentland, 2003), the commonly known pattern of action within an

organization is defined as the organization's shared cognition (Cannon-Bowers & Salas, 2001). More so, the explicit identity of an organization's processes is referred to as the cognitive representation of the organization (Gavetti & Levinthal, 2000). Therefore, in building a fine argument for defining routines in cognitivist terms, the core conceptualisation for defining boundaries of *what* represents an organization's routines and *what* routines are in practice offers a starting point (see Feldman & Pentland, 2003; Pentland & Feldman, 2005). Pentland and Feldman (2005), for example, identified explicit components of organizational routine artifacts, which are usually stable and predetermined, and a tacit component, which is usually flexible and may be in constant change based on various contexts and conditions. These distinctive artifacts, in turn, form the bedrock on which the ostensive and performative aspects of routines are defined (Feldman & Pentland, 2003; Pentland & Feldman, 2005).

Against this background, the ostensive aspect of organizational routines, on the one hand, provides an abstracted or generalised idea of what the organizational process entails and guides modes of action or procedures in organizations (Feldman, 2000). As Feldman and Pentland (2003, p. 101) sharply proclaimed: "the ostensive aspect of a routine shapes our perception of what the routine is". These routines are explicitly stored in formalised standards of operating procedures, and they represent the explicit knowledge that is codified and transmittable in the formal systematic language of the organization (Cohen, 2007). Knowledge from this routine can be acquired from materials in the form of books, technical specifications, and designs, or as embodied in machines (Pentland et al., 2012). In this regard, ostensive routines are the articulable elements that underlie the organizational actor's ability to understand the organization's processes (Cohen et al., 1996). Fairhurst and Putnam (2004), in their construction of the organization as an entity, also argued that the organization is often writ large, and thus assumes its identity through formal properties, conveyed by "publicly available, collaboratively organized world of artifacts and actions" (Suchman, 1987, p. 50). In this regard, drawing on insight from Weick and Roberts' (1993, p. 5) discussion on the collective mind of organizations and their analogy on the parallels between the organization of neurons in the brain and the organization of

activities in organizations, the authors highlighted that "connected activities encode concepts and ideas in organizations much like connected neurons encode concepts and ideas in brains", and thus "organizations are minds". They further emphasised that, among other reasons, the coordination among activities in the flight operations which they studied is explicit and visible and therefore was a fruitful avenue to illustrate the organization as a mind. They argued that this mind is an activity of complex patterns that can be encoded, and is also a "dispositional term that denotes a propensity to act in a certain manner […] actualized in patterns of behaviour" (Weick & Roberts, 1993, p. 5). Therefore, since the mind is analogously referred to as cognition (Secchi & Cowley, 2021), and routines can be conceived as organizational depositions (Hodgson & Knudsen, 2004), it follows that those routines which represents an organization's encoded patterns of action can be cast as *cognitive routines*. Moreover, Parmigiani and Howard-Grenville (2011, p.10) argued that there are varying "emphases on behavioural versus cognitive regularities as the underpinnings of routines", which shows that the behavioural element of routine is included in the performative aspect, whilst the cognitive element related to the ostensive aspect. Thus, the ostensive or explicit routines defined by Feldman and others can be best conceived as an organization's *cognitive routines.*

On the other hand, the performative aspect of routine represents the specific actions taken by specific people at specific times when they are engaged in an organizational routine (Feldman, 2000; Feldman & Pentland 2003). Feldman (2000, p. 620) notes that the performative aspect is one that is created through practice, and it emphasises "agency as an important element of routines and helps to explain how routines change". In this regard, the cognitive routines of an organizations acquire meaning through interaction with the actual practice or execution of the task by the atomised individual actor. However, Pentland and Feldman (2005, p. 799) argued that the performative aspect becomes increasingly tacit: a knowing-in-practice. In Winter and Szulanski's (2001, p. 739) replication strategy, the authors observed that "routines involve tacit components that can only be acquired through 'hands-on' training". The tacit nature of the performative aspect implies that it eventually transforms into knowledge which is deeply rooted in the human mind and body such that it is difficult to codify and

communicate (Pentland & Feldman, 2005). It can be expressed only through action and involvement in a specific context and acquired through experience, observation, imitation, and practice (Kim, 1998). In Nayak et al.'s (2020, p. 282) microfoundation of dynamic capabilities, tacit knowledge, as defined in cognitivist terms, represents "…a tacitly honed capacity for improvisatory adaptive action that is unconsciously acquired in situ through extensive immersion in changing environmental conditions that are often tacit in nature [and] do not lend themselves to codification". In keeping with these arguments, the performative aspects of routines, which are largely defined in terms of the tacit knowledge of the individual actor, can be described as the *noncognitive routines*. It is worth emphasising that the use of the term 'noncognitive' here does not imply that the routine is mundane or mindless, but rather that it is used in contrast to the organization's cognitive representation/routines. Moreover, Feldman (2000, p. 622) argued that "ostensive routines may be devoid of active thinking, but routines enacted by people in organizations inevitably involve a range of actions, behaviours, thinking, and feeling". However, since the tacit knowledge which is acquired through the performative aspects is defined in cognitivist terms as noncognitive (Nayak et al., 2020), it is well situated if actions that are not explicitly expressed in an organization's codified routine processes but are conceived from organizational members' experience are recast as the *noncognitive routines* of the organizations.

2.6 Situating regulatory review processes within *routine-as-practice*

Given the comprehensive delineations of organizational routines so far, it follows that regulatory review processes could be located within the theoretical concept of routines. Specifically, by reflecting on the conceptualisation of routines as practice, which is widely imprinted in the writings of Martha Feldman and colleagues, it is only appropriate that the regulatory review processes are defined in terms of the practice perspective of routines (see Figure 2.4 for conceptual model). As Cohen et al. (1996, p. 662) indicate, the "effectiveness of a routine is not measured by what is achieved in principle but by what is achieved in practice". As such, it is also imperative that the core concepts in this conceptualisation of routine are revisited to fully establish a clear path towards situating regulatory

review processes in this perspective. In this regard, as was apparent in the literature, the practice perspective of routines resonates with the sociological thoughts of Giddens (1984) on the recursive relationship between structure and agency. Giddens (1984, p. 377), defining structure as constituting "rules and resources, recursively implicated in the reproduction of social systems", argued that the existence of structure is dependent on the knowledge agents have about what they do in their day-to-day activities. These practices are, however, enabled or constrained by the same structures. Accordingly, Feldman and Orlikowski (2011, p. 1240) emphasised that "central to a practice lens is the notion that social life is an ongoing production and thus emerges through people's recurrent actions". Therefore, the creation and development of routines occurs through their enactment, such that the duality of action/structure, which constitutes routines, and stability/change, which defines the dynamism in routines, are relational and mutually constitutive (Feldman & Orlikowski, 2011, p. 1245). As such, the relationships between work practices, organizational routines, and change, among other theoretical perspectives, are best conceived through the medium of practice (see Feldman, 2004, p. 297); hence, the production of routines is in a constant flux and emerges through the participant's situated actions. Although these situated actions are accomplished individually, "they do so in a context created by the actions of the other participant" (Feldman & Pentland, 2003, p. 104). Therefore, regulatory evaluation routines can further be conceived as processual and relationally constituted through everyday actions of the product evaluators.

Furthermore, Schatzki (2001, p. 3), highlighting the material configurations involved in specific practices, argued that practice theory recognises how "bundle of activities interweaves with ordered constellations of nonhuman entities". In his explication of the post-humanist practice perspective, Schatzki further argued that "nonhumans do not just mediate, but themselves propagate practices" (2001, p.3). Also, Orlikowski (2007, p. 1436), in his essay on the sociomaterial aspect of practices, argued that "*every* organizational practice is *always* bound with materiality", as "materiality is not an incidental or intermittent aspect of organizational life; it is integral to it". In addition, Shove et al. (2012, p. 9), in their discussion on the material element of practices, emphasised the constitutive role of material in

everyday life. Thus, the nexuses of routine-practices are mediated and conceived by artifacts or materials employed within practice. On this note, Pentland and Feldman (2008, p. 242) argued that "routines exist within a multiplicity of material and ideological structures that influence the patterns of action that participants create and recreate". For Pentland et al. (2012, p. 1486), "it is safe to say that most routines would grind to a halt" in the absence of material. Thus, the human and nonhuman or material as agencies are intimately constitutive and intertwined, such that 'organizational routine' and material are effectively indistinguishable (Pentland et al., 2012, p. 1486). In this regard, the intellectual tradition of routines as practice acknowledges that routines are bound up with the material forms and spaces through which participants act and interact. Thus, providing a comprehensive delineation on specific routines in context requires an understanding of the material configurations through which practices are performed.

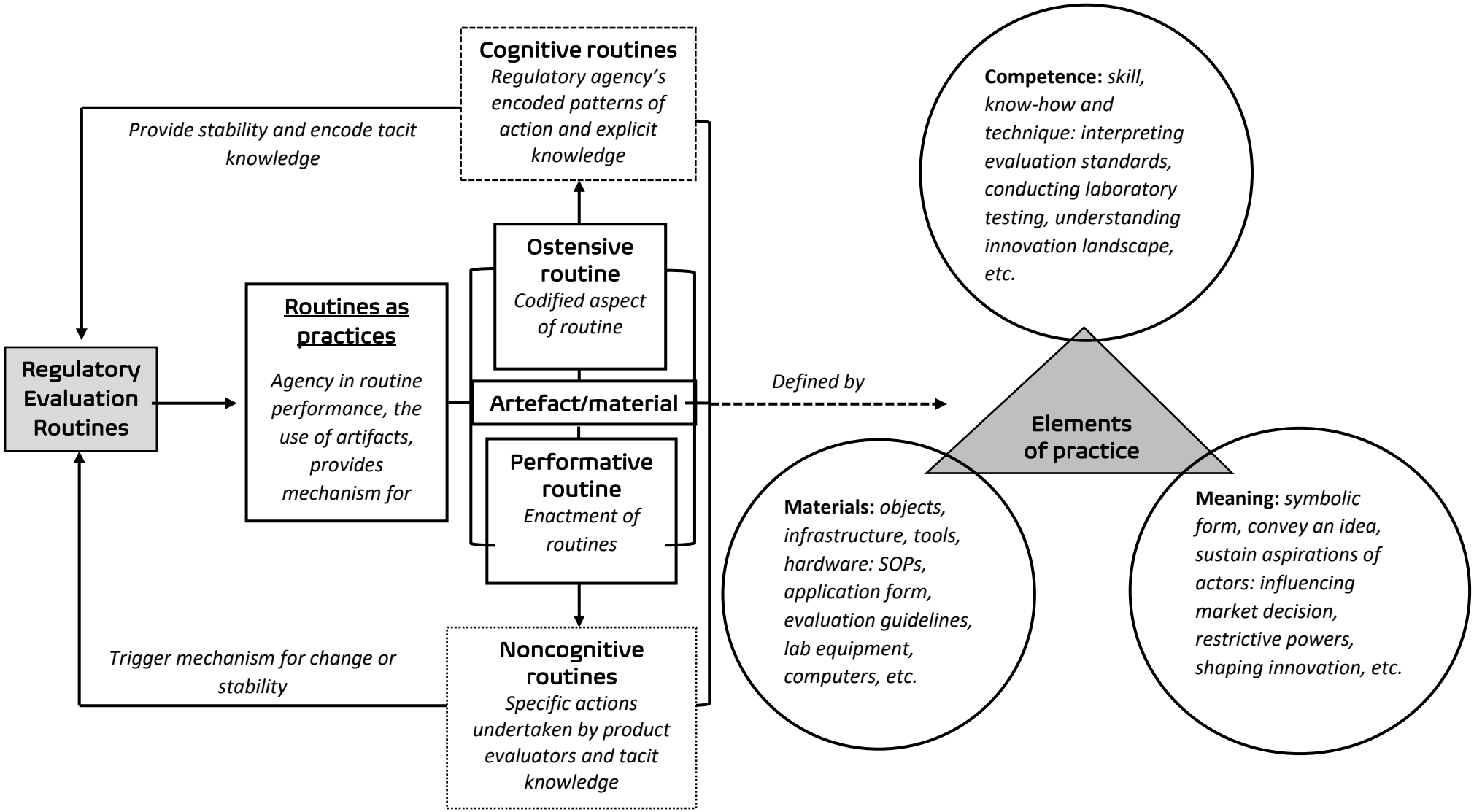
Against this backdrop, insights from Shove et al.'s (2012) conceptualisation of practice as constituting three active elements that are integrated in a web of performative linkages between materials, competence and meanings may serve as an important theoretical lead to clarify how the bundles of routines and material arrangements, and hence change and stability, unfold. In *The dynamics of social practice,* Shove and colleagues (2012) argued that "stability and change are not end points of a linear process of normalisation, rather they should be understood as ongoing accomplishments in which similar elements [of practice] are linked together in similar ways" (Shove et al., 2012 p. 24). This implies that the effective configuration of routines that provides basis for stability and the inevitable change in patterns of action are implicated in the active integration of some elements of practice. The first element of practice put forward by Shove et al. is the material, which revolves around arguments that "practices are intrinsically connected to and interwoven with objects" (Schatzki, 2002, p. 106). In this regard, "objects, infrastructure, tools, hardware and the body itself" (Shove et al., 2012, p. 23) may constitute the material. In the conceptualisation of routine as practice, these materials or artifacts may include "those that may deliberately attempt to capture or prescribe the routine" (Pentland & Feldman, 2005, p. 797). And in the context of regulatory reviews, these materials may include standard operating

procedures, product review application forms, evaluation guidelines and parameters or standards, lab equipment and chemical solutions or solvents, and computers, among others. The second element of practices, namely competence, encompasses the skill, know-how and technique used in an activity (Shove et al., 2012, p. 14). Thus, this element constitutes the capability to effortfully enact or accomplish a routine. In this regard, the regulatory evaluation process constitutes the ability to conduct laboratory testing, using computer software and IT tools to streamline processes, competence in understanding and interpreting evaluation standards, the capacity to perceive the prevailing technological knowledge in the innovation landscape, and so on. The third element of practice reflects meanings which may be in symbolic form, convey an idea, or sustain the aspirations of actors. In organizational routines, this may be defined in terms of the interpretation of the impact of a routine, which, based on the dynamic interrelation between material and competence, may influence or trigger change and/or stability of the routine (Pentland & Feldman, 2008). The meaning element is signified in the form of the *power* of regulatory agencies to protect public health and ensure safety, influencing decisions that are elicited on the selection environment, restriction or otherwise of products from commercialising, and in shaping the trajectory of future innovation.

In conceptualising regulatory review processes from this routines–practice perspective, an empirical focus is therefore rendered to what is espoused as the cognitive routines of the regulatory agency and what is actually done in practice; a theoretical consideration for how the practical actions embedded in the noncognitive routines inform, shape and are shaped by social and organizational ordering of the regulatory agency; and an ontological conception of the repetitive patterns of evaluations as produced by bundles of actions that are spatially distributed (Feldman & Orlikowski, 2011; Giddens, 1984; Rerup & Feldman, 2011; Schatzki, 2001). Such conceptualisations not only emphasize the mutually constitutive roles of (non)cognitive routines in defining regulatory review processes, but also highlight the potential to account for how the generative nature of routine predisposes stability through variations that occur in the every-day effortful accomplishment of product evaluators. As such, the regulatory review is rendered an unfolding process of producing and

reproducing evaluation framework according to the social or local situations. Thus, in theorising how the dynamic interplay between (non)cognitive routines may trigger change or stability in regulatory reviews, special emphasis is placed on the socio-organizational context, competences, meanings, and materials that shape the organizing routines of regulatory agencies. And as the majority of activities that are shaped and enabled by structures depend on forms of practical knowledge (Giddens, 1984), attempting to strike a balance between the sayings and doings of the product evaluators in their situated practices would unpack the powerful cultural, social, and organizational forces that underlie the mechanism for change or stability in the regulatory evaluation process. On this basis, a focus is to be rendered to understanding the (un)conscious thoughts, reflections, tacit knowledge, and discernible patterns of relational actions that are not easily codifiable but may define the process of producing and reproducing organizational reality and undergird the inertial qualities of regulatory agencies.

Figure 2.4 Conceptual model of regulatory reviews within routines-practice perspective



2.7 Chapter summary and conclusion

This chapter has focused on drawing together the existing body of literature on new product innovation and regulatory reviews to identify relationships, connections, interdependencies, and subtle nuances in the prior research. A substantial portion of the chapter was thus allocated to capturing the existing body of knowledge on regulatory review into themes of arguments that explicate specific regulatory concerns that influence product evaluation processes and decisions, as well as highlighting empirical gaps that need immediate scholarly attention. In addition, the chapter extended the analysis of the literature by identifying a theoretical lead that will be able to address the known shortcomings in the literature in more detail. Specifically, the chapter situated exploration of the areas that have received empirically modest attention within the recent burgeoning theoretical arguments on organizational routines. Special emphasis was placed on identifying and underlying the significance of routines in defining and shaping regulatory review processes. In this regard, the chapter conceptualised in cognitivist terms specific aspects of routines through the practice perspective on routines. The perusal of the literature on this perspective of routines led to the conclusion that the interlacing between routines and practices is inextricable, as we cannot make sense of or assume the existence of one without the other. Therefore, in providing means to fill the lacunae in the existing body of knowledge on regulatory reviews, the chapter rendered priority to situating and conceptualising regulatory review processes within the routines-practice perspective. This was important to help to provide the basis for delineating how the situated practices of product reviewers could potentially account for the underlying mechanism through which change and/or stability in regulatory evaluation routines unfold.

Therefore, in the discourse on regulatory reviews, routines and practice are very much foregrounded, such that the noncognitive routines enacted in the situated practices of product evaluators form the linchpin in accounting for the mechanism through which the intended, unfolding, and emergent flows of connected ideas, tacit knowledge and presuppositions that maintain and stimulate change in regulatory review processes are defined. In other words, the routines-practice perspective serves as a metatheoretical lens to unpack how the web of socio-cognitive and

organizational relations in which change, adaptation and inertial qualities of regulatory agencies and their evaluation frameworks may come to be identified and labelled.

CHAPTER THREE
Methodology

This chapter presents the methodological tools and strategy adopted to gather and analyse the empirical data for the study. The chapter begins with a detailed description of the research setting, together with discussions and justifications for the case study approach adopted. Following this, fine details of the research design are presented, including the sampling strategy and how access to the research site was negotiated, as well as how recruitment of participants for the study was organized. Next, a detailed explanation of the data collection process is presented, highlighting each of the data collection tools employed. The subsequent section presents the analytical procedure and data coding phases for generating theoretical insights from the data, after which measures for ensuring the validity and accuracy of the theorising process are discussed. The penultimate section highlights some methodological limitations and reflections, while the final section concludes the chapter by way of a summary.

3.1 Research setting

The contribution of this study is empirically developed in the context of the Ghana FDA review of new products. The Ghana FDA is a national regulatory agency charged with the primary responsibility to evaluate and approve products for commercialisation (Dowuona-Hammond, 2018). Its activities include the control of manufacturing processes, importation, exportation, product distribution, and advertisement of products, and conducting clinical trials, as well providing guidelines for clinical trial protocols (FDA, 2021a; Laar et al., 2020). The institutionalisation and establishment of this regulatory agency has its historical narratives from periods before 1990, when the focus of product regulation was on the control of drugs and the practice of pharmacy as a profession under the Ghana Pharmacy and Drugs Act (Act 64) 1961 (FDA, 2021a). In 1990, the then Provisional National Defence Council (PNDC)

government passed a Narcotics Drugs Control, Enforcement and Sanctions Law (PNDCL 236), which established a Narcotics Control Board to deal with the rising incidence of drug abuse and to control illicit drug dealings in the country (FDA, 2021a). However, in 1992, the government separated the control of drugs other than narcotics from the practice of pharmacy and enacted a Food and Drug Law, PNDC law 305B (FDA, 2021a). This law was amended in 1996 to address a growing concern about nutritional deficiencies in Ghana, and to bring the provisions of the law to conform with the then newly drafted 1992 Constitution. Following this, a Food and Drug Act 523 was passed in 1996, and the first members of the Food and Drugs Board (FDB) were inaugurated in August 1997 (FDA, 2021a; Laar et al., 2020). A later revision and integration of the Food and Drug Act into a new Public Health Act 851 in 2012 led to a change of name from the FDB to the Food and Drugs Authority Ghana (FDA). Following this amendment, the FDA was granted the legal authority to enforce product safety laws, initiate market surveillance, and impose sanctions on noncompliant firms, and where necessary, to refer to the courts for prosecution, revoke product licenses, impose fines and charges, enforce closure of unlicensed premises, reject, ban or blacklist products from market entry, and recall commercialised products from the market (Dowuona-Hammond, 2018; FDA, 2021a, 2021b). The FDA's regulatory power covers a wide range of products, including food and food supplements, drugs, herbal and homeopathic medicines, veterinary medicines, cosmetics, medical devices, household chemical substances, tobacco and tobacco products, and others (FDA, 2021a, 2021b).

As a national regulatory agency, the FDA operates under the Ministry of Health and provides advise to the Minister for Health on measures to protect public health. Also, the FDA works closely with other regulatory institutions such as the Ghana Standards Authority and the Consumer Protection Authority, as well as state security agencies and local government authorities. The operational objective of the FDA is directed by a governing board, who are appointed by the government, with the aim to collectively ensure proper and effective performance of the FDA in order to meet the interests of all stakeholders (FDA, 2021b, 2021d). Also, the FDA benefits from five advisory committee, which provides it with technical advice on the safety of medicines, vaccines and biological products, medical

devices, nutrition, and the conduct of clinical trials (FDA, 2021a). Although decisions that are made regarding the approval of products for commercialisation remain the mandate of the FDA, insights from this committee are significant to assisting the FDA in making appropriate risk management decisions (FDA, 2021a). Administratively, the operational management, service delivery, and strategic issues of the FDA fall under the direct responsibility of the Chief Executive Officer (CEO). These administrative duties are, however, distributed amongst departments at the CEO's office, including Import and Export Control, Laboratory Services Departments, Communications and Public Education, Internal Audit, Research and Management Information Systems, and other Regional Offices. The CEO oversees the overall operational structure of the FDA, which is aggregated into five divisions: the Food Inspectorate Division, the Food Safety Division, the Drugs Evaluation Inspectorate Division, the Medical Devices, Cosmetics and Household Chemicals Division, and the Safety Monitoring and Clinical Trials Division. In addition, there are other specialised divisions, including the Safety Monitoring and Clinical Trials Division and the Monitoring and Evaluation Division, which augment the work of the six main divisions (FDA, 2021a, 2021d). Each division has a specific operational mandate, and these mandates are merged to define the day-to-day activities of the FDA. The Food Inspectorate Division, for example, is responsible for the registration of locally manufactured, imported and exported food products, provides industrial support, and enforces regulatory standards (FDA, 2021b). In addition, it ensures that all food products are labelled, packaged, and advertised in accordance with the standard guidelines in order to protect the public from deception and to control brand imitation (FDA, 2021b). The Drugs division and Medical Devices, Cosmetics and Household Chemicals division also ensures that all products under its purview, either locally manufactured or imported, are evaluated and registered, labelled, packaged, and advertised in accordance with regulatory guidelines (FDA, 2021b).

The FDA operates a robust regulatory framework embedded with multiple routines that characterise the product review process, from the evaluation, registration, and commercial authorisation of products to conducting post-market surveillance, providing industry support, and

enforcing regulatory standards. More importantly, these routines are adopted and replicated from comprehensive regulatory codes of practice and guidelines such as Codex Alimentarius standards and the recommendations of the World Health Organization (FDA, 2021b). At the time of the study, a new operational software system has been developed in consultation with the product evaluators to allow the FDA to benefit from processes that help the evaluators to conduct swift and effective reviews of products. The FDA receives overwhelming numbers and increasingly new arrays of products requiring evaluation and market authorisation, making it challenging for the agency to provide rapid responses and adapt to the changing product patterns and technologies. In 2019, for example, the FDA reported a 39% increase in applications received, a 51% rise in processed applications, a 64% increase in the number of registered products, and about a 1% increase in the number of deferred products from the previous year (FDA, 2021d). In addition, between 2017 and 2019, an average of 10,344 applications were submitted, 8972 were processed, and 8497 were approved (FDA, 2021d).

However, the FDA continues to grapple with resource constraints and the capacity to accumulate knowledge to understand the attributes of new products in order to provide prompt regulatory responses. This has rendered the performance and extension of the FDA's regulatory reach to control and standardized all products that are commercialised on the market particularly daunting (Dowuona-Hammond, 2018). Moreover, the Ghanaian economy is characterised by a large informal, rural sector, which is estimated to form about 91% of the economy (Ghana Statistical Service, 2015; Turkson et al., 2020), thereby creating a grey market where trading in sub-standard and unsafe products thrive. This large informal sector thus poses a challenge for the FDA in executing its mandate to protect the market from harmful products. As such, the execution of the product evaluation routines in Ghana is fettered with challenges of resource inadequacy and underdeveloped markets. Consequently, consumers are bound to be exposed to "health and safety hazards from poor quality, unsafe, sub-standard, and improperly labelled products; lack of accessible, easy, and cost-effective redress mechanisms; unfair trading and business practices; deceitful and misleading advertising; misbranding and inadequate information on product identity; and non-compliance with standards" (Dowuona-

Hammond, 2018, p. 335). As a result, the FDA often relies on issuing public health alerts and warnings on the influx of substandard products in the market, and post-market withdrawals (Dowuona-Hammond, 2018; FDA, 2021c).

Nonetheless, these conditions within which regulatory evaluations are conducted in this setting render the FDA a useful context for generating both theoretical understanding and empirical characterisation of how socio-cultural and cognitive factors may emerge and fall out of use in the regulatory review process. As Schatzki (2001, p. 9) argued, "the prominence of practical understanding is tied to the body's mediative positions between mind and activity and between individual activity and social manifold". Therefore, the ability of formulations to guide "what people do rests on abilities to *use* and *understand* them" within the *social* world (Schatzki, 2001, p. 9). This implies that the interpretation and enactment of routines are shaped by the context of actual practice, and therefore that the social is constitutive of the actual performance of the product evaluation routines. In addition, this context is fruitful for understanding how the dynamic interplay between (non)cognitive routines and the influences of artefacts (scarce or abundant) may come to define the regulatory review process for NPIs. D'Adderio (2008, p. 770) underlines that "framing rules and standard operating procedure is never complete, as there is always overflowing, which opens up search spaces, thus introducing scope for divergence, adaptation and change". In this regard, the enactment of noncognitive routines in this context could yield variations that may be assimilated into the cognitive routines, thereby helping to account for the mechanism of change and adaption of regulatory review frameworks (D'Adderio, 2008; Pentland & Rueter, 1994).

3.1.1 Case study approach: Regulatory review of alcoholic beverages

The empirical context affords the opportunity to observe multiple processes within the FDA's product evaluation framework, which is composed of rich and complex routines that may satisfy the overriding interest of this study. However, as the objective of this research is to account for the adaptation of regulatory review processes in response to changes in the innovation landscape, insights are drawn

from the ethnographic case study approach for building theory which helps to "unravel mechanisms that can otherwise remain implicit and that are crucial for tracking change" (Michel, 2011, p. 333). Therefore, following recent studies adopting inductive theory-building through observation and analyses of single exceptional cases (e.g., Aversa et al., 2021; Vaccaro & Palazzo, 2021), the research focuses on the FDA's review of New Alcoholic Beverage Applications (NABA). There are two other key motives for choosing to focus attention on the FDA's process for reviewing NABA. First, the extant body of literature on regulatory reviews is empirically dominated by the pharmaceutical drugs and medical devices industry. Thus, the locus of the dynamics of the complex but phase-gate structured process for evaluating pharmaceutical products may be difficult to find in the generalisation of the discourse on regulatory reviews across multiple industries. In this regard, the focus on NABA presents an opportunity to provide a more holistic characterisation of the regulatory review landscape, thereby extending the stock of knowledge beyond the existing boundaries of thought. Second, the theoretical issues of interest are apparent and the potential to access and gather rich data is abundant. On this note, an overview of alcohol consumption in Ghana is important to establish how relevant NABA becomes to the research interest.

To begin with, Ghana is a country with a population of 30.8 million people, of whom 58.2% are aged 18 years and above (Ghana Statistical Service, 2021a, 2021b). However, nearly 43% of this population are involved in the binging of alcoholic beverages (Biney et al., 2020). The consumption of alcohol spans both genders, with over 7% of young women and 8% of young men between the ages of 15 and 19 binging on alcohol (Baraka Policy Institute, 2016). Variation in the proportion of alcohol consumption is observed at age 40 and above, where 52% of men and 26% of women consume alcohol (Baraka Policy Institute, 2016). The heightened consumption among men has been found to be due to cultural expectations of male sexuality in intimate heterosexual relationships (Fiaveh, 2020), thereby leading to patronage of alcoholic beverages mainly as aphrodisiacs to boost sexual performance (Baraka Policy Institute, 2016; Biney et al., 2020). This has created a large informal sector for the local alcoholic beverage industry, producing potentially lethal concoctions known as local herbal bitters (Baraka

Policy Institute, 2016). As of 2016, these local bitters constituted 57% of Ghana's per capita consumption of alcohol (Baraka Policy Institute, 2016, p. 4). Also, a recent media report listed over 46 alcoholic bitters in the market, signalling a high number of new alcoholic bitters that are authorised to be commercialised on the market (Joe, 2021). Luginaah and Dakubo (2003), however, cautioned that as beer and other imported alcoholic drinks remain expensive and scarce, the local informal sector, which is largely underregulated, would continue to find avenues to satisfy the market demand by producing cheaper alternatives. Also, the accessibility of these alcoholic beverages to those as young as 15 years is particularly alarming (Luginaah & Dakubo, 2003). As such, despite the sociocultural, health, economic, and political explanations for the supply and consumption of alcohol in the country (Akyeampong, 1995, 1996; Baraka Policy Institute, 2016; Luginaah & Dakubo, 2003), there are rising concerns among scholars, health experts and policymakers about the use and abuse of alcohol in recent times. Several scholars have argued that the challenge in Ghana has been the absence of a national policy to control the proliferation, sale, and advertisements of alcoholic beverages (Osei-Bonsu et al., 2017; Tampah-Naah & Amoah, 2015). Thus, in 2016, strident discussions on alcoholism in Ghana as a public health concern led to the drafting of Ghana's first National Alcohol Policy (GNAP) (Baraka Policy Institute, 2016). The policy sought to synthesise the existing but dispersed policies on alcohol into a single document, and brought together and (re)established several alcohol taskforces for the implementation of this policy (Baraka Policy Institute, 2016).

In this vein, since the FDA is a national regulatory body, whose evaluations determine the commercialisation of products and whose approval stamps influence selection decisions in the market selection environment, the successful implementation and enforcement of the alcohol policy was heavily dependent on its activities. The FDA was therefore mandated to exercise regulatory oversight over the production, sale, and advertisement of alcoholic beverages in Ghana (Baraka Policy Institute, 2016). Thus, following the launching of the GNAP, the FDA introduced specific requirements for the registration and advertisement of alcoholic beverages. As such, in addition to the general requirements for commercialising food products, the FDA sought to enforce the indication of health warnings and

limits on labels and in media adverts of alcoholic drinks (FDA, 2016). This means that the general evaluations of NABA, including details on the products' labelling and the decision to approve, defer, or reject a product, would not be solely based on the scientific analysis of the 'technological' constituents of the product. Rather, the social practices, including the dispositional mindsets of the product evaluators about alcohol consumption, could cumulatively influence the evaluation routines and decisions. This also implies that the scientifically bounded logics of regulatory review processes and decisions of the FDA may be fraught with the influences of discretion, improvisation, and organizational constraints, as well as social and religious values (Garud & Rappa, 1994; Winter & Szulanski, 2001). As such, the embeddedness of the FDA's evaluation of NABA in this context helps to bring into clearer view how product evaluators establish a viable and comprehensive shared understanding of their situated practices, not only in terms of the general representations of the cognitive routines, but also in terms of the socio-cultural dispositions of the individual evaluator. More importantly, focusing on NABA presents an opportunity to understand how the interactions between organizing routines and socio-cultural context shape the outcomes of the product evaluation process. In other words, observing the review process of NABA offers a transparently observable and unique empirical confirmation of how socio-cultural practices and ideological mindsets operate in combination or serially to influence the dynamics of regulatory evaluation routine, playing out to define and facilitate the adaptation of regulatory review frameworks and/or as a barrier to change in the evaluation routines.

3.2 Research design

The impression left in the literature on regulatory reviews is that the various regulatory concerns that cumulatively influence the evaluation process and decisions can only be expressed in quantitative modules to deductively test and provide theoretical confirmations and explanations of the relationships that exist between these concerns (as factors) and regulatory reviews (as events) (Carpenter et al., 2012; Polidoro, 2020). However, with the identification of several socio-organizational, cultural, and

cognitive constructs that serially combine to shape and inform regulatory decisions, and the paucity of research to address these issues, it has become imperative that this research is designed to achieve full immersion in the social context and mindsets of actors who are actively engaged in the day-to-day evaluation of NPIs. In addition, the routines-practice perspective underpinning this research finds its empirical grounding in the agential activities, situatedness, materiality, relationality, and processuality of practices that determine the internal dynamics of routines (Dionysiou et al., 2021; Feldman, 2016). As such, the regulatory review process is perceived to be 'enacted' into life by the multiple and situated performative accomplishments of product evaluators, which are in constant flux and deeply entrenched in the dispositional realm of emotions and cognitions as well as the material and social world (Pentland & Feldman, 2003; Reckwitz, 2002). Especially, as Feldman (2000, p. 614) argues:

> "routines are performed by people who think and feel and care. Their reactions are situated in institutional, organizational, and personal contexts. Their actions are motivated by will and intention. They create, resist, engage in conflict, acquiesce to domination. All of these forces influence the enactment of organizational routines and create in them a tremendous potential for change".

Thus, the situated practices that define the regulatory review process can be better understood not as events or merely complementary actions but as mutually recursive and constitutive of the corporeal and social (Feldman & Orlikowski, 2011). As such, in accounting for the mechanism through which situated actions can inform the evolution of regulatory evaluation routines, attention is directed to understanding the (un)conscious thoughts, reflections, tacit knowledges, and discernible patterns of relational actions, which are not easily codifiable but define the process of producing and reproducing reality. On this basis, an inductive qualitative research design is adopted to construct a theory that can provide a comprehensive explication of the mechanism through which change, or adaptation of regulatory review processes and frameworks comes to be implicated in the dynamic interplay between the artifact-embedded (non)cognitive routines of the FDA. As Pentland and Feldman (2008, p. 344)

would argue, "we cannot discern the significance of an artifact by inspecting it from our own (etic) point of view". Thus, in terms of the emic, the research is designed to render primacy to the observation of regulatory officers in their effortful enactment of routines in their situated practices, which are guided by documented procedures and codified processes, while unveiling their experiences and tacit knowledge through the verbal accounts of their purposeful everyday actions.

3.2.1 Sampling strategy

As a critical part of the data-gathering stage of this study, a purposeful sampling strategy was employed to select participants who have had meaningful experiences in the product evaluation process and could reveal in-depth insights into the issues that are of importance to this enquiry (Koerner, 2014). In this regard, two basic criteria for inclusion were established, which provided a focus for sampling all the participants. First, the study targeted product reviewers, who are at the coalface of the evaluation of new product applications; laboratory analysts, who engage in the biological and physiochemical testing of products; the heads of units and departments, who act as supervisors in the evaluation process and engage in the deliberations leading to the final regulatory decision; and field evaluators, who ensure continued evaluation after products have gained authorisation to be commercialised through surveillance and enforcement. Second, since the objective of the study is to account for the change and adaptation of the regulatory evaluation framework through the tacit knowledge and presuppositions of evaluators, honed from their experiences from the continuous enactment of noncognitive routines, the sampling targeted participants who had worked with the FDA for a minimum of six months. The determination of this period was informed by the FDA's 28-day cycle to complete an evaluation process, as stated in its publicly available application guidelines. This implies that, on average, a selected participant would have experienced six cycles of the evaluation process and thus could potentially make some insightful commentary to include in the data set. The sample was collectively labelled *regulatory officers*. It is worth noting that since the interpretative qualitative research approach adopted involved a simultaneous process of collecting and analysing data and seeking new

informants based on information provided by prior informants and observations, there was an increasingly evolving sample until no additional information on the FDA's routines for evaluating a NABA was deemed important. This was, however, guided by the basic criteria for sampling.

3.2.2 Negotiating access and participant recruitment

Access at the FDA was facilitated through a fortuitous discussion on the role of the FDA with an individual who, at the time of study, worked at the FDA as a regulatory officer. After discussing the main ideas of the study with this individual, they suggested that an official letter be written and addressed to the CEO of the FDA. Based on this, the key objectives of the research, including the methods to be used and potential contributions, was put into writing and submitted to the FDA. The FDA responded, granting access on condition that a confirmation of ethics approval from both Brunel University and the Ghana Health Service Ethics Review Committee (GHS-ERC) was provided. On this note, the Brunel Research Ethics Online (BREO) application was completed and submitted. Concurrently, a request was sent to GHS-ERC via email for ethics clearance to conduct the study. A dossier of application documents was returned by the GHS-ERC, which were also completed and submitted. After two rounds of review and corrections, the GHS-ERC granted approval and issued a confirmation letter, which was later collected in person (See Appendix 3.1). This approval letter was submitted to BREO as a supporting document, which in turn aided the subsequent conditional approval from BREO (See Appendix 3.2). The primary condition was that the research was to be conducted only if strict Covid-19 safety measures could be observed. Given that such safety measures had been included in the research protocols and the FDA had guaranteed a safe environment and granted full access to conduct the study, the data collection began in July 2021.

Embedded within the FDA and armed with a well-defined sampling strategy, participants were recruited for the study via emails. Once participant(s) had accepted the invitation, which was aided by informal introductions and conversations, they were sent a participant information sheet and a consent form to sign (see Appendixes 3.3 and 3.4). These documents clearly stated the objectives of

the study and how the interviews would be recorded, and highlighted the Covid-19 safety protocols that were to be observed during the study. Participants were recruited from six main departments, namely the Food Evaluation and Registration Department (FERD), the Food Microbiological Laboratory (FML), the Food Physiochemical Laboratory (FPL), the Post-Market Surveillance Unit (PMS), the Food Enforcement Unit (FE), and the Industry Support Unit (IS). It is worth noting that although the study was designed to collect data at the Head Office of the FDA in Accra, some of the participants had their operational offices at different locations, as the Head Office only housed most of the administration staff. Specifically, the FERD and the FML had their operational space at the Head Office, whereas the FPL was located in Accra city centre. Also, the PMS, FE, and IS had their operations at the industrial city of Tema in the Greater Accra Region of Ghana. Since the data collection tool included observations and documentary data, emails were exchanged between the Head Office and the various department and unit heads to inform them of the study. Subsequently, all members of the unit or department were briefed on the purpose of the ongoing observational study. The documentary data was then accessed via the various heads of departments and units. Also, the regulatory supervisors provided contact details of potential participants who were working from home, as the Covid-19 safety measures on social distancing would not allow the FDA to have all regulatory officers on the premises. These participants were contacted via phone calls and later sent an invitation email. They were then scheduled for interview on their next day at the FDA office.

3.3 The Covid-19 pandemic

It is worth reflecting that prior to the data collection period, the Covid-19 virus outbreak, which was declared a public health emergency of international concern and a pandemic by the World Health Organization (WHO, 2020) was still a concern. As such, the international community was keenly mobilising to finding ways to curb the spread of the virus. Measures such as travel restrictions or bans, and national lockdowns were established worldwide in order to contain the outbreak. At the time of data collection, Ghana had just opened up after a six-month lockdown. However, in view of the

potential for the virus to continuously spread, the Ghana Health Service and the Ministry of Health (GHS) issued a national Covid-19 safety protocol. This included several guidelines for travelling into the country, such as providing a negative Polymerase Chain Reaction (PCR) test result and completing a health declaration form, among others (GHS, 2020a). Also, within the country, safety measures such as mandatory face masks in public places, maintaining social distancing, and regular handwashing and sanitisation were being implemented (GHS, 2020b). In light of this, the FDA Ghana had also established Covid-19 safety guidelines to ensure compliance with the government's health regulations. For the FDA, this meant that work patterns would need to change, as a work-from-home policy to minimise the number of persons at the premises was initiated to ensure that safe distance could be maintained. In addition, the FDA had set up a cleaning station at the entrance of the premises for handwashing, sanitising, and temperature checks. All these measures, however, caused a jolt which altered the routines of the FDA, thereby further rendering the context fruitful for collecting data on the triggers of change in routines, which is also of particular interest to this research. The data collection process was therefore designed around strict Covid-19 safety protocols. As such, during the data collection period, news updates on Covid-19 safety measure were closely followed in order to ensure strict adherence to health and safety regulations in Ghana. Probing questions about Covid-19 were also included in the interviews, informal conversations about the impact of the pandemic were engaged in during observations, and documents including memos and emails on Covid-19 safety measures were collected.

3.4 Data collection

Qualitative data was collected between July and October 2021, tracing the evaluation process for a NABA. The research question and the practice-based ontology of routines required that the cognitive routines (or espoused routines) and the noncognitive routines (or enacted routines) of the FDA, as well as the cognitive efficiency in the form of tacit knowledge, were identified. In this vein, the situated practices of product evaluators and supervisors were observed as they occurred, thereby generating data in the form of observation notes. Also, several documents were extensively accessed to generate

documentary data on the codified processes of the FDA. In addition, ethnographic interviews were conducted to record the verbal accounts of regulatory officers sharing insights embedded and sealed away in their tacit cognitions, thereby generating interview data to clarify and bolster the observational and documentary data. These data were collected at the FDA Ghana as a non-participant observer each weekday (except on public holidays). The data collection was designed to combine and triangulate the three overlapping sources to construct theory and support the validity of the data, as well as to ensure the integrity of the analysis (Guba & Lincoln, 2005). Specifically, it focused on gathering enough data to develop a rich understanding of how the (non)cognitive routines coevolved to shape and define the review process for NPI at the FDA. Table 3.1 presents a quantitative summary of data collected from all three sources, and the information extracted.

Table 3.1 Data sources and information retrieved

Data sources	Volume	Information retrieved
Documents	25 FDA documents. 373 pages assessed.	Codified process for receiving new applications; The stages of new product evaluation; Parameters that determine the final regulatory decision; How the FDA ensures stability in the evaluation routines; The means of replicating routines and introducing new evaluators to the cognitive routines of the FDA.
Observation	350 hours of observation. 113 pages of observation notes.	Organizing routines of the day-to-day evaluations of the FDA; How socio-cultural practices influence evaluation routines; When and how tacit knowledge comes to bear and attempts to become codified; The coordination and communications that define and refine the evaluation routines.
Ethnographic Interviews	31 semi-structured interviews ranging between 30 and 90 minutes. 317 transcribed pages.	Tacit knowledge of product reviewers; Personal opinions and experiences; Recommendations for change; Dispositional and interpretative mindsets of evaluators.

3.4.1 Documents

Twenty-five (25) internal documents, approximating 113 pages, were assessed and analysed. These included internal memos, newsletters, presentations, and standard operating procedure (SOPs) of the FDA describing the key tasks and activities, behavioural and ethical codes, and rules for organizing routines. These documents were made available on the first day of arrival at each department. Although each division or unit had its own specified set of documents, most of the core processes overlapped and were often a continuation of previous routines from other divisions or were to be completed by another unit. Data from these documents served as the basis for engaging in reflections and discussions with the interview participants about specific issues and helped to clarify quotes and themes that emerged from the data. More importantly, versions of the SOPs which served as a handbook for new evaluators to familiarise themselves with the scope and structure of the evaluation framework were particularly useful in understanding the acculturation of routines to ensure replication and stability in the cognitive routines of the FDA. Of particular focus in the reading of these documents were the cognitive routines, which gave form and structure to the FDA's evaluation process, and which served as a legal guide in the purposeful accomplishment of the review process.

3.4.2 Observations

Over the data collection period, approximately 350 hours were spent observing product evaluators in their situated practices. Notes and audio-recordings (when taping would be disruptive) of every meeting and training session (that which I knew of and that which I was invited to/allowed to join) were taken and later transcribed and extended to generate 60 double-spaced pages of ethnographic field notes (Emerson et al., 2011). Most of the observational data were collected at the Evaluation and Registration department and the Microbiological and Physiochemical Laboratory. During the observations, the focus was on how regulatory officers coordinate their routines to ensure successful completion of the evaluation process. It was observed that although the product evaluators constantly referred to the evaluation guidelines and standards to accomplish their tasks, they often sought clarity and advice from supervisors on the aspects of the evaluation guidelines that are not explicitly related

to the product under review. Also, varying patterns of action across hierarchical levels were observed. The dynamics of role status were also in play: thus, each regulatory officer recognised their boundaries of action. Some of the evaluators refrained from exercising the slightest discretion, as they referred every single challenge to supervisors. This phenomenon was predominantly exhibited by those who had fewer than five years of experience at the FDA. It was also inferred from informal discussions that this was a cultural phenomenon, as the context in which the evaluations were conducted recognizes the need to practice "covering their backs" to avoid threats to their job security. Also, the Covid-19 safety guidelines had led to work schedules being restructured to accommodate those working from home. Thus, the regulatory officers were working on what they referred to as a rotational system where each staff member had an alternating five-day work shift at the FDA premises and five-day shift working from home. Here, it was observed that general evaluation, such as labelling and advertisement, could be completed from home. However, since laboratory evaluations were impossible to conduct from their homes, analysts would have to complete almost double the workload before spending time off work. Nonetheless, this also meant that the analysts at home were on standby to help whenever needed.

Another important setting where observational data was gathered was the FDA's evaluation meetings and training sections. Two of such engagements were especially noteworthy. The first was an advertisement meeting where head of units met to deliberate on the various transcripts that had been recommended for approval (or rejection). This meeting revealed how the cognitive, social, or religious constructs became the locus of the debates leading to the final decisions. The second was a training session which was organized to introduce evaluators to a new software interface, called *Product Evaluation and Registration System* (PER), to harmonise and conduct evaluations with ease and speed across units. The regulatory officers' discussions on how to replicate and standardize the workflow on the software helped to clarify how changes in the cognitive routines of the FDA could be achieved. Also, during the observational period, informal conversations were witnessed and engaged in to develop a good rapport with product evaluators. This was very helpful, as such conversations provided

insights into evaluators' perceptions on how work routines had changed due to the Covid-19 pandemic and the alternatives they felt could have been implemented to improve their work. In addition, these conversations provided an understanding of how product evaluators perceived the work of the FDA and how hierarchical hazard (Nickerson & Zenger, 2004) in their organizing routines had become a bottleneck in the bid to initiate new routines or influence regulatory decisions. From the observations, a repertoire of action responses to the novel cases was identified. Follow-up questions after observing a practice which could pose a challenge in understanding the data were immediately asked. Another set of observations which provided important insights to the study was the laboratory technicians conducting analysis of products under review. It was the practice that each result should be written in a lab notebook, which was later reviewed and marked by their supervisors. Also, the use of improvised methods was observed to be dominant in the situated practices: hence, questions were asked in the interview section for clarification. These observations helped to identify how the improvisations in situated actions and deliberations serially combined to define the regulatory review process.

3.4.3 Ethnographic interviews

Semi-structured interviews were conducted with heads of divisions and units, evaluators at the Food Evaluation and Registration Division, analysts at the microbiological and physiochemical labs, and field evaluators at the Post-Market Surveillance Unit, which included officers from the Food Enforcement Unit, and Industry Support Unit (see Table 3.2 for a biographical sketch). The interviews were organized in batches. The first set of participants were those who worked at the Food Evaluation and Registration Department of the FDA. They were responsible for evaluating the products' labelling and packaging, requesting laboratory testing, providing recommendations for approval or otherwise, and writing response letters to clients. The second set of participants comprised the Food Microbiological Lab technicians, who were responsible for testing the microbial status of the products. The third were the Food Physiological Lab technicians, who tested the physical constituents of the products. The fourth group was a combination of the post-market surveillance and the enforcement and industry support unit, which had different operational units but common objectives: to ensure and

enforce continued adherence to regulatory standards. As the market surveillance unit was responsible for ensuring that products that were commercialised were registered, the enforcement unit served to ensure that producers adhered to safe food manufacturing and safety protocols. The multiple informants were significant in reducing informant bias and added complementary perspectives to the analysis (Rerup & Feldman, 2011).

The interviews were conducted while adhering to strict Covid-19 safety protocols. This included sanitizing the interview area, wearing of face coverings, and ensuring that a safe distance was maintained between the interviewer and participants. In addition, the participants were required to sanitize their hands, before and after the interview, with alcohol-based sanitiser, which was made available at the interviews. The ethnographic interviews were designed to be cancelled or postponed if a participant or the interviewer were to show symptoms or test positive for Covid-19. Although this information was made available to the participants prior to their accepting and attending the interview sessions, it is important to reiterate to ensure that they had independently made a firm decision to participate. At the start of each interview, the participants were informed that their voices would be digitally recorded on a mobile phone device. This was followed by confidentiality assurances that the information would be provided in confidence and that no information would be disclosed in public. They were also assured that all the original recordings would be destroyed on completion of transcription and that the data analysis would be anonymous, as no names would be used in the data analysis and all data were to be aggregated. Accordingly, the digital recordings were transcribed verbatim within 24 hours after each interview, and the participants were accorded pseudonyms to guarantee their anonymity. Table 3.2 presents a biographical sketch of the interview participants with the pseudonyms reflecting their gender. Each interview lasted between thirty and ninety minutes, and the audio recordings were played more than once to ensure that accurate details were captured. Ambiguities were rectified through informal conversations with the participants on the phone or at the office on the subsequent day. The adoption of this strategy was effective, as participants were either working from home in the subsequent days or would not be willing to undertake another interview for

the purpose of clarifying lost details. This ensured reliability of the transcribed data, as it provided accurate depictions of the interviews. The transcription of the 31 interviews generated 317 double-spaced pages of ethnographic interview data.

The interview questions were categorised into five main sections to extract direct responses to the research questions driving this empirical study. The first section sought to garner information on the participants' job role and description, as well as the number of years they had worked at the FDA. The second section aimed to identify each participant's knowledge and understanding of the codified process of the FDA and their role. For instance, some questions were framed as: "*Can you tell me about procedure for receiving and analysing products?", "What is your role in the product evaluation process?",* and *"Can you tell me the standard/minimum criteria a product must meet to be recommended for market authorisation?".* In addition, this set of questions provided insights into how the evaluation process was organized and how they coordinated with other divisions and units to accomplish their work. Following this, a third set of questions was asked to gather insights on the noncognitive routines of the FDA and experiences of participants. The questions were geared toward gathering insights into the work culture of the participants through their narrative accounts of their experiences as product evaluators and technicians. Examples of questions asked here include "*What are the specific tasks you perform in the product evaluation process*?", "*Can you describe a situation where personal/religious beliefs appeared to influence your/others' decisions?",* and *"Can you tell me about your personal experience where social concern/pressure sought to influence the speed of the review process, and how did you respond? How often does this occur?".*

The penultimate section attempted to identify the organizing routines that enable or impede the noncognitive routines in the review process. Here, the participants were asked if they were allowed to exercise discretion, when they were allowed to use such discretion, the extent to which they exercised this power, and to describe practical situations where they had to, or were allowed to exercise discretion. The section also attempted to identify whether cultural or religious belief influence their

decisions. The final section provided a set of questions that helped to gather data on how and when the participants' tacit knowledge found its way into the formal evaluation processes and their recommendations of potential ways to improve the evaluation framework at the FDA. Questions typical of this section included but were not limited to the following: *"Per your experience, can you tell me how the review process has over the years responded to new technologies or manufacturing processes?"*, *"How would you describe the pace at which the review process is changing to match with changes in technologies?"*, and *"What would you do differently if you had the power to reject or approve products?"*. There were, however, other questions that were derivatives of the participants' responses to the interview questions, and which were in the form of improvised follow-up questions. Also, the practical instances and examples participants cited were based on their experiences in the review of alcoholic beverages. Adopting *think-aloud* protocols (Baldacchino et al., 2022), the participants were asked to reflect on their situated practices and suggest potential changes, or envision new forms of evaluation routines, in order to understand their intuitive navigation of the socio-cognitively bounded performances. As the participants spoke openly in response to the questions, most of the sealed-away knowledge and understanding that remained difficult to codify was deciphered.

Against this background, the interviews were designed to generate insights on how the evaluators understood their tasks and responsibilities in relation to the organizing routines of the various units and departments, and how coordination of routines within and between units, divisions and departments was facilitated. From these interviews, specific routines were identified by the participants as being central to the work of the FDA. This included the receipt and processing of an application, selecting product evaluators, running laboratory testing, discussions and approval of products, post-market surveillance, and enforcement of regulatory standards. Each of these processes had a series of embedded routines constituting the everyday situated practices at the FDA. Therefore, the interviews helped to fill in gaps in the observational and documentary data. Also, by asking participants to report on how the pandemic had impacted or influenced evaluation routines and organizing, the interviews provided an overview of how the FDA routines had been jolted. More so,

the interviews were useful in extracting and understanding the tacit knowledge, social concerns, religious or moral issues and organizing routines that cumulatively influenced and shaped their work. The participants expressed how their subjective experiences in the evaluation routines could inform change and improve the regulatory review framework of the FDA.

Table 3.2 Biographical sketch of informants

#	Division/ Unit*	Name	Gender	Qualification	Position/Role	Years spent in Division	Years at FDA
1	Food Evaluation and Registration	John	Male	MSc Food Legislation	Regulatory Supervisor	10	21
2		Mike	Male	MSc Food Safety	Regulatory Supervisor	15	16
3		Lucy	Female	MSc Nutrition	Regulatory Supervisor	5	22
4		Nora	Female	MSc Food Safety	Regulatory Supervisor	9	14
5		Mary	Female	BSc Nutrition	Regulatory officer	3	3
6		Mina	Female	MSc Food Quality	Regulatory Officer	14	14
7		Dave	Male	BSc Biochemistry	Regulatory Officer	3	3
8		Pat	Female	MSc Nutrition	Regulatory Officer	3	11
9		Zoe	Female	MSc Food Science	Regulatory Officer	3	13
10		Kate	Female	BSc Food and Nutrition	Regulatory Officer	3	3
11		Joan	Female	BSc Nutrition	Regulatory Officer	2	2
12		Mel	Female	MSc Nutrition	Regulatory Officer	8	8
13		Dan	Male	BSc	Regulatory Officer	2	2
14		Tom	Male	BSc Biochemistry	Regulatory Officer	2	2
15		Billy	Male	BSc	Regulatory Officer	8	12
16	Physiochemical Laboratory	Jane	Female	MSc	Laboratory Supervisor	19	19
17		Fred	Male	BSc Chemistry	Laboratory Analyst	9	11
18		Matt	Male	BSc	Laboratory Analyst	3	3
19		Dirk	Male	PhD Food Science	Laboratory Analyst	12	12

20	Enforcement, Market Surveillance and Support Unit	Kim	Female	MSc	Regulatory Supervisor	5	14
21		Gabi	Female	PhD	Regulatory Supervisor	6	23
22		Tina	Female	BSc	Regulatory Supervisor	6	6
23		Eric	Male	PhD	Regulatory Supervisor	7	7
24		Eve	Female	MSc	Field Officer	6	14
25		Ana	Female	MSc Food Science	Field Officer	6	11
26		Ben	Male	BSc	Field Officer	3	3
27	Microbiology Laboratory	Rose	Female	MSc	Laboratory Supervisor	19	19
28		Shad	Male	MSc Public Health	Laboratory Analyst	6	6
29		Josh	Male	BSc	Laboratory Analyst	7	7
30		Sam	Male	MSc	Laboratory Analyst	5	5
31		Tami	Female	BSc Laboratory Tech	Laboratory Analyst	1	1

3.5 Data analysis and coding

The data analysis followed an iterative approach, moving between data and existing theoretical concepts to progressively construct theory from the data (Mantere & Ketokivi, 2013). Although qualitative analysis software, such as NVivo, could have been used to assist in the analysis (Wright et al., 2021), the analytical process was carried out manually to avoid the tendency of failing to pick up on nuances of expression and contextual cues. In this vein, the triangulation of the multiple data sources required that a systematic protocol for analysing the data should be established (Ravasi & Schultz, 2006). As such, the initial focus of the analysis was set on the documentary data, specifically on the standard operating procedures (SOPs) and other evaluation guidelines of the FDA. These material artefacts, which provided a representation of the FDA's cognitive routines, served as ideal loci for identifying, dichotomising and abstracting understandings that are sealed away in the noncognitive routines of the FDA. These artefactual materials remained important in theorising change in organizational routines because they were more stable and visible, which in turn allowed them to act as reference points against which variations occurring to performances could be more easily detected (D'Adderio, 2008). Following this, the analysis relied extensively on the observational data which captured the day-to-day practices of the FDA staff receiving new product applications, through the evaluation process and to the final regulatory decisions. It was, however, critically important that the analysis here was grounded in the conceptualisation that the routines that were being observed had spatial, dynamic, temporal, and relational features, and that they represented the outcome of a complex web of performative linkages between tools/materials, competences and meanings that give shape to the performance of the product evaluation routines (Schatzki, 2001; Shove et al., 2012). Moreover, the core characteristic of routines as rooted in local order and therefore accommodating the complexities of social context was crucially important (Feldman & Pentland, 2003).

In this regard, the context specificity of routines in historical, local, and relational forms assumed primacy in the analysis due to the constellation of socio-organizational and cultural factors that enable or impeded their existence in organizational reality (Becker, 2004). Thus, progressing with

this understanding helped in analysing the observational data to theorise the mechanism for change and adaptation of the regulatory review process, as the agential and situated practices of product evaluators was temporarily unfolding in the social-cultural space. Finally, on the interview data, the locus of the analysis was specifically drawn to focus on the influences of socio-cultural constructs on the interpretive mindsets that are often obscured from the evaluator's consciousness, and the hierarchical and cognitive constraints that may trigger or halt change in the evaluation routines. Here, the participants' verbal accounts were relevant in confirming and clarifying the insights that were being generated from the observational and documentary data. Therefore, the approach at this stage was to find as much information as possible about the FDA as an organization, the role of its members in the form of evaluators and technicians, their descriptions of everyday situated practices, their personal experiences, and their dispositional and interpretative mindsets. In this regard, although the data analysis combined core information encoded in the documents, practical perspectives from observations, and interpretations of the interviews, the ethnographic interview data was extensively relied upon for analytical quotes and representative data to develop theoretical constructs for the study.

Against this background, it is important to note that the analytical process sought to provide an empirical response to the research questions by identifying and theorising how the concept of (non)cognitive routines comes to be labelled and identified in the established discourse on regulatory reviews. The analysis strove to provide empirical basis for conceptualising the regulatory review process as constituting both cognitive and noncognitive domains which interact to define the work of the FDA. Also, the analysis went on to address the concern on when and how the noncognitive routines leads to the identification of opportunities for innovation in the regulatory review process. In this regard, priority was rendered to analysing how the situated patterns of relational activities enacted by product reviewers may contribute to change and adaptation in the review process. Thus, the routines–practice perspective was given primacy in order to leverage the fundamental characteristic of routines as a generative system to better understand and unpack the mechanism through which the change in the regulatory evaluation framework may unfold. Furthermore, the analysis identified the organizing

routines that enabled and impeded the noncognitive routines in the regulatory review process. Here, the assumption was that although tacit knowledge becomes encoded into the cognitive routines (Levitt & March, 1988), there is a series of hierarchical hazards, allocated controls, cognitive and material limitations, and structural and cultural loops that may constrain or facilitate the modes of conversion or absorption of the performative knowledge that underlines the organizing routines of the FDA.

It is therefore worth emphasizing that in the processes described here, the level of analysis runs from the individual to the organizational level, and the goal of analysis is to develop a theoretical account of the mechanism through which the evolution of regulatory review processes is triggered, given the inertial qualities of the regulatory evaluation routines. More importantly, the analytical process was aimed at making credible theoretical inferences to create new insights that could connect the empirical data with existing theoretical concepts in the literature (Jarzabkowski et al., 2019). Thus, in light of the insights from the extant literature, the interpretations of the data were continually questioned, constantly comparing initial and emerging themes in order to ensure clarity of interpretation and to provide a credible and persuasive explanation of the routines that were being studied (Zbaracki & Bergen, 2010). In this regard, following established practices for inductive theory-building (Kim, 2021), the data was systematically coded to develop a data structure (see Figure 3.1) that contained codes and themes, which were increasingly consolidated, abstracted, and theoretically aggregated (Gioia et al., 2013). This process for triangulating and coding the data proceeded through three overlapping phases. It is, however, worth noting that although the coding strategy is presented in sequential phases, it was an iterative and dynamic venture which involved travelling back and forth between data, emerging themes, and theory (Jarzabkowski et al., 2019).

3.5.1 Phase 1: Building first-order concepts

A line-by-line coding of the dataset was initiated (Chown, 2021) by engaging in a tedious but inevitable phase of intensive and fine-grained reading of the entire dataset (including observation notes, documents, and transcribed interviews). As the reading progressed, key phrases and statements which

seemed to define the organizing routines that were enacted to accomplish the product evaluation process were identified. Other strong statements which suggested ways of triggering change in routines, as well as the cultural and structural loops which seemed to facilitate but also constrain and control change, were identified. The consistencies and connections between emerging codes from the triangulated dataset were particularly striking; hence, they led to the identification of the initial set of open codes from the dataset (Strauss & Corbin, 1997). This led to the creation of a spreadsheet to zoom in on these explicit statements, concepts, actions, and comments that conveyed core information on the evaluation routines (Feldman, 2000). Iteratively zooming out to identify patterns and linkages between them (Kremser & Blagoev, 2021), the open codes were sorted, consolidated, and gradually collapsed into sets of first-order concepts (Giudici et al., 2018). The 'find' tool in Microsoft Word was useful in identifying additional quotes that fitted into each subcategory. In this regard, the emergent concepts were continually refined to reflect a comprehensive description of the language used by informants (Clark et al., 2010).

To illustrate, open codes such as "Oh, sometimes I can easily see that this product isn't going to get approval, but I can't just recommend deferral or rejection – I still have to take it to the lab for them to verify" (Lucy) and "Our work is guided by standards and guidelines, so we cannot make a decision without stating which guideline informed that decision" (John) were grouped together under the concept "Acknowledging routine boundaries" (see Figure 3.1c). Also, open ended codes such as "We always discuss issues amongst ourselves and other department on how to go about new products" (Billy) and "Sometimes I ask colleagues with more experience to help me" (Tom) were subsumed into "Providing spaces for ideas sharing" (see Figure 3.1a). Statements about how the evaluation routines have changed over the years, and those about how and why evaluators need to wait for reports from other regulatory officers before they could commence their work were labelled "Contrasting old and new processes" and "Co-relying on performance", respectively (see Figures 3.1a and 3.1c). Critical attention was, however, rendered to ensuring that this set of first-order concepts was as proximate as possible to the empirical dynamics of the routines under study (Rerup & Feldman, 2011), and that they

were grounded in the experiences and reality of the day-to-day activities of the FDA's evaluators (Cardador et al., 2021). This was important in order to make accurate sense of the evaluation routines and how the cumulative knowledge of evaluators in their everyday practices influenced and informed the adaptation of the regulatory review process or ensured stability.

3.5.2 Phase 2: Consolidating first-order concepts into second-order theoretical categories

The second phase involved engaging in axial coding of the dataset by piecing together the first-order concepts to develop a set of second-order categories (Locke, 2001). Here, the coding progressed towards a more theory-driven explanation of the dataset (Gioia et al., 2013). In this vein, the data was approached from a theoretical perspective, constantly juxtaposing the emerging themes with insights from the literature in order to move beyond descriptive statements about the data (Gioia et al., 2010). At this point, taking a step back from the initial themes to reflect on the dataset and to scan for specific information helped to accurately abstract and bundle the first-order concepts (Farny et al., 2019). A comment section was therefore created in the data spreadsheet where conceptual connections between the first-order concepts were highlighted (Massa & O'Mahony, 2021; Ravasi and Schultz, 2006). This was done to ensure that the assumptions of the emerging theory were consistent, and to further enhance interpretation of the theoretical categories (Giudici et al., 2018). Insights from the literature on routine dynamics (Howard-Grenville & Lodge, 2021; Pentland et al., 2012) and practice theory (Shove et al., 2012) provided conceptual references that helped to continuously refine, clarify, and strengthen the theoretical categories that were being developed. Further conceptualising these categories to create a complete picture of the theoretical constructs from the dataset, terminologies were designed to qualify the second-order categories (de Rond et al., 2021; Rerup and Feldman, 2011). To illustrate, it was identified that first-order concepts such as "Contrasting old and new processes" and "Restructuring operations" suggested that evaluation routines of the FDA evolve over time: thus, they were bundled into the theoretical category "Decaying patterns of action" (see Figure 3.1a). Also, the concepts "Relying on scant information" and "Making do with what is available" suggested that the FDA relied on an imperfect system yet was able to effectively conduct the product evaluations; hence, they were

integrated and labelled as "Cultural holes and replication". All other theoretical categories, such as "Frequency conceives mastery" and "Jolts and exogenous shock", were formed using the same consolidating process, yielding twelve higher-level second-order categories (see Figures 3.1a, 3.1b and 3.1c).

3.5.3 Phase 3: Setting out aggregated theoretical dimensions

This third and final phase involved identifying how the data fit together by exploring the relationships between the abstracted second-order categories. Specifically looking for underlying theoretical dimensions in the second-order categories, critical focus was rendered to identifying and understanding fit or misfit between the theoretical categories in order to provide a coherent description of the relationships between them (Cardador et al., 2021; Zuzul, 2019). Further brainstorming on how these categories may relate to existing theory on organizational routines led to the construction of an aggregated theoretical dimension (Boghossian & David, 2021; Locke, 2001). This was done in order to present an overarching theoretical understanding of how the data is linked together to explicate how aspects of routines, socio-cultural and dispositional mindsets, as well as the inertial qualities of regulatory agencies, are intertwined in the characterisation of change in regulatory evaluation routines. In keeping with the inductive theory-building process, effort was made to re-examine the data to ensure that the aggregated themes best summarized the empirical insights from the data to present a coherent theory (Gioia et al., 2013). The aggregate dimensions were therefore designed based on the theoretical insights to provide a well-structured response to address the overriding research questions. In this vein, all themes that captured aspects of evaluation routines which shaped how tasks were accomplished were collectively labelled "Logics of action". Also, theoretical categories that delineated how and when context specificity provides a lead for changes in the evaluation routines were labelled "Thriving on chaos". Furthermore, in capturing the organizing routines that underlie the inertial qualities of the FDA, the theoretical categories were subsumed under "Agility in evaluation routines". Figure 3.1 is a graphical representation of the data structure.

Figure 3.1: Data Structure

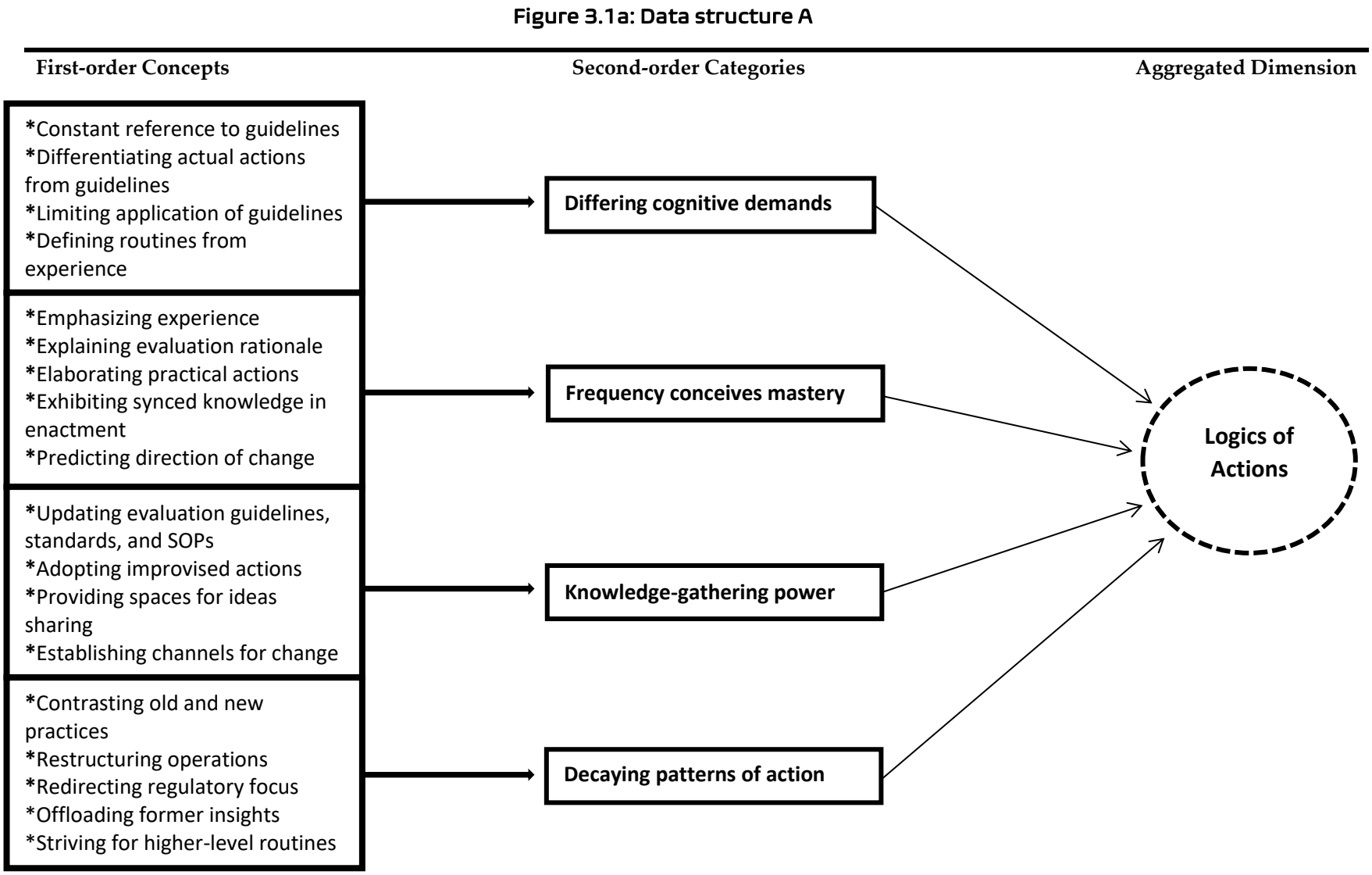


Figure 3.1 continued...

Figure 3.1b: Data structure B

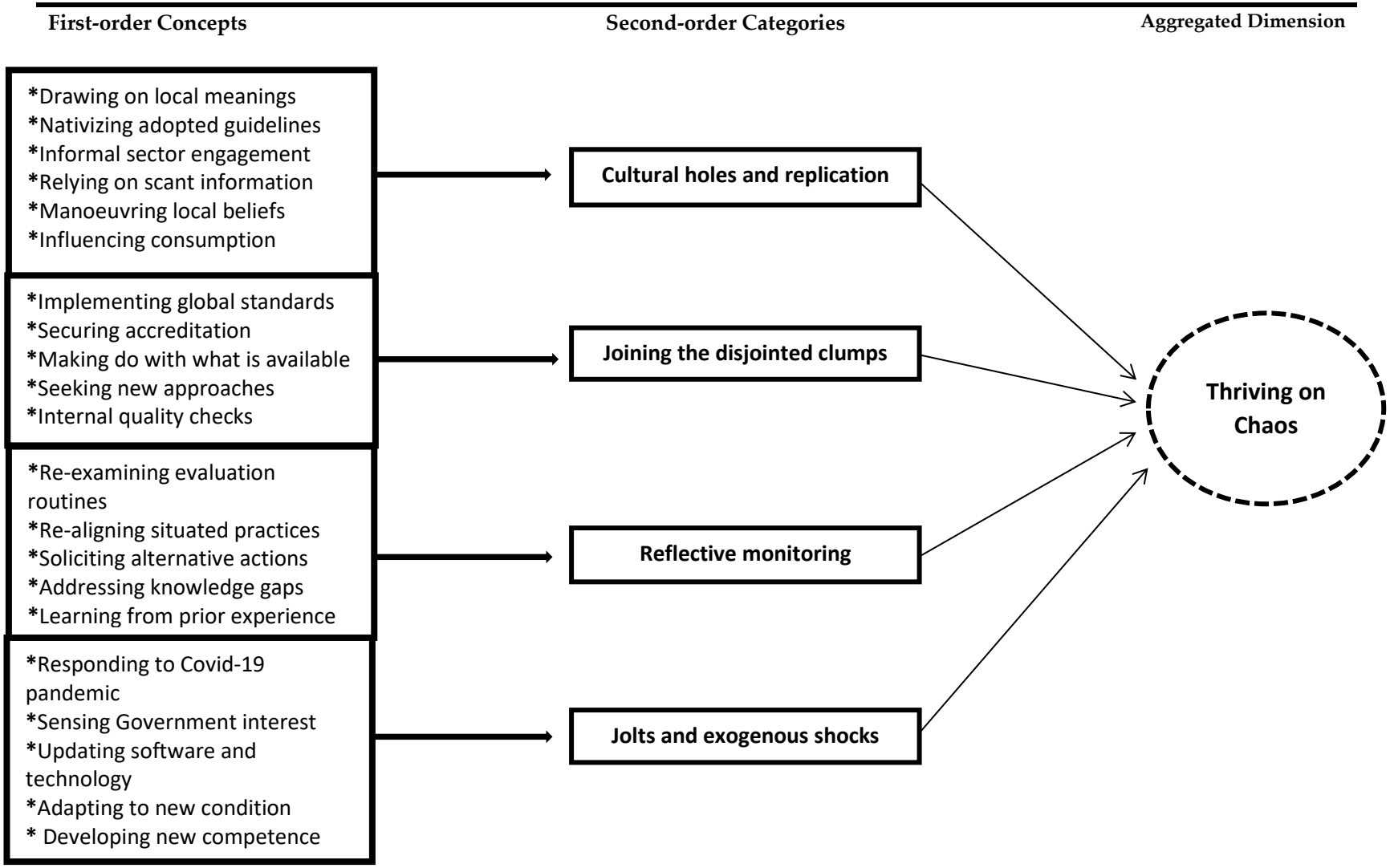
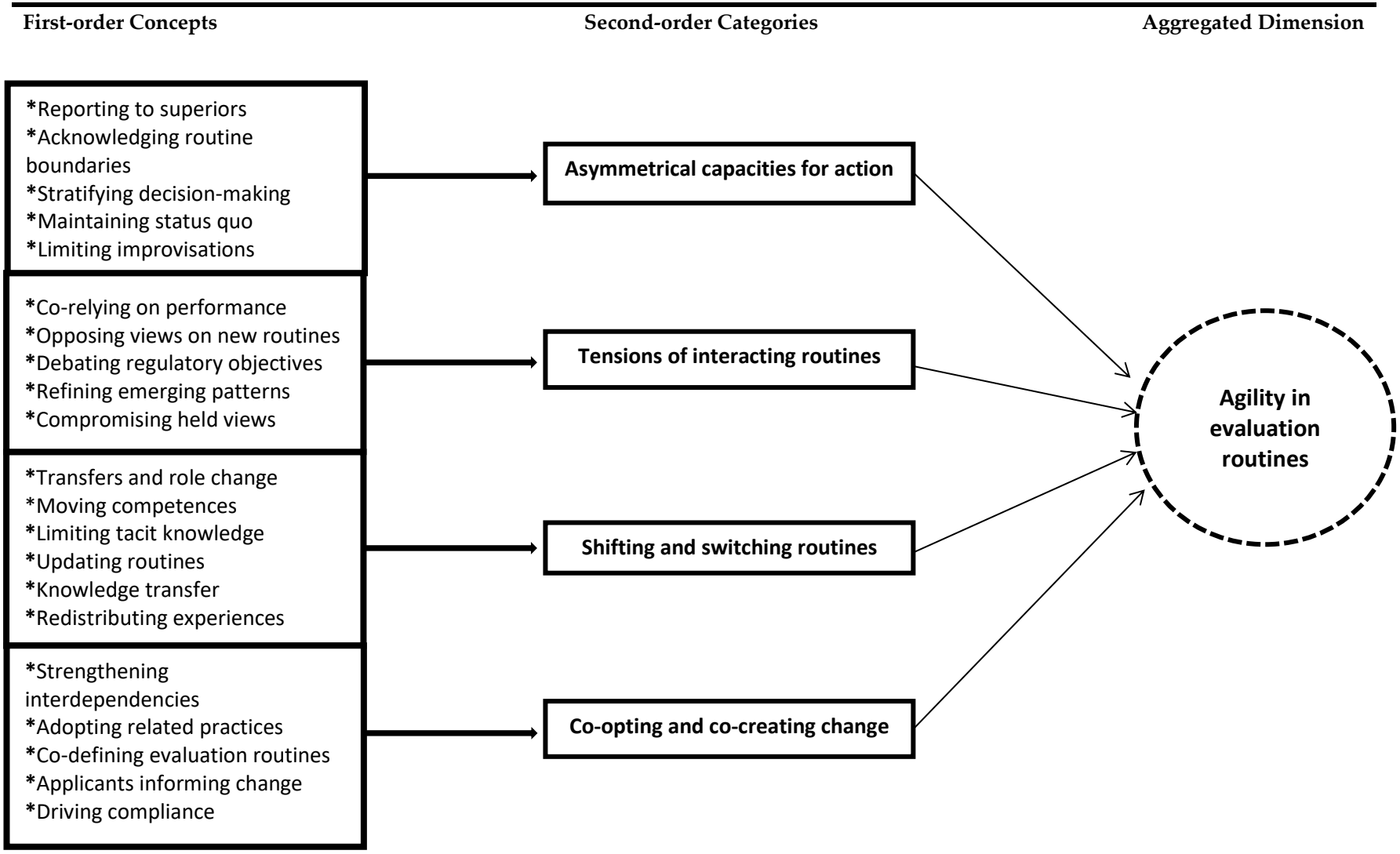


Figure 3.1 continued...

Figure 3.1c: Data structure C



3.5.4 Ensuring validity and accuracy

Throughout the analytical process, efforts were made to ensure the validity and accuracy of the theorising of the organizing routines that constitute the FDA's regulatory review process for NPIs. Specifically, keen focus was drawn on a critical construction of the socio-organizational reality in organizing by turning back on the analysis and taking account of its interpretive rigour (Hibbert et al., 2010). Thus, the situated nature of the knowledge production as defined within institutional dynamics, socio-political embeddedness, and the constructive effect of language, which cumulatively informed the theorising, was reengaged by exercising reflexivity (Alvesson et al., 2008; Whiteman & Cooper, 2016). In this regard, the ontological assumptions and epistemological specifications through which the theoretical constructions emerged from the data were systematically challenged to reveal inherent (in)stability of the realities and knowledge that was being constructed (Cunliffe, 2003). In doing so, concerns about limits of accuracy were raised, leading to the casting of doubt on the precision of the initial interpretations (Alvesson et al., 2008). This helped to identify irregularities and find fits or misfits between the data and the emergent theory. Following this, a more pragmatic approach was taken by presenting the theoretical explanations to an audience of academics and research students at a series of webinars where several rounds of critical feedback were received. These intellectual critiques helped in refining the provisional knowledge and the understandings being developed thereof (Alvesson et al., 2008). The interpretations from the data were then shared with key informants for clarification, which also served as a form of respondent validation (Locke & Velamuri, 2009). Altogether, the iterative execution of these techniques in the analytical process led to the final themes reported in the study.

3.6 Methodological limitations

Regardless of methodological rigour demonstrated so far, there remain some limitations that are worth reflecting upon. First, as a characteristic of qualitative research, the subjectiveness of the methodological approach implies that the world as we know it is the (partial) result of our own social constructions, rather than that which is discovered (Alvesson et al., 2008; Whiteman & Cooper, 2016). As such, the

underlying assumption of the methods adopted here inherently demonstrates the fact that personal intuition and creativity were instrumental in the theory development (Sutton & Callahan, 1987). Therefore, there is a potential that claims and assumptions that undergirded efforts to capture the complex socio-organizational dynamics at the FDA were narrowly construed within a personal social experience of the research context. Furthermore, it would be rather presumptuous to ignore the influences of situated cultural, historical, and linguistic traditions that permeate this approach, as well as the single organizational context which in turn may limit the external validity of the theoretical explications presented. Also, given the focus on the regulatory review process for a single product, there is a possibility of failing to account for some unique practices that may generate distinct insights on situated practices that could determine the dynamics of the regulatory evaluation routines at the FDA.

3.7 Chapter summary and conclusion

This chapter has provided a vivid account of the endeavour through the empirical wilds to present a valid characterisation of the routines–practice approach to understanding the dynamics of (non)cognitive regulatory evaluation routines. The chapter has laid the foundational argument for how the uniqueness of context – defined within socio-cultural practices and the dispositional realm of agential emotions, cognitive and corporeal world – comes to serve as a fruitful avenue for developing deeper insights into the contents and typology of situated actions that underlie the bundles of routines which constitute regulatory review processes. In this vein, the context relevance as well as the distinct nature of the product as a counterplay to the conventional focus in the extant literature was established. Thus, following a qualitative research design, three empirical data sources on the FDA evaluation routines were accessed and triangulated. Based on rigorous analysis of the observational and documentary data and the meticulous interpretation of the verbal accounts of product evaluators at the FDA on their patterns of evaluation in the NPI review process, how the generative quality of the FDA's

evaluation processes is implicated in a dynamic interplay between the (non)cognitive routines of the regulatory agency, has been defined for a fine-grained explication in the next chapter.

CHAPTER FOUR

Unpacking the logics of action: (Non)cognitive routines in the regulatory review process

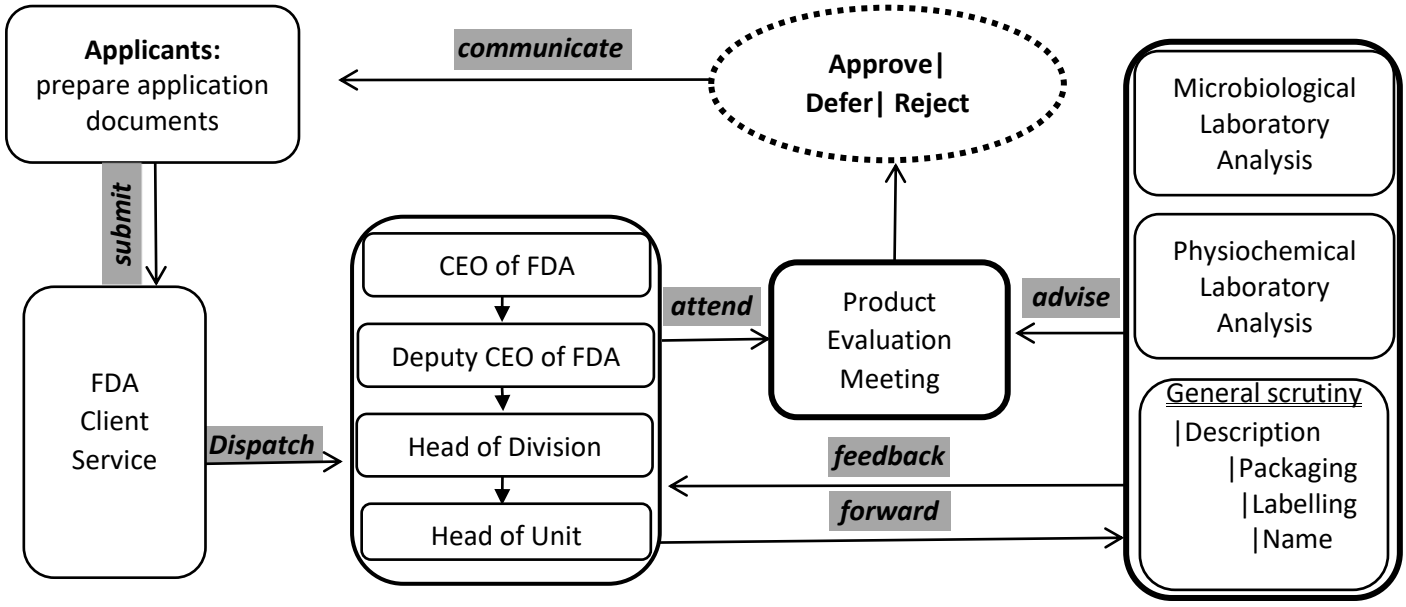
This chapter explores the conceptualisation of routines as a cognitive affair. Specifically, it submits an empirical characterisation of how the construct of (non)cognitive routines comes to be identified and labelled in the discourse of regulatory reviews. In doing this, the chapter first provides an overview of the repetitive patterns of action that define the process of evaluating products at the FDA. Following this, the practical underpinnings of the organizing routines that constitute the regulatory review process are unpacked. While attempting to unpeel the espoused routines of the FDA, the chapter provides an explication of the logics of action that define the evaluation routines, which are delineated along the following lines of attention: *differing cognitive demands*, *frequency conceives mastery*, *knowledge-gathering power*, and *decaying patterns of action*. Finally, a summary of the findings is presented to conclude the chapter.

4.1 The regulatory review process

The traditional definition of routine as "repetitive, recognizable patterns of interdependent action" (Feldman & Pentland, 2003, p. 95) suggests that an element of repetition is required in order to identify an action as routine (Parmigiani & Howard-Grenville, 2011). From the data, this sort of repetitive pattern, which survives on the substrate of interdependent activities of regulatory officers and laboratory analysts in the empirical setting, was identified. The espoused process that defines the organizing routines enacted to accomplish the task of product evaluation, which were also weaved into a web of interdependent activities from start to finish, was systematically cast as follows. First, the applicant or client would complete and submit an application for product registration, along with other documents including a business registration certificate and a certificate of analysis (COA) for the product(s), at the FDA client service (CS) desk. In addition, product samples are received at the CS desk

and recorded in a Sample Room Book to ensure that the samples match the right applicant and that the numbers of the samples tally. The samples are divided into four categories, namely the evaluator's sample, the laboratory sample, the registration sample, and the responses. Following this, the details on the application documents, including the applicant's name and location, product description, name of manufacturer, name and address of distributor/agent and country of origin, were checked and verified for conformity with the requirement for product registration. An application reference number is then generated and indicated on the application documents, endorsed, and returned to the client. The client is then directed to make a payment (ranging between 150 and 900 Ghana cedis, or approximately £19 and £113) at a cash desk managed by an independent financial institution. Following this, the details on the application documents were keyed into a *product functionality software system* after proof of payment has been shown to the client service officer. The application checklist is then verified and signed by both client and officer. Following this the application documents are forwarded to the CEO or their representative for endorsement. These hard copies of the documents are however delivered to the CEO's office through a dispatch office. The product samples are also handed over to the sample custodian. At this stage, the CEO, after minuting the application documents to confirm receipt, forwards them to the Deputy CEO (DCEO).

Figure 4.1: The espoused sequence of product evaluation



A confirmation text message is then sent to the applicant to acknowledge receipt and notify them of the start of the evaluation process. The DCEO then submits the documents to the appropriate division. Based on the product category (e.g., imported or locally manufactured), the head of the division, after receiving the documents, hands over the application details to a Head of Unit (HOU) for the specific product category. At this stage, preliminary evaluations of the product(s) are conducted by the HOU by reviewing the application document to ensure that it conforms to the registration requirements before assigning it to an evaluator. This quote from a regulatory officer mirrors this process as was observed and prescribed in the SOPs and guidelines:

> First, it starts with the client service, who receive the application documents and check if they meet the requirements according to the SOPs, the evaluation requirements, standards, guidelines, the labelling requirements, and if they provided certificates of analysis. Those are made available to the client service officers…They go through it to ensure that everything is okay and then push it over to the departments through the dispatch office. Once everything has been checked and signed by the CEO, the document is then forwarded to our desk for the preliminary review, where we look at what the applicant says the product does and whether the documents are intact. We also ensure that whatever information they put on the forms were correct. After this, we assign the product to a specific evaluator, who then conducts the actual analysis. That is the actual labelling, content, and documentation review. [Mina]

At this stage, the regulatory officer may collate documents, such as the licensing of storage facility and manufacturing location issued by the Food Enforcement Department, the descriptive form containing the product name, contents, net weight, expiry or best before dates, etc. The initial analysis of the product then starts with the labelling, packaging, naming, and description of the product, among others. Samples that are due for lab analysis are prepared by completing a lab request form and submitting to the lab with approval of the Head of Division (HoD). Here, both microbiological and physiochemical lab analysis are conducted, and the reports were returned to the evaluator. A regulatory officer also described this in detail:

> First, we look at the application documents to make sure all the requirements are met. Important documents such as business registration certification and a letter addressed to the CEO and payment receipt for the registration should be included. And of course, the application form ought to be added to the documents. After ensuring all these are presented and filled out perfectly, we start the evaluation from the label. We look out for whether it meets the general guidelines. There are some basic requirements that should be visible, for example the product name, there should be a list of ingredients, the best before date, the manufacturing date, the name of the manufacturer of the product, and then the exact location and address of the company or applicant. We also look out for any claims that may be on the label. [Zoe]

She continued:

> When this aspect is done, we crosscheck with the documentation that was presented to see if it matches or if there are any disparities that we can raise concerns or ask the client to clarify. Sometimes, based on their claims, we check if documentations we submitted to substantiate those claims. From there, we write our comments and then move on to the COA, that is the certificate of analysis, which has to do with the composition of the product. We look at the biological and the physiochemical aspects of the product. There are standards that we use. The standards are not for every single product, but for product category. Sometimes we request for lab testing to confirm the parameters presented. When that's done, then we look at the COA that is submitted and compare it with the results from our lab. Per the results, the product could either be marked as conforming or not. Based on that, we write recommendation as evaluator or first line officers. [Zoe]

The situated activities at the laboratory are therefore triggered by the FERD regulatory officers who conduct the preliminary evaluations. Also, sometimes the laboratory activities were initiated in response to a notice from either the post-market surveillance unit, who may find a noncompliant product on the market, or from the police services, who may be investigating cases of food poisoning. An analyst at the microbiological laboratory also described these situated routines, saying:

> Our work starts when the Quality Assessment officer [(QA)] receives a request for laboratory analysis. This is after all the procedures from client service to the FERD are

complete. And sometimes it is either a complaint sample from a consumer through the police service or suspected product samples from the post-market surveillance unit. The request usually comes in the form of a memo stating exactly what they want us to test. The QA then deliberates on the parameters and methods to use with the department requesting the test to ensure that the laboratory has the capacity to run the test or not. Details of the product are then recorded on a Laboratory Information Management System (LIMS). The Head of Laboratory (HoL) will then receive the request, including the samples. Using the same system, she will assign the product to an analyst. Upon receiving the samples, we record the details of the product in our books and then conduct the requested test. We record the results, indicating whether the sample conformed with parameters or not, and then forward it to our head who would then verify our result. A laboratory test report will then be written and signed by the QA, HoL and the analyst who conducted the test. The signed report is then sent to the requesting department to take appropriate regulatory action. [Sam]

This process for initiating routines at the microbiological laboratory is replicated at the physicochemical laboratory of the FDA. An analyst at the physiochemical laboratory also described their situated activities, saying:

> What we do here is the physical and chemical analysis of food products, including drinks. The sample we analyse could come from the FERD, PMS, or from the regional offices. The samples are submitted through QA section of the laboratory service department, or centre for laboratory services department. The samples are submitted with a register or list containing a sample description and code given by the QA. The QA representative here then gives the sample register to the head of the laboratory or [their] assistant. The details of the sample are recorded on our computer system to generate another sample register and code for the laboratory. After this, the samples are distributed to the officers or the analysts. The analysts also have logbooks or notebooks where we input the details of the sample, such as sample name, manufacturer, manufacturing date, expiry date, and the batch number, before we go on to run the test. We then write the analysis requested and the method we are using to test the sample. [Matt]

He further elaborated:

> After running the test, we write our conclusion as per the results by stating whether the sample met the requirement or not: that is, whether it was compliant or not compliant. After this, we take our test record book to the supervisor who assigned the sample to us for review; he or she reviews the work and then will proceed to type the COA or certificates of analysis. It then goes to the QA to sign; then the head of department and the analyst will also sign. The COA then goes to the source that the request came from, for them to make regulatory decisions based on the COA. [Matt]

The regulatory officer, after receiving the laboratory test results, would make a recommendation for approval, deferral, or rejection, which then informs the deliberations at the final product evaluation meeting. At the product evaluation meeting, where HoDs and the CEO as well as Head of Legal affairs are present, discussions are held and the final decision on the reviewed product are made. The varying professional insights and contributions leading to the final decision ensures that the decisions held at the meeting are robust and unlikely to be contested. At the deliberation table, the reports attached to the recommendation of the evaluator are probed and discussed. In some cases, the meeting may be adjourned to allow time for further research and insights. After a decision had been reached, the department handling the focal product under review then writes a formal letter to inform the applicant of the decision and issue a certificate of registration and market authorisation if the decision was to accept the product. Otherwise, the applicant might be required to address concerns raised in a deferral decision and resubmit for evaluation or the product would be rejected. The following quote by a regulatory supervisor succinctly captures this:

> At the final meeting, there is a maximum 16-member committee from various departments, not just FERD. We have experts from the legal team, the communication team, drugs unit, cosmetics, the laboratories, and post-market surveillance. These experts meet to deliberate on the recommendations made by the evaluators. There are cases where we would approve a product or an advertisement and it goes to the meeting, some issues may come up here and there, and the final decision is a deferral. Or we can have a situation where we defer a product, it goes for the meeting, issues come up here and there, there's a consensus and the product is approved. Sometimes

> the meeting or a particular product has to be put on hold, and then, after further research has been done, a decision is made. [Mary]

The process then continues until the applicant received a regulatory response. In this feedback loop, a deferral decision would mean that the applicant was given time to address issues that were not of health risk and resubmit. A regulatory officer highlighted this, saying:

> Our recommendation after conducting the evaluations is approval, conditionally approved or deferral, and sometimes too we reject. Afterwards this recommendation goes to the final evaluation committee meeting, which has members from diverse educational backgrounds and expertise. They come together to sit and deliberate. They may affirm what we recommend or may also overturn the recommendation. But the point is that their decision is final, and it becomes the FDA's decision. The head of department will, based on the final decision, then write a letter to the clients. And for the letters we write to the client, they sometimes come back for clarity on the decision, especially when it is a deferral. It happens because sometimes there are certain statements they may not understand, and others that they may have to substantiate, make corrections, and then resubmit. [Mina]

Although the overall evaluation pattern through which a product needs to sift through for commercial authorisation (as summarised in Figure 4.1) culminates at the 'feedback to client' phase, the data further revealed that the regulatory evaluation was an ongoing process and thus required post-market surveillance activities. The situated activities that provided meaning to the regulatory framework were therefore accomplished through the complementary routines of other units and departments whose activities were triggered after the products were commercialised on the market. Thus, at this stage, the intention of the routine was to ensure continued compliance. A regulatory supervisor at the post-market surveillance unit and an officer from the enforcement unit explained the specific activities involved:

> For market surveillance, we have different process lines, and all of them take us out of the office. One of them is the retail outlets monitoring. When we say retail outlets, what we look at is everything that is being offered for sale, especially the pre-packaged foods. So, we visit the shops, supermarkets, and the traditional market settings that we

> have. We go into the big shops, the kiosks, and the tabletops that are in the retail market. For this particular activity, what we do is that we look for non-compliances, such as whether the sampled products are registered or not. [Kim]

Kim went on to provide further details on how the actual patterns of action were executed:

> We work with the food functionality system that food registration uses; we have access to it. So, on the field with our phone, we're able to know the registration status of all the products. Now whether it is registered or not, we are also looking at the potential damage. So, if you take a food, like let's say, a current product, and it is bloated, whether it is registered or not, you cannot allow that kind of product to remain on the shelf. Also, there are some products that you wouldn't be able to specifically know, just by visual inspection, whether they are good or bad: those ones are detained, and samples are taken to the lab for them to determine through testing. And then if it's okay we release it to the seller. We also look at the counterfeited products or fake products, so you now know the features of the products that we're dealing with. [Kim]

The regulatory officer at the food enforcement department added:

> Our role is the inspection of both foreign and local facilities. Basically, we ensure that we bring all the activities at the various manufacturing and storage facilities into compliance with FDA standards. We do the inspection and issue licenses to the firms, which they attach to their application for product registration and market authorisation forms. We also issue memos to the FERD to inform them on whether the product in review had been produced and/or stored under approved standards and conditions. But since the facilities need to be inspected even after they have gained approval to produce and sell, we continue to review and renew the licenses after annual inspection. [Eve]

As the informants shared their understanding of the routines involved in the product evaluation process, they underlined the cognitive underpinnings of the specific activities in the evaluation process. Their exposition of the routines, as stated in the evaluation guidelines, procedures, and standards, showed an understanding of the collectively organized cognitive systems that define the situated activities at the FDA (Hutchins, 2014). Also, their interpretations of the logics of action

revealed how the enactment of the routines in their situated practices has come to be rooted in elaborate cognitive skills that are sealed away in their tacit knowledge. Thus, the accounts of the informants signalled the interdependent and mutually enabling cognitive demands that interplayed in the successful accomplishment of the evaluation routines at the FDA. Fine details of this theoretical saturation are empirically explicated in the following sections.

4.2 Differing cognitive demands

The routines of the FDA can be represented as comprising several repetitive patterns of actions within the product evaluation process. However, given that "routines can be understood as cognitive regularities or cognitive patterns" (Becker, 2004, p. 645), it was observed that these patterns of action at the FDA were developed according to two complementary logics—*cognitive* and *noncognitive*. Here, the organized knowledge that defines the regulatory review framework and which serves as a guide for the modes of action at the FDA is identified as the cognitive routines of the FDA. These routines provide what Pentland and Feldman (2008, p. 242) describe as the "ideological structures that influence the patterns of action that participants create and recreate", and hence constitute "a set of possibilities from among which members accomplish specific sequences of action" (Pentland & Rueter, 1994, p. 486). They are recognizable patterns which capture both declarative and procedural knowledge of organizing (Becker, 2004; Miller et al., 2012), and translate the intents of the regulatory framework into the situated practices of evaluators (Gajendran et al., 2014). Therefore, the cognitive routines are conceived here as the knowledge structures of an organization that provide accurate explanations and expectations of tasks (Lazaric, 2021; Hodgkinson & Healey, 2008; Walsh, 1995); hence, they are themselves repetitive and identifiable patterns of action (Miner et al., 2008). At the FDA, these cognitive routines were extensively captured in artefactual representations such as the SOPs, Ghana Standard Authority (GSA) standards, Codex Alimentarius, and WHO guidelines. Such formal material representations provided the ideological structures underlying how the constellation of activities at the FDA are interwoven to provide the ordered processes for accomplishing product evaluations (Orlikowski, 2007; Shove et al.,

2012). In the enactment of the routines, these codified rule-like representations served as the point of reference to guide the evaluation process (Cohen et al., 1996; Pentland & Feldman, 2005). A regulatory supervisor, discussing how the artefactual representations were used, said:

> We have a general standard that we use to evaluate products, which we call GSA 955. These standards deal particularly with the safety of the product. So, we depend on the standards to make sure whatever product that we review falls within the parameters prescribed in the standards. Also, we rely on other standards, particularly international standards like those that are provided by the WHO, in situations where we cannot find a parameter or guideline in the Ghana standards for evaluating specific products. Another important international guide is the Codex Alimentarius standard, which provides guidelines for a wide range of products. [Nora]

A laboratory analyst also provided an account of how the regulatory standards and guidelines provided the logical framework underlying their situated activities:

> We are always guided by the regulatory standards and guidelines when we receive samples to analyse. For instance, the SOP clearly states the duration that a sample is supposed to be with the analyst, so, we try as much as possible to work within the given time frame. The SOP also requires that we input the date we received a sample from our supervisor, which is the day that sample arrived, including the sample name and code, manufacturer details, batch number, and the type of analysis requested, in our sample register. [Fred]

He further elaborated:

> In testing for a parameter, we look for a suitable metric that is within the GSA standards. We often rely on AOAC and the Mean-House metrics. The standards also provide the range that a parameter is supposed fall within in order to be regarded as conforming. If the sample falls out of the range, that means the sample has failed. Also, the guidelines suggest that if we are testing for two or more parameters and one parameter fails, the sample has failed. And in writing our report or COA, we quote the standard and its corresponding number. So, this is how the standards and guidelines are used in our work here. [Fred]

This articulation of the modes of executing the evaluation process reinforces the understanding that routines, by virtue of their abstraction of the patterns of action, account for the individual evaluator's action and provide the cognitive representation of what the regulatory agency is recognized for. The cognitive routine at the FDA was thus observed to be embedded in the espoused processes that represented the reproducible patterns of action in the organization. The agents in this context, drawing on the cognitive routines, were able to develop a shared understanding of the evaluation process and align their logics of action accordingly. As the responses suggest, the regulatory officers indicated that they extensively relied on this cognitive representation of the FDA. The response of a regulatory officer who conducted general evaluations was also typical:

> In evaluating a product, there are documents the evaluator should have at hand, as well as some important information they should have. According to the SOP, the evaluator must have the application form of the applicant. And then to guide the process, the evaluator should have the Li 1567 for the nutrition aspect, or the Li 1541 for the general labelling guidelines. Also, we need the standards that GSA has provided, and the certificate of analysis, what we call the COA. So, according to the guidelines, we look at the product label for the claims stated on the labels, for example health claims, Halal claims, acid claims, comparative claims, as well as nutrition information. So, generally these are some documents and information that guide how we do our work here. And I must add that it is important the evaluator has all these at hand before considering evaluating a product. Well, that is what I do. [Tom]

While non-deliberate actions and responses are embodied in the enactment of routines, the data revealed key insights which reinforce the argument that the expression of such implicit or tacit knowledge does not form part of the codified routines of the FDA. Thus, on some occasions, the substrate upon which the action patterns of the evaluation process were accomplished was built, not on the cognitive routines of the FDA, but from contingently driven and practically honed set of activities that the evaluators enacted in their situated practices. Here, the display of expertise in the enactment of routines was dependent on the acquired knowledge of the evaluator, which allowed them

to navigate limited variations in every repeated pattern. A regulatory officer, highlighting how this became evident in practice, said:

> We have a set of parameters that are our standards for evaluating the product. But sometimes we don't strictly go by those because things change. Practically, food evaluation is dynamic, so what works for a category of food or drinks might not work for another, as we always find new things coming up. So, you know, because the combination of ingredients in the products we receive here varies, we need to use both science and understanding, rather than just following the set procedures. So, even though we have those SOPs and standards, they are essentially guidelines for what we have to do, but sometimes we don't necessarily go by it and tick boxes. It is just to guide us as to what to look out for. [Mary]

In this regard, the cognitive demand for enacting the routines transitioned from those encoded in artefactual representations that defined the shared embodied knowledge or cognition of the FDA to that which was nurtured in the intuitive understanding of the existing routines. The FDA evaluators therefore relied on their acquired practical skills and intelligence, and 'ways of knowing' (Sarpong et al., 2018, p. 586), to coordinate their situated activities and adapt to the demands of the task. Another regulatory officer puts this in perspective:

> So personal opinions and understanding of the process here come into play once a product or category of products have proven to be safe over the years. This is why we have implemented what we call a risk-based analysis. So, if we have a product that has come in and given the history of the products, that we have consistently observed about the product, the review process becomes simple. So, for instance, let's say for the past five to ten years of studying a particular parameter for a particular product category that we evaluate have been consistently OK. Then the law of probability dictates that the product from that category is also highly likely to be as consistent as the rest of the products in that category. So, in such situation, on risk-based analysis, we can say with some appreciable degree of certainty that the product is safe and can be approved for the market. So, such decisions can be made without even the client submitting a particular range of tests for parameters. And so here we exercise some level of discretion, but it is based on the safety history of the product and experience.

> And this is justifiable because when we go back to investigate the bases for the decision, it is science. And that is allowed. [Billy]

The accounts of the regulatory officers also revealed that this practical knowledge was deeply rooted in the minds of the product evaluators, such that it was difficult to codify, as it was unconsciously acquired. The evaluators tended to invoke and rely on this set of knowledge as a routine in order to provide adaptive responses to even less-thought-about cues. A regulatory supervisor, Mike, further elaborated on how tacitly acquired knowledge in the noncognitive routines continues to serve as a practical logic for accomplishing the evaluation routines at the FDA. He intuitively explained:

> So, let me give you an example. We have a certain standard for, let's say, product X, and it needs to meet certain requirements, say A, B, C and D. And it happens that this product is coming from a region where there has been a volcanic eruption incident. Even though the standard for that product does not require certain parameters to be asked, we may ask for other parameters to make sure the product is safe, even though it is not included in the standard. Similarly, if the product we are reviewing is produced from a region where there is mining activities going on, I can infer on the basis of the location that there could contaminants like arsenic. And even though we have a standard for evaluating that category of product, we may test for the presence of such contaminants which the standards may not be asking for, because of the mining activity. So yes, the standards are there but the requirements are not exhaustive. So, the evaluator must be able to consider these minor issues that are not necessarily stated in the standards and request for laboratory testing to verify. [Mike]

He added another practical scenario to illustrate how tacit knowledge, subsumed in noncognitive routines, may take active control of the successful accomplishments of the product evaluation process:

> Another example is, let's say, there is a product produced and imported from Ukraine and similar product produced here in Accra in Ghana. We may have standards that apply to both products, but as an evaluator, and as scientists, we need to be proactive if we should hear that there has been nuclear activity taking place in Ukraine. So, it's prudent for the evaluator to ask for extra tests to be done on the product just to make

> sure that there are no remnants of such chemicals getting into that particular product. [Mike]

Although this set of responses suggests somewhat intuitive navigation of routines by the individual evaluators, other expressions by the respondents also revealed that such actions were always informed by artefactual representations containing guidelines or standards, including those that may not be readily available or explicit in the FDA standards. Thus, the situated practices that informed the enactment of non-organizational-cognitive routines were carried out against the background of formal rules and expectations (Feldman & Pentland, 2003; Pentland & Rueter, 1994). It is most revealing to find that in this empirical context, although the noncognitive routines were drawn upon to accomplish tasks, such efforts remained guided by codified, formal guidelines and procedures. The cognitive routines in the evaluation process constantly provided a frame of reference or boundaries to guide what specific actions should occur in the situated practice of the product evaluator. Therefore, the intentions of the routines in this context were not achieved through mere trial-and-error experimentation (Rerup & Feldman, 2011). Rather, the routine enactment survived on a pre-existing cognitive abstraction and competences that allowed new conceptualisation and improvisational spaces while creating consistency between situated practices and the intentions or meaning of the regulatory framework. A regulatory supervisor, highlighting how deliberations on regulatory decisions were carried out, noted:

> Because the FDA is an institution made up of people with different expertise and academic backgrounds, everyone will have their level of conviction on a particular issue or concern. So, as we deliberate issues, I may have a different view about a product, and another person will have a different opinion about it. But that is why we have our standards, guidelines, and SOPs to guide us: so that whatever an evaluator or analyst may suggest, we just compare with what we have in the guidelines. And that is how we are able to provide scientific and legal justification for our decisions. [John]

Another regulatory officer also shared her thoughts:

> Even though we sometimes know by observation whether a product is good for the market, we have guidelines that bind us to how we are to evaluate the products. For instance, in reviewing the product labels, the labelling guidelines we employ here, which was approved by the legislative instrument, together with CODEX Alimentarius guidelines, suggest that a product must be prescribed by law, a product should have the name and address of the manufacturer and have a net weight, storage condition, list of ingredients, manufacture and expiry date, etc. So, those are the first set of information we investigate, even before we review the COA or send the products to the laboratory for toxicological analysis report to confirm safety or otherwise. [Mel]

Ensuring that the noncognitive routines were not in any way grounded in subjective judgements leading to deviance in practice, there was persistent reliance on multiple regulatory guidelines to conform to the collective objective that the regulatory process intends and prescribes. Another regulatory officer shared her experience on how this is achieved in practice:

> When a novel product comes in for review, we sometimes compare it with an existing similar product and find standards to evaluate the product because we need to provide scientific justification for our recommendation. And although it is difficult to have a closely related product, we usually find one or two similar ingredients that we may have parameters in our standards for evaluating them. Also, we rely on books, and search online for other regulatory standards that we can rely on. So, it's not solely my discretion – we actually check other sources before the final decision. [Joan]

Against this background, the empirical setting paints a practical picture of how the dynamic interplay between the (non)cognitive routines comes to shape and define the regulatory review processes at the FDA. In this respect, there was a dichotomy between systems that made up the organizational cognitive routines and the situated activities that satisfied the intents of the defined patterns of organizing. However, the actions in the situated practices may not be explicitly captured in the cognitive routines, but rather subsumed within the noncognitive routines. Nonetheless, the accounts on the situated practices of the product evaluators suggest a co-functioning of these (non)cognitive routines. This implies that while the cognitive routines embodied the specific procedures, configurations, intentions, and dispositional intents of the regulatory agency, the

noncognitive routines sustained the practically honed tacit knowledge that was expressed in situated actions within the boundaries defined by the cognitive routines. As such, although generative actions in the situated practices might not be explicit in the representational artifacts at the FDA, they potently satisfied the intentions of the evaluation routines.

4.3 Frequency conceives mastery

As a necessary condition to identify an activity (or series of activities) as routine, the patterns of action must be characterised by frequency and repetition (Becker, 2004; Rerup & Feldman, 2011). As such, agents involved in the enactment of routines must have the cognitive capacity to remember, understand, and execute the repetitive patterns of actions that sustain the operational identity of an organization (Danner-Schröder, 2021; Miller at al., 2012; Pentland & Rueter, 1994). The regulatory officers at the FDA personified this notion by demonstrating in-depth understanding of how the patterns of activities were triggered, the material/artefacts and competences required to enact the routines, and the symbolic meanings that the routines must accomplish (Shove et al., 2012). This was divulged in the informants' accounts of the various stages through which an application for regulatory review would have to pass for approval. Indeed, the data suggests that the evaluators understood when and how the evaluation process was initiated, from the client desk to the final deliberation and decision-making stage. Their accounts further shed light on how they had come to develop a shared embodied knowledge of the day-to-day activities at the FDA. They demonstrated that their situated activities, as defined by the cognitive routines, were conceived as a repetitive pattern, thereby indicating some expectation of how the routines ought to be actioned and what intentions they must satisfy. Demonstrating such understanding, a regulatory officer succinctly described her work as follows:

> So, when my supervisor assigns the alcoholic beverage or product to me, I go for the entire application documents as well as the product samples from the sample custodian. I then begin to do the general labelling evaluation. Since they attach the COA to the documents, I'm able to evaluate the certificates to confirm the chemical content of the product by looking at whether they satisfy the maximum or minimum

> criteria for the parameters prescribed for that product category. Depending on the nature of the product, the microbiological test results, the alcoholic contents, or the risk assessment of that category of product, I may request for further laboratory testing. I do this in order to confirm what has been provided in the COA and to provide evidence to support my recommendation. So that is basically what I am expected to do here. [Joan]

Several of the regulatory officers unveiled how they sometimes improvised to navigate the repetitive patterns and to achieve the intentions of the evaluation routines through experience. This was evident in their ability to adopt and apply routines that are external to those defined by the FDA guidelines and standards. The regulators' prudent drawing of insights on 'ways of doing' from other standards and guidelines in cross-border, unspecified regulatory frameworks to successfully accomplish their tasks underlines a unique mastery of the patterns and logics of action. This form of rich knowledge was portrayed in practice through their understanding of the intentions of the patterns of actions to provide consistency and stability in the outcome of these actions. What is striking in this setting, and more pronounced in the accounts, is how the regulatory officers who had years of experience performing varying roles in different units and departments of the FDA unpacked some unique understandings of the evaluation process. A regulatory supervisor who has had twenty-one years of experience working in multiple roles and departments of the FDA articulated this:

> There are three key factors that determine the approval of a product for commercialisation. These are the product itself, the facility in which the product is manufactured and stored, and the quality analysis of the product in the form of a COA from a laboratory. So, for the registration and market authorisation of a product, I always see it as an event. Largely because it is granted once and in every three years the authorisation is renewed. But in terms of assuring the safety of products, as it is the mandate of the FDA, the product evaluation is a continuous process, as we follow up on the market to check the safety and quality conditions of the product after granting the authority for commercialisation. This is where the role of the PMS comes in. [John]

Another regulatory supervisor, who has had twenty-two years of experience in the regulatory evaluation process, added:

> Well, because of my experience, I am able to know that some combination of chemicals or substances might or might not pose health threats. But I always make sure I am making the decision based on what is stated in the guidelines. Even if they are not clearly stated, I go ahead to look at other international standards or regulatory guidelines in other jurisdictions. So, in most cases, I read around to find out what is the practice elsewhere, and then have an idea about what current ways of evaluating the product or what I should look for in terms of parameters. After that, I can confidently conclude on what to do and make my recommendation accordingly. [Lucy]

A quote from Mike, who has engaged in the evaluation of products for fifteen years at the FDA, reflects how years of experience nurture a thorough understanding of the evaluation routines and their prescribed meanings, and even recommended a change in the parameters:

> If we have a product of animal origin – say, meat or cheese – that is coming from the European Union, for example, there is an oval mark on them. Every detail of the product can be found from this mark when scanned, including the premises within which the product was produced. So, though the labelling guidelines require that we look for the country of origin and batch number for traceability of the product, the products from the EU will not conspicuously indicate that this is the batch number or origin. In this case, we do not insist on the applicant providing those details, because we can use an alternative means to verify those details. This is how we have been evaluating such products, and I think we need to now incorporate that into our guidelines. [Mike]

The acquired cognitive competences that facilitated the evaluators' ability to initiate complex and adaptive responses in accomplishing the routine intentions were therefore developed over a relatively long period of involvement in the enactment of the product evaluation routines. It was observed that evaluators' understanding of the interdependence and complementariness between the multiple routine clusters (Kremser & Schreyögg 2016) that operated to constitute the regulatory review process allowed them to unleash the noncognitive routines with a rather strict infusion of the cognitive routines. Also exhibiting how invested he was in the evaluation routines of the FDA, John expressed

an erudite account of the evaluation and registration process and made reference to the legal and legislative frameworks that guide their situated actions.

> With regard to the actual task involved in the registration and authorisation of products, we conduct preliminary evaluation starting with the labelling of the products. This is done to ensure that the labels on products are conforming with the Li 1540, which is the main piece of legislation on labelling. In addition, if we look at our Public Health Act, Act 851 2012, it states clearly that the FDA has acknowledged the utilisation of other international regulatory standards and guidelines. So, we also have other labelling guidelines that we rely on, which is called CODEX Alimentarius. I am mentioning CODEX because we often rely on their guidelines and it has been very helpful, especially when products have a lot of additives and when the products have health and/or nutrition claims. For the other general evaluations, and of course same with the laboratory analysis, we also use other international standards, like EU standards, WHO and the US FDA guidelines. [John]

John added:

> I believe these documents help to effectively evaluate products, because sometimes we are faced with the challenge of selecting scientific information or parameters that would help in taking a decision, especially with products that are novel, which we may not have clear guidelines in our GSA standards and FDA guidelines. In fact, all this varied information or knowledge that we resort to are essentially to back our recommendations and decisions. [John]

Providing interpretation of the intentions and outcomes of the evaluation routines, this account reflects how the continuous execution of tasks had come to serve as a mechanism to synchronise the (non)cognitive routines in their intuitive mode of conduct and everyday actions. The infusion of applicable guidelines into the tacit coordination of activities thus created a unique and stable flow of the regulatory evaluation process. A regulatory supervisor who had worked in various units and was currently engaged in the vetting of advertisement scripts shared insights on how she perceived her role:

> It is important to understand that even the label on products is some form of advertisement, and must be treated as such. So, when evaluating a product or vetting

> an advertisement script, we have what we call public sensitivity, which the evaluator should be mindful about. In doing so, I put myself in the shoes of the consumer and ask myself how would I rate the work of FDA if I am to see a product label or watch an advertisement on TV? If my perception is not going to be right, then I need to restrict the advert or product, and request that changes be made…And I have come to understand that it's not always about strictly following the guidelines. Sometimes we need to take into consideration our own perceptions because we are also part of the public. For instance, if I'm watching it in my house with my kids, how would I cope when nude pictures are showing on the screen? What would I do if my child buys an item from the shop and the label has images that connote violence or sexuality? So, in that case, [the] label or advert may not contravene any of the scientific guidelines we have, but public sensitivity must inform our recommendations and decisions. [Nora]

Nora had abstracted from the cognitive routine patterns, unique intentions, and objectives of the regulatory framework, which she believed to serve as the underlying logic for practice. Underpinning this sustained conviction, belief, and confidence were her years of practice and continuous use of the evaluation guidelines. The questions she posed, coupled with her evaluation technique of situating herself in the minds of the consumers, suggest that her acquired finesse captured the intentions and orientations of the regulatory review process into a personal arena where tacit knowledge enriches its stability and effect. This unique command over the objective of the organizing routines of the FDA thus enhanced the development of the skills needed to ensure that the regulatory framework was fit for purpose. Further unveiling this unique knowledge, developed through consistent and prolonged involvement in the enactment of the evaluation processes, a laboratory supervisor who had nineteen years of experience in the FDA and many years working with various regulatory bodies provided a unique response. As she divulged how her tacit knowledge and skills helped to provide consistency and stability of the regulatory review framework, mastery of the evaluation routines predominated:

> Since the Covid-19 pandemic, we have been receiving a lot of food and drink mixtures that we haven't seen before, and we have no standards for them in the country, which

> is a big challenge…That notwithstanding, those products must be analysed, verified, and be registered. So personally, having worked in this area for a very long time, literally all my life, I'm able to just look at the product and tell that these are the tests that are required analyse such product. [Rose]

She added:

> I am very familiar with how to develop the parameters and criteria for evaluating products, as I am the FDA representative for the technical experts that sit on the GSA standards formulation committee. So, in times when we may not have the microbiological criteria to be able to analyse a product and report whether it is conforming or not, I'm able to look at the composition and suggest the type of test that the analyst is to run and the range or limit they are supposed to work within. Ultimately, the test will have to satisfy our objective to ensure safety and quality of the product. So, if that is achieved and we make reference to existing key standards and explain how our test satisfies the requirements in those standards, then we make progress. [Rose]

As attention is drawn towards the sealed-away stock of knowledge that has become the preserve of those who have had long periods of participation in the design and implementation of the evaluation framework, the adaptive responses are no longer obscured in a tacit category but are increasingly revealed in the patterns of responsive actions that the regulatory officers enact in their situated practices. Nonetheless, Rose's account revealed the enactment of routines in noncognitive forms, which prioritized the explorations and exploitation of frequency and prior engagement in evaluation routines with a skilful infusion of cognitive routines. Another regulatory supervisor provided an elaborate account of how in-depth understanding of the evaluation routines of the FDA became increasingly useful:

> What I have observed, particularly in our local industry, is that most of the new alcoholic beverages are simply addition of new ingredients to the existing ones. For an existing product such as brandy, which we have a well-defined evaluation standard for evaluating it, the next moment we get a new product which has added some sort of value, in the form of tastes, smell, or even nutrients. In this case, the standard for

> brandy may not necessarily apply. What this means is that we have to look at a combination of standards to review the product, or search for a standard that would help us to look into just the safety of the product. This is possible because some of the parameters required for the standards are just for qualitative part of the product. But the primary aspect of the organization is to ensure that, first, the product that is placed on the market is safe, and that obviously will have been met. [Mike]

In this regard, reconciling the logics of action that are embedded in the (non)cognitive routines does not pose a threat to the stability of the routines in the regulatory review process. Rather, it brings the evaluation process up to date with the emerging trends of the innovation landscape, thereby reinforcing the intentions and meaning of the evaluation framework. However, by conceiving routines as the organizational mind and memory, the activation of a mechanism for absorbing the adaptive practices of the regulatory officers and analysts in order to continuously rebalance their organizing processes and routines becomes increasingly important. This effort was observed at the FDA.

4.4 Knowledge-gathering power

In the context of the FDA's evaluation of products, the complementary enactment of (non)cognitive routines dissolved into a hybrid structure that reflected the underlying logics of the regulatory evaluation framework. In this respect, transfer of the effective elements of the noncognitive routines into the codified processes of organizing at the FDA characterised the knowledge-gathering power of the regulatory evaluation framework. Thus, the ongoing navigation and accomplishment of the evaluation routines was (re)framed around both the cognitive patterns of actions, as formally defined by the FDA, and the adaptive actions of the evaluator. The FDA had defined a process for absorbing the tacit knowledge that underpinned the improvisational forms of action in order to provide relatively stable and up-to-date organizing routines for the organization. A quote from a regulatory officer highlight how the knowledge-gathering mechanism was initiated:

> Based on the things we find here and how new thing are coming up, the FDA normally writes to the GSA, the agency that develop the standards, that there are some grey

> areas that we need to develop a standard for. This also happens when there are some studies that suggest that we need to improve our standards or procedures. The FDA has officers who liaise with the GSA, and they go for meetings, so whenever the FDA has concerns, they channel it to them. So, the main objective of the committee is to fine-tune the standards, guidelines, and requirements for evaluating the products. And they've been doing this for a while now. [Mel]

The absorption, formalisation, and codification of the *tacit-knowledge-in-action* into the evaluation routines of the FDA reinforced the basis for casting routines as a cognitive construct. This conception was also grounded in the conscious efforts that unfolded in the process of learning the effective navigation of the evaluation process, which was exhibited through the enactment of the noncognitive routines. Therefore, the characterising of the routines in this context in the form of psychological memory further suggests that the regulatory evaluation routines are worth conceiving as a cognitive affair. The informants revealed that the codification of the noncognitive routines was purposefully executive to provide legitimacy to the situated and improvised activities of the regulatory officers and analysts. According to a regulatory officer:

> There's a committee that sits to review the standards we use here. So, if for instance the sub-committee for food identify a parameter that needs to be amended or added to the standards, they task the food division to form a team to look into it and provide a report that substantiates what they have observed. The team usually solicit our opinions, suggestions and what we have also observed concerning the particular parameter for what they want to make changes on. Sometimes we the first line officers may also task the committee to look into a particular parameter or standard. While evaluating the products, we may identify some information, which are not clearly stated in our guidelines or standard, but we may be consistently using it to help us evaluate the products. In that case, the process is that we discuss with our supervisors and HoD, and when we all agree on it, we write a proposal to the CEO and then the committee will sit, look into it, and make the necessary changes if possible. [Kate]

Therefore, cognitive routines conceive their continuous relevance and existence by internalising the external knowledge that tends to be sealed away in the noncognitive domain. Thus,

the situated learning accrued to the evaluators at the FDA found its way into the codified expressions of their organizing routines. As such, it was found that the collection of situated action endowed the overall recognizable patterns of activities and the logics of organizing at the FDA. This explains some of the characteristics of a routine, which are exhibited in the ability to capture tacit knowledge into declarative memory (Miller et al., 2012). This form of organizational memory, in turn, yields efficient cognitive routines that create fit and alignment with the transactive memory which informs the improvisational forms of situated activities initiated by the evaluators. In other words, this process at the FDA offered a systematic mechanism for organizational memory formation and further emphasised the cognitive nature of routines. A regulatory officer shared her experience on how such knowledge-gathering power was exhibited to change the evaluation process at the FDA:

> Taking the recently adopted risk-based evaluation system, for example, it all started when we realized that there was a need to review the parameters we evaluate on CoA. We identified some parameters that were product-specific, which sometimes makes our work cumbersome because we do duplicate testing. So, a committee was set up to look into the concerns, and after their study, [they] submitted a report to the CEO and then the final approval of the risk-based approach by the board was granted for us to start implementing it. What the risk-based approach did was to put products into broader categories, and the committee came up with few parameters that are of high risk to those product categories by observing the result patterns over the years. I must say this is a much simpler way to do our work. [Pat]

While providing this response, Pat made it clear that the cognitive routines were (re)organized to match the demands of the situated practices. In this regard, a system that codifies the learned rationales, which facilitate adaptive responses that are not explicit in the cognitive routines, was designed to help create a web of complex cognitive competences at the FDA. A regulatory supervisor also shed light on the relevance of capturing new and tacit knowledge into the codified processes of the FDA:

> We are ISO 9020 accredited, so when there is a reason to change some processes or guidelines, there are standard procedures for initiating such change. There are a set of

> documents we use, which requires the provision of evidence, justifications, and reasons for calling for an amendment. The documents are submitted to various committees at different levels who review certain aspects of the document at different times before finally granting approval. [John]

He added:

> I think this is one of the most crucial parts of regulation because knowledge is important so that we don't become static, we need to learn. And that is why these systems have been put in place, so that when new things come up, we would have a scientific basis for taking them on board. It also helps to avoid being boxed in a regulatory framework that might restrict us, say, 'This is how we do things' – no. We go through the process in line with the ISO guidelines to learn new ways of doing our work. [John]

The evaluation routines of the FDA extracted value from the situated practice of the evaluators by relying on the ability to code tacit knowledge and experiences into the cognitive routines. As memory became important to the formation of routines (Becker, 2005), the organizational cognitive routines strove to capture the ongoing patterns of successful accomplishments. Also at the FDA, technological systems served as artefacts that were used to capture the tacit knowledge from practice to streamline the evaluation process. At one of the FDA's training sessions where a new software system – referred to as the Product Evaluation and Registration System (PERS), which is an upgraded version of the Product Functionality System (PFS) – was being introduced, insightful contributions were solicited from the regulatory evaluator. This was done to ensure that the system captured every detail of the dynamic responses that could be invoked in practice. During the deliberations, a regulatory officer who was later interviewed advocated:

> This is not an entirely new software. We have been using the functionality system for some time and I believe we all have had some great deal of experience and challenges that we sometimes discuss to find alternative ways to addressing them. So, if this PERS has been introduced as an upgrade, then I suggest we get the system to address all those challenges. [Billy]

As such, although the technological systems could only go far enough to capture more of the iterative patterns in the evaluation process, efforts were made to inculcate into the system specific situated activities, upon which the evaluators could tacitly call to sustain the intentions of the regulatory review process. The situated practices of the product evaluators, coupled with the cognitive benefits of experience, came to shape the codified processes that exist at the FDA when replicating the manual process on a computer software system. The noncognitive routines here were thus conceived as tried-and-tested solutions to address what Billy described as 'challenges', or problematic situations: solutions which the cognitive routines do not readily provide. A regulatory supervisor also commented on the significance of this knowledge-gathering power to enhance the routines at the FDA:

> Our current system requires that every product is recorded under a specific category. The applicants also adhere to this system and submit their products, describing them according to predefined categories listed in the application forms. But sometimes we have products that qualify to be part of multiple categories. It is common when a single product has variants that extend beyond its category. We usually use parameters from the various categories that we identify with such products to do our evaluations. So, this is the key challenge this new software system will help to resolve, and then eventually we will update the application documents as well. [Nora]

The practical knowledge gained through the situated practices shaped the evaluation routines at the FDA, thus underpinning the dynamism in the regulatory framework in response to the changes in the product contents and technological variations. As such, the evaluation routines of the FDA were regarded as incomplete and in flux, as it continuously absorbed new knowledge and information to sustain its relevance, intentions, and meanings. The thread of coherence that joined the interactions between the cognitive routines, which were presumably independent of individual evaluators, and the actual situated practice that gave life to these routines, reflected an active construction of organizational memory. While explaining the need to solicit evaluators' contributions to the design of new and improved systems of routines, a regulatory supervisor said:

> All the issues being addressed by the new system are based on their current application forms and procedure. Although in earlier meetings held with the software developers, we attempted to raise these issues for them to address in the new software, we agreed the evaluators have been using these documents to evaluate the products and so they are better positioned to provide the ways to improve the processes here. That is why the training was organized to get the inputs of the evaluators themselves. [John]

The organizing routines at the FDA were a combination of individual and organizational cognition, as the adaptive practices of the evaluators became embedded in the organizing repertoires and artefacts of the FDA. In this respect, the evaluators' situated activities transcended into the organizational cognitive structures which constituted the bundles of routines that underpinned what and how organizational reality is negotiated. However, as the organizing structures were designed to acquire as reliably as possible the adaptive practices of the evaluators, quasi-irrelevant aspect of the cognitive routines became eroded as new routines were (re)invented.

4.5 Decaying patterns of action

The interaction between (non)cognitive routines established an inextricable logical pattern of action that defined the systems of organizing at the regulatory agency. This condition led to some repeated patterns or actions that could be accomplished without the need to search for new responses, and which were efficient in the enactment of routines. However, the cognitive routines that functions as the unchanging receptacles that the noncognitive routines navigate in practice to derive coherence in intentions are also susceptible to conditions of obsolescence and decay (Becker, 2004). This was typical of the routines at the FDA, as cognitive patterns of action became obstacles to change when they lost their relevance over time. As the noncognitive routines continued to satisfy the intentions of the evaluation routines and became embedded in the cognitive patterns of actions, new orientations to the routines were formed. A regulatory officer noted that:

> I can say that product evaluations here have really improved, particularly when it comes to the speed. Before, we will have to look for a new parameter to evaluate almost

> every new application we receive. But due to the product categorisation system and the risk-based approach, we are able to evaluate the products quickly, without necessarily having to search for new parameters and standards. This has helped us to focus on our mandate as a regulatory body, which is to ensure products are safe for the public. [Dan]

Another regulatory officer added:

> Now we are focused on ensuring product safety, although we also ensure that the public is not deceived. Unlike before, what we do now is to reject an application on safety grounds. All other concerns raised would lead to deferral so that the applicant can make necessary changes. I think this system is in some way supporting the local manufacturers to improve their products. We more or less give them a chance to get their product to the market, and it's really helping. [Tom]

The effective attention of the organizing structures at the FDA to the successful capture responses of product evaluators in their situated practices thus provided fertile conditions for aspects of the cognitive routines to be eroded. This underlines the emergent quality of routines, which triggers an evolutionary trajectory in patterns of action, grounded in the notion of orchestrating a "higher-level routine" (Winter, 2003, p. 991). Thus, to the evaluators, this elimination of aspects of routines marked an important point in reimagining the intentions of the routines in the face of a rapidly changing innovation landscape. The following quotation from a regulatory officer mirrors this assertion:

> What we usually find is that a parameter that was being asked for, let's say 10 years ago, is no longer required. This is usually because systems have now been put in place by product developers to ensure that those issues that would require us to run our analysis to confirm are already taken care of before the product comes in for evaluation. So, what we do is that particular standard is reviewed [and] taken off our standards. This is our way of keeping up with the technological advancement that the industries are putting in place to make sure those issues that have been of concern before are no more of concern. And of course, it makes our processes simple. [Mike]

As noted by the above informant, changing the repertoires of cognitive patterns of action is of absolute relevance to the context in which the product evaluations are executed. Here, transfer of

cognitive skills yielded what the informants regarded as a distinction between old and new routines. Consequently, most of these decaying patterns also triggered dramatic changes in the operational structure of the FDA to produce new forms of organizing. In other words, changes to the organizational cognitive structure, which were triggered by adaption of the cognitive routines that sustained those structures, led to dramatic change in the organizing architectures of the FDA. A regulatory supervisor described how such structural change occur:

> The risk-based approach we adopted is reforming our processes by eliminating delays in our work. On the average, the timeline for registration of product applications here is six weeks, and a minimum three months for those applying at our regional offices. For the evaluators at the head office, we have managed to cut down the number of laboratory analysis required, which also contribute to the delays, by using the risk-based system. For the regional offices, this new approach to product evaluation has helped remove the transit time in forwarding every single application to us, as well as the time it takes for us to finish working on the products and communicate back to them. Now they only forward the application to us when there is real need. [John]

As John explained how the new routines had changed the evaluation process, he went on to reveal that hitherto, no actual evaluations were conducted at the regional level. Thus, the organizing structure of the FDA had been established to permit the regional offices to receive applications for registration but relinquish all technical evaluations to the head office. The change in the evaluation routines therefore led to a change in the organizing structures of the FDA, thereby eliminating regulatory delays and creating efficiency in the evaluation framework. Gabi, a regulatory supervisor at the food enforcement unit, also noted:

> We were formerly the Food Enforcement department, which included the post-market surveillance and advertisement units. But over time we realised that the activities of the enforcement department were geared towards warehouse and manufacturing facilities inspection, which is required for both before and after the product registration. This led to the post-market surveillance being detached from enforcement. The advertisement unit was also moved to registration, as the adverts are usually evaluated in conjunction with the product evaluation and registration. So now we are

> solely involved in the inspectorate of warehouses and manufacturing facilities for both local and imported food products. [Gabi]

Gabi's response underlined that a change in the organizing routines and its intentions provided a basis for a change in the organizing structure. She highlighted the realisation of distinct routine objectives and hence a need for a change in structure. Therefore, the underlying logic for the structural adjustment was revealed in the informant's assertion that the greater the need for tacitly honed skills in the noncognitive routines to fulfil the intentions and meanings of the evaluation framework, the greater the anticipated change required in the organizing structures. This 'learning to unlearn' characteristic of routines thus underpinned the adaptive capabilities of the FDA. Thus, the ability to initiate change in organizing routines was dependent on the understanding of the objectives of the routines and intentions of the established logics for the patterns of action enacted. The elimination of some existing cognitive patterns therefore became consequential in the bid to (re)design efficient structures of collective action.

4.6 Chapter summary and conclusion

According to Cowley et al. (2017, p. 326), "cognition is everywhere in the organisation and … it becomes very difficult to disentangle it from organisational human activities". Therefore, emphasising on the distinction between organizational cognition and the cognitive and motor activities that encompass situated actions of organizational agents, this chapter has sought to provide both theoretical and empirical characterisation of the active cognition involved in the enactment of regulatory evaluation routines (Lazaric, 2021). The chapter focused on how the patterned sequence defined as organizational cognitive routines interacts with the creative enactment of the routines by active agents in ways that are conceived as the noncognitive routines of the organization, hence providing a fine balance between the organizational cognitive routines and the situated practices that yield noncognitive routine enactments. The chapter relied on several accounts from informants at the FDA, which led to the finding that the (non)cognitive routines were constitutive of the complementary substrates of the

organizational mind and agents' thinking, which shaped the patterns of organizing that defined the processes of (re)negotiating organizational reality. Specifically, it was identified in the context of regulatory reviews at the FDA that organizational cognitive routines, on the one hand, were the representation of the knowledge structures about what repetitive patterns of evaluation ought to be enacted and how. On the other hand, the noncognitive routines were cast within a deep structure of the acting agents' minds, which were repetitively expressed in the situated enactment of the cognitive routines.

Against this background of differing cognitive demands that were required to successfully enact and accomplish the intention of routines at the FDA, the chapter further delineated how frequency in routine enactment and experiences gathered from the prior engagement in multiple clusters of organizational routines helped to refine agents' competences in executing situated activities. Thus, the tacitly honed knowledge, which enabled adaptive responses in unfamiliar events, was an accumulation of in-depth understanding of the logics and intentions of the cognitive patterns of action. However, given that legal and scientific justifications underpinned the decisions that emerged from the enactment of routines, the empirical context did not allow for a mere trial-and-error experimentation of new routines without the involvement of cognitive representations. As such, the intentions of the routines were preestablished and creatively imagined in the enactment of the noncognitive routines. Hence, although routines enacted in the situated practice might require an immediate design of new routines to allow for situational sensitivity and affordances, "abstract analyses and deliberate intention" established in the broader regulatory framework continued to drive such actions (Nayak et al., 2020, p. 293).

Furthermore, the chapter has drawn attention to the process of codifying such tacit knowledge and skills into the cognitive routines of the organization. The situated experiences that enabled evaluators to effectively navigate the dynamics of the innovation landscape were extracted and absorbed to provide more efficient patterns of action. Akin to the interaction that exists between

declarative and transaction memory (Cowley et al., 2017; Miller et al. 2012), the organizing structure of the FDA was designed to ensure that the effective creative responses of the evaluators were captured to modify and sustain the intention of the cognitive evaluation routines. The mechanism through which this knowledge-gathering activity was purposefully initiated to encode the noncognitive routines into the organizational cognitive routines was thus highlighted in this chapter. In the context of the FDA, however, the process led to creative destruction of some of the existing patterns of action. Thus, aspects of the routines that had been rendered inefficient were seen to experience decay and elimination from the codified routines, which recursively tiggered a change in the organizing structures of the FDA. In this respect, it is reflected in the efforts to highlight the evolutional trajectories of the organizing routines of the empirical context that the chapter has established empirical characterisation for the endogenous mechanism that trigger, define, and establish the adaptive qualities of routines and structural changes in organizing.

In conclusion, the duality of stability and change which was conceived by the concept of routine dynamics was reposed in both identifiable action patterns that were coded in artefactual materials to inform situated practices, and skilled adaptive actions of the routine participants in the bid to sustain the relevance and intentions of the organizing routines (Feldman, 2000; Feldman & Orlikowski, 2011; Feldman & Rafaeli, 2002; Nayak et al., 2020). The dynamics of routine enactment at the FDA therefore suggest that the cognitive realm of routine conceptualisation becomes relevant in unpacking the active cognitive interactions between the rules and learned practice, which provided stability in coordinating day-to-day organizational activities (Danner-Schröder, 2021). In this regard, the interactions between the (non)cognitive routines created stability in activity patterns and enhanced the adaptive capabilities that were needed to sustain the intention of the evaluation framework in a fairly evolving organizing context. On this basis, the chapter has defined how stability in coordination and change in improvised forms of organizational routines come to be implicated in a cognitive arena characterised by activities that are in constant flux and transformation. Also, while emphasizing the interrelation between explicit, deliberate, conscious activities and the tacit or implicit processes that provide adaptive responses in

organizing, the routine in this context underscores that the cognitive routines are not higher abstractive conceptualisations that are independent of the individual enactors. Rather, they are themselves actions that are manifested in the situated practices of the routine enactors. The situatedness of the routines further suggests that the connections between (non)cognitive organizational routines are important for developing understandings about both what needs to be done in a specific instance of performing a routine and the goals of the organization that routines help to accomplish. As such, the competence in accomplishing product evaluation routines is subsumed in a bundle of cognitive structures and expressions.

CHAPTER FIVE

Thriving on chaos: The beauty of imperfection

This chapter delineates the socio-cultural practices underpinning *when* and *how* noncognitive routines in new product evaluation lead to the identification of opportunities for innovation in regulatory review processes. Specifically, the chapter presents an empirically grounded explication of how imperfect organizing conditions are navigated to yield new forms of organizing repertoires that come to define how the situated role-routines of product evaluators are enacted to initiate change in codified patterns of actions. The chapter begins with an analysis of how the socio-cultural persuasions determine the context-specific dynamics that yield variations in the replication of established regulatory guidelines and evaluation standards within global regulatory discourse. Following the presentation of a concise heuristic framework that captures the mechanism underpinning this phenomenon in practice, fine-grained explanations of the core theoretical mechanisms are provided. Thus, the chapter first delineates the pragmatic paradoxes of the ways through which socio-cultural persuasions ignite variant forms of organizing routines relevant to prevailing conditions. Next, it reveals how these cultural practices spell out the institutional configuration which defines ways of adopting and enacting cognitive regulatory evaluation routines. Following this, the power of reflexive monitoring of organizing routines in shaping tacit knowledge to navigate the complexities of the regulatory landscape is presented. The penultimate section delineates how the situated practices of product evaluators inform emergent forms of organizing when there are shocks to established routines, as well as the role of technology in ensuring the stability and sustainability of such adaptive outcomes. The final section provides a summary and conclusion of the chapter.

5.1 Socio-cultural persuasions in regulatory review context

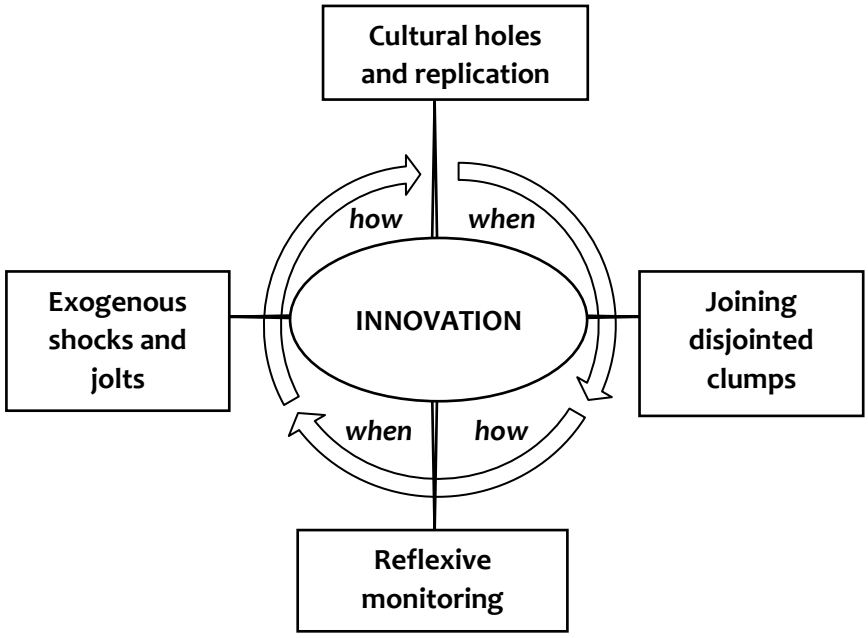
The data evidence suggests that the socio-cultural practices in organizing combine with the contextual dynamics to give form to new routines and offer possibilities that may lead to the identification of

opportunities for innovation. Thus, as endemic as the socio-cultural orientations and persuasions are to the situated practices at the FDA, a local rationale for evaluating new products is constituted to shape the scientific patterns of evaluation. These patterns are therefore sanctioned by socio-cultural artefacts of the local context within a network of 'chaotic' conditions, which in turn define when and how noncognitive routines lead to innovation in the regulatory review process. Highlighting the cultural norms that support situated actions and decisions to create new means of achieving the core intents of replicated regulatory frameworks and routines, the imperfectness of the conditions of enactment is navigated with a rather refreshing outcome of bounded improvisation. This implies that the habits of actions and frames of interpretation acquired through the evaluators' embeddedness in the local context inform the modes of improvised enactments, yet the outcomes are constrained within the ostensible recognized logics for evaluating products. In other words, the socio-cognitively wired rules that drive improvisations that are aimed at creating 'fit' for the adopted regulatory frameworks and guidelines in the context are recursively shaped by the need to satisfactorily meet the requirements of the broader regulatory landscape. In this vein, effort was made by the FDA to construe these situated dynamics into a legitimate course of action within the wider regulatory practice. In the bid to pursue even more 'higher-level routines' (i.e., innovative ends that ease the regulatory review process), legitimacy-seeking strategies were adopted to establish the validity of such practices. In this regard, the potential for the dominance of socio-cultural persuasions to cast doubt on the rigour of the regulatory review process and decisions, which threatened the FDA's privileged position as a gatekeeper of public safety, was attenuated through collective enactment of internal and external deference (Goffman, 1956; Jourdan et al., 2017): symbolic acts offered to widely recognize regulatory guidelines in order to gain cross-border acceptance.

However, changes in these legitimised enactments became emergent through reflective monitoring of the very same rules that informed the contextual fit for the collectively verified regulatory practices. This implies that the product evaluators re-examined their underlying logics of action patterns in order to define a continuously adaptive evaluation standard and routines at the FDA.

Furthermore, it was observed that the tendency of unanticipated events to destabilise (or propel) this process was hedged by the adaptive situated responses to exogenous elements and jolts. As this phenomenon emerged over space and time, with nuances in prevailing conditions, it was also evident in the data that socio-cultural frames informed the re-constitution of responsive order for stabilising such chaotic contingencies. These adaptive outcomes, however, became encoded into the cognitive routines of the FDA. Cumulatively, these socio-culturally informed practices allowed the actioning of noncognitive routines, which led to opportunities for innovation in the regulatory review process. Before embarking on a fine-grained explication of these observations, a summary of the conditions described here is presented in Figure 5.1. The four poles in the figure indicate the cardinal theoretical explanations for the underlying mechanism that sustains *when* and *how* (as identified in each of the four quadrants) the identification of opportunity for innovation in the regulatory review process comes to be implicated in the enactments of noncognitive routines. An intermittently discontinuing arrow running across each pole emphasises the iterative nature of this processes at each episodic and/or emergent condition for change in the product evaluation routine.

Figure 5.1: Noncognitive routines for innovation in the regulatory review process



5.2 Cultural holes and replication

It is worth highlighting that "routines themselves provide stability while the surrounding organizational structures and practices facilitate [their] adaptation" (Parmigiani & Howard-Greville, 2011, p. 20). As such, the organizing contingencies of meaning, practices, and cultural repertoires that enable social structure spell-out the institutional configuration, which determines the patterns of evolution in routine enactments. This understanding is clearly echoed in the data, which reveals that, at the FDA, the broader cultural norms that define social practices establish a set of contextualised knowledge that informs the situated logics for enacting the regulatory evaluation routines. For instance, a regulatory officer described how locally known brands of products may not fit into the codified category of products but were nonetheless allocated to that category, since the local context recognised them as such. He elaborated:

> We have an alcoholic beverage that is widely known here as 'tampa beer', which is a local beer. But when you look at the definition of beer in our documents, it doesn't fall within the category of beer. But once it is locally accepted as beer, we also accept it. Because the people know exactly what it is. So, for us, if it a locally recognized product, it is accepted, especially when it is widely understood that it is exactly this type of product. Yes, we know some of the products in the categories we have may not be internationally recognized as such, but it is how we see it to be within the country. [Ben]

Another regulatory officer also highlighted how the value of products could be transubstantiated to satisfy some superstitious objectives, and thus evaluating and approving such products required tactful analysis of all details, especially the name labelling:

> You know a lot of people are very religious and superstitious. So, if an applicant submits a product and let's say the product is being presented as 'holy water or wine', it will mean that the product has some supernatural powers to offer consumers. In this case, we won't allow the product with such connotations, because it plays on the minds of people and borders on superstition. So yes, when a product is designed to benefit from these superstitions, we defer it, because it might lead to consumers abusing the product. [Mina]

As this was tacitly subsumed and unveiled in the active enactment of the noncognitive routines, the product evaluator's social orientation to the nature of product under review also tended to influence, in particular, the speed with which such products are reviewed. Although the evaluation of alcoholic beverages was observed to pass through the codified processes, the accounts of the regulatory officers further suggested that evaluators paid particular attention to the review of such products to ensure that they met every single compulsory, or even supplementary, requirement. A regulatory supervisor shared insights on why additional analysis needed to be done on locally manufactured alcoholic beverages (for example, the bitters) in order to provide a convincing report. Rose put these cases into perspective:

> You know the evaluation standards are developed by committee set up by the Ghana Standards Authority, on which I represent the FDA as member. And I must say that the standards we develop there, it is based on local conditions. So, for these alcoholic products, they are not supposed to contain any micro-organisms. But we have a situation where despite the fact that alcoholic volume is high, we still have pathogens in there, which for me, as a microbiologist, tells me that the initial load of microorganisms is really very high, and therefore, the alcohol level is not able to deal with it. So, we have realised that it's not just enough to do basic parameters, but we also need to screen for other pathogens. So that forms the basis of the development of the various standards for those products. It is to ensure that the products are indeed safe for the public. [Rose]

Another regulatory officer added that although the recommendations they provided did not incorporate issues related to the names or commercial effects the product might have, there were local laws and policies which required that such considerations be made, particularly with respect to alcoholic beverages, and thus affected the final regulatory decision:

> Let me tell you a bit about these alcoholic beverages. Personally, I think the registration process should not be concerned about the product names, except maybe we have two different products bearing the same name, or even the celebrities connected to those products. But with the way our work is done here, products that have names with sexual connotations are usually deferred. And when those products are linked to a

> celebrity, usually for commercial interest, we presume that there is a higher possibility for people to be tempted to abuse that product. So, based on our local customs here, they can defer or even reject the product at the final registration meeting. [Lucy]

It was observed, however, that this phenomenon was narrowly construed in somewhat socio-religious persuasion about the use and abuse of alcohol in the operational context. Although not explicitly corroborated in the accounts of all the participants, this was subtly expressed, suggesting some form of relational thinking, particularly among regulatory offices who conducted preliminary evaluations on the NABAs. The accomplishment of the regulatory review process was thus confined within a network of common socio-cultural meanings by which the product reviewers understood and enacted their situated roles accordingly. Given that such practices may provoke distrust in the market selection environment, the recent alcohol policy in Ghana, whose execution the FDA had been mandated to oversee, served as a local mediation to confer legitimacy to such socio-cultural controls. As a regulatory officer reflected, the policy had drawn in some social concerns, which were not necessarily based on physiochemical or biological constituents of the product, that should be considered in the approval of alcoholic beverages. She carefully argued that this meant that the product evaluations and the final decisions are often influence by the need to satisfy aspects of the envisioned systems of social affinity:

> Yes, we must apply the scientific and legal principles in our work. But we also need to understand that we are operating within a society and therefore our activities must complement what the society aspires to be once it does not pose any health threats. So, you can see that in the alcoholic beverage, for instance, we have put so many restrictions in place to control the consumption. We don't have the mandate to stop the industry from producing it. But we can influence the consumption of the product by educating the public. And indirectly we have put in strict measures that will reduce the number of alcoholic drinks going on the market, particularly with the introduction of the new Ghana alcohol policy. As you know, the moment we raise the bar a little bit, most of the products, particularly our local manufacturers, cannot meet the standard, so it will reduce the number. [Nora]

In addition to this influence of context-specific dynamics or persuasions in the evaluation of products, it was also observed that the regulatory framework had developed permeable boundaries between the ongoing patterns of new product review processes and other widely recognized evaluation standards and regulatory frameworks. As such, aspects of the socio-cognitively configured regulatory evaluation routines at the FDA allowed for the assimilation of other evaluation standards that were deemed relevant to achieving the intentions of the regulatory framework. The regulatory review process as established at the FDA was therefore seen to possess adaptive qualities, which helped to transfer and replicate other 'high level routines' (Blanche & Cohendet, 2019) in order to keep up with the emerging trends in both the broader regulatory context and the product innovation landscape. More importantly, the FDA had established a system of continuous adoption and assimilation of new routines and standards, such as the Codex Alimentarius, ISO standards, and ANSI-ASQ National Accreditation Board. The enactment of the evaluation routines was therefore characterised by the integration of emerging regulatory processes or requirements with the pre-existing ones as well as the operational capabilities of the FDA to adequately select and execute the required changes. The following quotes capture this:

> If we look at our Public Health Act 851 2012, it states clearly that the FDA has acknowledged the utilisation of other international standards, which CODEX is one. So, we use CODEX a lot in terms of the additives. Also, in terms of the labelling, especially when it comes to health and nutrition claims, and any other scientific information that we think would help in taking a decision on products, especially products that are novel, we also use other international standards like EU standards, US FDA and WHO guidelines. All this varied information or knowledge that we resort to are basically to back our decisions. But primarily as a country, the main piece of standards is a Ghana standard, the national procedure or standards, which is developed by the Ghana Standards Authority. So, these are the framework or the references we use. [John]

> I can say that there are a lot of products that were difficult to categorise, and that we do not have specific standards for. So, we often rely on our understanding of what the product is known to be in our locality to provide some evaluation standards and

> guidelines from the ones we already have. But, while we are doing the evaluation, we also make sure that we are compiling the list of those products; then a committee meets to look into ways for defining categories and standards for them. Often, they try to find evaluation parameters from the international standard-setting organizations like the ISO and Codex to guide this exercise and ensure that the applicant can conform to those new standards. Similar approach is applied to the completely new products that are coming. So, our work here is always improving, and it is up to date with the current food regulation standards around the world. [Mina]

In addition to clearly underlining the relevance of such adaptive systems at the FDA, these quotes also highlight that the assimilation process was designed to nativize the adopted standard in order to fit into the social context within which the FDA conducts its product evaluations. As such, the adopted standard would undergo various forms of dilution, including being transformed into a supplementary criterion to an existing evaluation requirement or collapsed into separate units of evaluation standards. However, depending on the magnitude of change that might be expected of the applicant to fully satisfy and operationalise such a new standard, it was observed that the FDA tended to navigate this challenge by identifying some aspects of the adopted standard to which the applicant could easily adhere. Here, achievement criteria were sometimes designed to provide multiple rating bands where aspects of the adopted criteria that might be regarded as more demanding were categorised within a higher band, whereas those that applicants could easily satisfy were defined within a lower band. In this regard, the applicant might, at the initial approval, qualify for the lower bands; however, renewal of their market authorisation might be tied into their meeting of those requirements in the higher bands. This stratification system in the replication of the adopted evaluation standards was, however, perceived by the FDA as an incremental procedure to help upgrade the local products, which were largely regarded as inferior, so that they would meet international standards. This phenomenon is vividly captured in the following quotes:

> Now there is a committee that meets and look at all the products to see how the process can be become less complicated for the applicants. This is because you take the current documents on the evaluation standards and guidelines, you'll see a lot of parameters

> that have been copied from the international regulatory bodies and sometimes become difficult for our clients to find a credible lab to run those tests for them. So, we end up deferring such products, yet the applicant is unable to resolve the issues we may raise. And this is a serious challenge with the use of these standards developed from elsewhere. So sometimes we have to listen to them and find other ways of verifying those parameters, because even if we are to go exactly by what is stated in the guidelines, and the applicant is willing to comply, there is no capacity to help them do it. [Zoe]

> You know, most of these standards we have documented, we looked at other regulatory guidance from abroad. But the development and application of these standards, we consider that for some of them it is very difficult to achieve at particular levels. The levels are set based on the application of the food safety standards and requirements, so ideally, what we have set is supposed to be achievable. But in our local setting, it is not possible for some of these small informal firms, so we have different standards for them. So, we do adjustment to ensure that it is achievable. [Nora]

The data evidence therefore reveals that regulatory evaluation routines were emergent and socially dynamic; such that local norms and social practices imprint some distinctive agential and organizational practices. The cultural nuances and social practices informed the construction and execution of product evaluation, and how cognitive states of the individual evaluator, as well as the FDA as a whole, were attributed. In this regard, the data emphasise that the ecological uniqueness of the social setting within which the product evaluations were conducted designed selective frames that assimilate useful and compatible elements of the outsourced evaluation standard through the replication of such evaluation standards. This phenomenon was, however, dominated by what were observed to be the situated practices actioning the codified organizing routines into life. In other words, the situated practices of the product reviewer were being informed by socio-cultural artefacts of the empirical setting. Thus, a situated social control emerged in the accomplishment of the regulatory review process, thereby allowing the evaluators the operational space to navigate strict regulatory guidelines. This was further emphasised in their ability to define innovative ways of replicating new

evaluation standards to accomplish the intentions of the regulatory review framework. A regulatory supervisor shared insights into how their socio-cognitive orientations came to serve as a way of identifying opportunities to improve the ongoing patterns of evaluation:

> If you think carefully about the risk-based approach that we are using now, you'll realise that we've moved from the rigid way of just looking at what the standard says. Because sometimes they make our work too complicated. The last time I checked, we had over 500 standards in the GSA standards alone, and then other global standards such as CODEX, US FDA, Health Canada, and the rest. So, there are a lot of knowledge to guide us. But now we are using what I call the common-sense approach. It is all based on the way we do our work and understand things in this country, the lessons we've learned and the data we've gathered so far. You know we are to ensure that our work is being done well to the satisfaction of the public and sometimes even the industry as well. [John]

As such, replicating frameworks and processes that were developed on the complementary substrates of (non)cognitive routines of the adopted context were not always smooth sailing, as they often gave rise to problems of contextual fit and led to complications in execution. Thus, lack of understanding of the tacit knowledge embedded in the replicated framework rendered the orchestration of the organizing routines overly ambiguous and hardly feasible (Blanche & Cohendet, 2019; Winter & Szulanski, 2001). This therefore emphasises how the embeddedness of routines in an ecological network underpins the emergence, dominance, and reification of socio-cognitive constructs in codified systems of routine enactment (Becker, 2004; Kremser & Blagoev, 2021). Nonetheless, it was also observed that the degree of overlap between the multi-logics of action in both the replicated and replicating contexts allowed for successful adoption and assimilation (Cohen, 1991). In other words, the familiar features of the context from which the cognitive evaluation routine was replicated would become the basis for evoking well-established evaluation patterns. John elaborated on this:

> [Using the risk-based approach] we still do not deviate entirely from the science and what the global standard tells us. We are only changing from the rigid way of doing things here and coming to a level that we apply the existing and new information that

> have emerged in the work we do. Mostly we see that the conclusion we are drawing from the data we have here is also consistent with what international regulatory bodies find from their research. So, in the end, the decision we make using this approach gives the same results as if we used those standards: therefore, they are valid. [John]

It was, however, found that weak operational interlocks, which were underpinned by frail constructions of clusters of evaluation routines, resource constraints, limited cognitive bandwidths of the product evaluator and the cultural preferences that underly compatible elements of new evaluation standards tended to impede the adoption and implementation of such technical and contextualised standards. A laboratory analyst lamented on these constraints:

> For me, I think we are struggling with implementing some of these borrowed standards. We don't even have the sophisticated equipment to run some of those tests that are recommended by the accreditation bodies. We also need more science-trained staff to help work here. And even when you look at the new risk-based approach that they are using at the FERD, it has been adopted from these jurisdictions that have well-funded regulatory agencies. The US, for example – they have so much data that they can make a risk-based decision with the data they have, and it's bound to be 99.9% accurate, because they're always testing. We are not always testing, because we don't even have the financial muscle to so. So, if we make a risk-based decision based on the small amount of data that we have, then we are more likely to be wrong. [Sam]

It is worth highlighting, however, that regardless of the somewhat imperfect organizing systems, which were widely acknowledged as a core challenge to situated production of internationally recognized regulatory standards or procedures, the FDA managed to thrive in conducting product evaluations. It was observed that this was made possible through its understanding of the need to be agile and attempt to re-build its regulatory framework to satisfy the perceived and preferred regulatory standards within the broader/international regulatory context. In other words, the regulatory officers at the FDA held a shared understanding of the need for agility in their operational spaces in order to transcend or maintain their activities within the widely accepted regulatory frameworks.

5.3 Joining the disjointed clumps

The regulatory review process at the FDA undergoes constant improvements and reorientation in order to keep up with emerging trends in both the regulatory and the innovation landscape. Thus, the regulatory evaluation routines at the FDA were observed to be a dynamic process of meaning-making in enactment. Hence, refining the existing framework for product evaluation was seen as important to the protecting of the agency's recognized role as a legitimate actor within the melded interactions of the market selection environment and the innovation landscape. In this regard, the data further revealed that, in a bid to maintain their valued position as intelligible agents who defined the precepts for market entry, a clear objective to override the existing framework with cross-jurisdictional evaluation standard that connotes operational rigour had been deliberately designed at the FDA. As such, the culturally held ideals that underpinned the situated enactment and contextual interpretation of the regulatory review process were refined to create alignment with established regulatory guidelines and evaluation standards. Here, it was observed that the adoption and use of such globally recognized standards or processes served as a measure of improvement in the FDA's product evaluation framework. More importantly, adopting such standards contributed to the efforts to render credibility to the FDA's product evaluation processes, and signalled quality and efficacy for products approved by the FDA as well as creating access to markets in other jurisdictions. Two regulatory supervisors shared their views on how the FDA ensures that the evaluation process is refined and regarded as robust in the local context and in other jurisdictions:

> Where we have the issue of additives, for example, there's a huge information available from Codex, which is updated every year, and FDA Ghana is a member of the Codex. The information guidelines and standard in Codex are developed through expert committee. So, for every additive, even emerging ones, we know the risk assessment and the parameters we have to check to ensure that the product is thoroughly evaluated. We usually find the exact test to do, what we should expect, and we measure to see if the analysis we are running is meeting what is being prescribed by Codex. So, I can say that the science backing our work here is really strong. [Mike]

> Currently, there is this African Free Continental Trade that the industry wants to take advantage of trade in that area. But before they can move their products into those markets for trade, they need to provide evidence that the product is of good quality and there are no safety issues with it. So, most of those products come here. [Rose]

The evaluative discourse at the FDA thus cultivated a symbolic interaction that was particularly important for signalling the robustness of their regulatory review framework. It was evident in the expression of the informants that a network of deference (Jourdan et al., 2017) was enacted through symbolic mentioning of the standardizing institutions, such as the WHO, ISO, Codex Alimentarius, ANAB, and the like, whose credibility resonates with the public. This was effortfully and purposefully executed in order to confirm the robustness and validity of the FDA's regulatory review process and decisions thereof. As such, a contestation of the normative system of conducting regulatory reviews at the FDA was attenuated through the symbolic affiliation with these evaluation and standardizing institutions. Furthermore, this was important because, as the data suggests, the interactional characteristic of the system of operation in the context of regulatory reviews were marked by the ability to action evaluation processes and procedures that were defined by organizations with high status in designing credible and widely accepted standards. In this respect, implementing evaluation guidelines and standards proposed by these highly regarded institutions was not a mere desire to establish relationships with such institutions but a means to affirm the rigour of the FDA's evaluation routines, which was a prerequisite to belonging and being accepted as a credible actor within the regulatory landscape. Thus, the cultural underpinning of the situated practices captured in the enactment of noncognitive routines sometimes risks exclusion from the broader evaluation process. In this regard, the cognitive routine of the FDA was able to capture and provide robustly refined versions of the situated practices in order to solidify the FDA's position as a credible actor within this product evaluation landscape. In the quote that follows, the informant, from the microbiological laboratory, touted their procedures as highly credible because they operated with the accreditation of the ISO:

> You know we are credited by the United States accrediting body called ANAB. We are also operating a quality management system, which is ISO 17025. And it indicates that when the client brings in a request, we must be able to satisfy the client. But there are instances where when we look at the parameters, we look at the product, and you cannot just accept them. Because if we go ahead to run those tests and then compare results for the standard, we'll realise that for that particular parameter, the standard does not require it. And then it becomes a problem for us to apply the specification as set out in the ISO quality management system. So, we communicate that to our clients, and they also understand because they know that whatever we are suggesting is credible and legitimate. [Rose]

Thus, joining the 'disjointed clumps' in the evaluation routines through adhering to and receiving accreditation from these standard-setting bodies was well situated within the scope of operational objectives of the FDA. The informant also recounted that the efforts to receive such accreditation come with the benefit of having the reputation and credibility to evaluate products that have been produced in other jurisdictions. More importantly, the FDA held a privileged position within the food evaluation landscape and thus attracted some revenues from other jurisdictions that were not so highly regarded. This was evident in records of cases when applicants from other countries, aiming to gain access to the international market, presented their products to the FDA for evaluation. It was observed that, in this context, the regulatory review process also became an allegoric symbol that conveyed legitimacy to the new product innovation. The regulatory stamp of approval therefore proffered a symbolic meaning to the successful applicants, which in turns enabled them to strategically signal the quality and efficacy of their product to the market. Again, drawing a deeper understanding of this phenomenon from the NABA, the accounts of the informants revealed that the locally manufactured alcoholic beverages are generally construed as being inferior to the imported products. Thus, after receiving market authorisation, the NABA was portrayed as possessing qualities that were on a par with the imported competitors. The deference that the regulatory agency offered to the new products thus provided a distinguishing feature that set an FDA-reviewed product apart from non-approved products. The accounts of informants further suggest that the applicants need not engage in

ingratiating behaviour, as deference was perceived as an obligation that the FDA owed to the locally manufactured products. A regulatory officer noted:

> We have a challenge with most of the local producers being uneducated, or even illiterates, so they struggle to read and conform with most of our guidelines. We are aware that they need our support in order for them to compete with others, particularly imported products, so that they can also be successful. So, the FDA organizes meetings from time to time with our local manufacturers, and based on various collaborations, we help them through the evaluation process in order to be recognized as FDA approved products. Mostly, we have a unit in charge of premises inspection that visit the manufacturing facilities to inspect facilities, and also provide those companies with training. All these come together to help them develop products that have been certified and approved by the FDA. [Tom]

Moreover, while defining a rigorous product review process through the symbolic association with well-recognized evaluation institutions had a ripple effect on the dynamics of the market selection environment, it was relevant that the situated enactment of the evaluation routines was also marked by such symbolism. Thus, the internal evaluative discourse at the FDA was characterised by a deference obligation that the regulatory review supervisors (as superordinates) owed to the regulatory officers, lab analysts, and field officers (as subordinates) to establish and signal the scientific objectivity of the product evaluators' preliminary decisions. As the interactional characteristic of the regulatory review process was defined in hierarchical order of role routine enactments, the regulatory supervisors' approval of the initial evaluation results provided by the regulatory officers conferred credibility to the situated activities of the individual evaluator. As such, improvised forms of accomplishing situated tasks found their validity through the co-approval of the preliminary decision. In this regard, it was observed that the regulatory supervisors had deeper knowledge on the tenets of food regulation, and of the importance of satisfying the requirements of international standards. In addition to their in-depth accounts of the activities at the FDA, these supervisors demonstrated high educational credentials. A number of these supervisors had engaged in series of training and workshop programs organized by

internationally recognized accreditation bodies within the food regulation landscape. Thus, the situated improvisational forms of accomplishing the regulatory review, which was subsumed in the noncognitive routines, did not inform the final regulatory decision without a 'competent' supervisor signing it off as being valid. As such, both the regulatory officers who engaged in the actual evaluations of the products and the field supervisors who ensured continuous conformity with the regulatory standards relied on this recognition to establish a valid influence on their recommendations. The informants described how this organizing routine had percolated their processes to provide an improved and efficient enactment of the evaluation process.

> When we finish analysing the products, our supervisor must look at what we have done, mark and sign. They are well vested in the methods we use here. And they also have years of experience in laboratory work. Sometimes they even provide alternative methods for us to use. [Tina]

> When there are no clear ways to go about evaluating a particular product in our standard, we rely on other books, regulatory guidelines and standards to help us to evaluate. But our head of unit must be made aware of how we evaluated the product. Because they are going to defend it at the final meeting anyway. So, they need to confirm that what we have done is credible and in accordance with the regulatory standards. [Mary]

The data further revealed a purposive framing of the product evaluation at the FDA to convey to the public the rigour embedded in the process. It is worth reemphasising that, in conducting regulatory reviews, the FDA perceive its audiences – including the innovating firms, the public, and other local or international institutions, whom its evaluative frameworks must satisfy – as critical to safeguarding its privileged position as a gatekeeper of public safety. These audiences enact relationships and espouse their evaluation of the regulatory review framework to establish a collective perceptual frame of the regulatory reviews within the operational context. The informants explained that the perceptual evaluations in which organizational audiences engage were controlled by shaping the perceptions of these audiences towards garnering support for the regulatory activities. The

perceptual evaluations of the audiences in this context thus conferred legitimacy to the work of the FDA as a regulatory agency (Avent-Holt, 2012). Therefore, satisfying their interest was characterised with deliberate efforts to continuously narrow the gap between the audiences' expectations and their actual experiences with the regulatory review process. This implies that, in the bid to convey the regulatory review process as a rigorous enactment of scientific evaluation routines, the FDA attempted to influence the perceptual understanding the process. The audiences' interpretations of the regulatory review process were then utilised to emphasise the rigour of the regulatory review process. As revealed in the following quote, such practices were a way of assuring the public of the safety of the products they consumed:

> The timeline is six weeks, or thirty working days – that's the timelines by the organization. But when the clients submit their application at the service desk, it'll have to go through the CEO's office to the head of department and then to the head of the unit before it gets to the evaluator. So, although the applicants are aware of the timelines and we are also ensuring we deliver within the period, when we explain the details of the process and tell them that along the line there may be delays, then they now appreciate that it is not just a simple process. Sometimes too we tell them that delays might come from the lab, and they may also be asked to submit additional samples. In fact, even the documentations that they need to prepare, including the COA that they must acquire from a credible institution and submit, tells them that the process is very rigorous. And I think it is important that they understand we're doing some serious work here. [Pat]

In this context, the cultural tools used to assign meaning to the evaluative discourse and shape the interpretation of what could be regarded as 'scientific rigour' were utilised to construe the received perception of rigour and safety. Specifically, although some efforts were made to improve the speed of evaluation, rigour was contrived through a perceptual frame of prolonged processes, which tended to resonate with audiences. Thus, the idealist standard for the measurement and judgement of evaluation rigour in this context was conceived within the complexities of the evaluation requirement and the time taken to complete evaluations to receiving the final regulatory decision. A protracted regulatory review

process thus provided some gestural markers that invalidated the perceptual domain which collectively characterises products as sub-standard. As such, although they might have the capacity to accomplish evaluations in a shorter period, such practices were avoided to protect the reputation of the agency. A regulatory officer proclaimed that they were sometimes able to complete the product evaluations before the stipulated timeline, but they would wait until the end of the period before communicating their decision to the applicants:

> Sometimes we are able to finish work in less than the 30 days stipulated, and the results will be submitted at the regulatory decision meeting. But we will wait till the end of the period before issuing the letters. You know sometimes when these letters go out early, the applicant think we did not really do anything. So even though we are trying to get things done quickly here, we also try not make them feel like it is a simple process. Even with the recent Covid-19, you will realise that vaccines we approved quickly, people were doubting whether it is safe. The same thing applies to food. For us, they might even say that the applicant had bribed their way through the process. So, we are very careful about some of these things. [Joan]

This suggests that the regulatory review process might sometimes extend beyond the stated timelines; however, such situations were construed as a need for thoroughness in their processes, which was simply a satisfactory condition for the applicant. Again, as noted in the above quote, the informant insightfully argued that expediting the review process would cast doubt on the safety of the product even though all required evaluations were complete. In this regard, delays in the evaluation process reinforced the efforts to cast the regulatory framework as an efficient, robust, legitimate, and trustworthy system. Thus, the cultural tools used to assign meaning and interpret the activities of the FDA were mobilised to frame the regulatory framework around a perception of complex scientific analysis and rigour. On this basis, the regulatory officers mobilised delays in the evaluation process as a form of framing to shape the interpretations of activities conducted at the FDA, as this approach resonated with the perceptions of both the innovating firms and the public about the efficiency of the

evaluation process. This served as a mechanism for establishing a positive social perception toward product regulation and in turn provided a well-structured system of conducting product evaluations.

5.4 Reflective monitoring

Reflective monitoring, as used here, captures a practice of looking back on already-accomplished evaluation routines as a tool for diagnosing the effectiveness or usefulness of the existing routines and providing adaptive solutions where required (Lazaric, 2021). Specifically, the regulatory officers created and enacted change-triggering conversational spaces that facilitated 'collective reflection' (Dittrich et al., 2016), which was aimed at initiating new, robust patterns for evaluating products. In this regard, a conscious attempt was made to understand how best cognitive routines can be made to fit the local variations while, at the same time, identifying what could be endorsed beyond their bounded social setting. It was observed that the organizing practices that effected change upon reflecting on existing routines defined the recursive nature of the dynamism in the product evaluation process, as the reorientation towards new routines was guided by the core principles within the wider regulatory framework. Thus, given that the organizing context precludes trial-and-error experimentation (Rerup & Feldman, 2011), the reflective outcomes on the evaluation process came to be infused in the ongoing patterns of evaluation, concurrently establishing supervisory actions to contain the new logics of action within the core boundaries and tenets of the evaluation framework. Through this practice, the product evaluators were able to navigate the constraints of pre-existing routines to alter their situated actions as well as refine the cognitive routines of the FDA. A regulatory officer elaborated on this phenomenon, saying:

> The interest of the industry, and in fact with those new applicants, is to speed up our processes to avoid the delays in getting their products to the market. And of course, we must also respond. And this is the basis for which we don't have to make our work static and that's why we are applying the risk-based approach. We looked at our processes and realised that over the years we have been taking certain groups of products to the lab and they have consistently been passing. So, there is a trend here

> and therefore we categorise them under low risk so we don't have to take them to the lab all the time. The important thing here is that our core mandate of ensuring public health and safety is not compromised, but the same time the processes that are bureaucratic, inefficient, are cleared out. [John]

The data further suggest that variations in existing evaluation routines came to be selected and enacted as a result of cumulative sets of reflective engagements. As such, the new routines were conceptually aligned with the ongoing patterns over time before they were introduced to the actual field of situated enactments. Again, this approach to defining innovative ways for accomplishing product evaluations was undergirded by the organizing practices at the FDA, which recognized such reflective spaces (Bucher & Langley, 2016; Kiwan & Lazaric, 2019) as crucial to constituting an agile regulatory agency that was responsive to both emerging and/or diverging trajectories of the industry. The following quote from a regulatory officer succinctly captures this observation:

> As you may have already seen some of us doing, we share our challenges and experiences with one another. Sometimes we simply look at what we have done so far and ask ourselves how best we can resolve the challenge. We try to find new ways to make our work easier and even easier for the applicant. I think we have progressed as a regulatory agency by doing all this kind of looking back and correcting thing. [Mel]

In this regard, the accrued knowledge on the FDA's cognitive routines established a basis for engaging in reflections to reconfigure their understanding and lay the foundation for future enactments. Utilising their shared understanding of the intentions of the regulatory review framework, as well as individual perceptual variations on the same, reflective monitoring allowed product evaluators to imagine how existing routines could be reconstituted and identify new ways of conducting product evaluations, and decisions thereof. The objective of this organizing practice, therefore, was to develop new action patterns that were strongly guided by the existing cognitive routines, yet responsive to both experienced and envisioned change in the NPI landscape. As a regulatory supervisor elaborated, the practice of engaging in reflections helped to refine their noncognitive routine enactments, and in turn initiate change in the cognitive routines. She said:

> We now defer alcoholic products that have aphrodisiac connotations. Before, we used to give conditional for them to change or revise the name. After a while, we noticed that this was not efficient, because most of the applicants just need the FDA verification number, so when we conditionally approve it, they take the number and then don't come back, and they don't change the names. With the conditional approval, they can sell the product but not advertise, which wasn't a problem for them, since they usually don't do any formal advertisement anyway. So as a control, we defer them, and then when they revise to a new conforming name, we grant them approval. This is actually a recent change. [Lucy]

The modes of interaction established during what was observed to be non-episodic change in existing routines helped to define the generative quality of the FDA routines in context and a reconnection of outcomes to core legitimate tenets of the broader context. They therefore provided a liminal space for prior accomplishments to be reviewed and resituated to accommodate emerging trends in both the wider the regulatory context and the innovation landscape. Far from being a mundane discursive engagement that wielded limited influence on the ongoing cognitive patterns of enactment, changes that were seeded through reflective mentoring re-shaped the noncognitive routines, which recursively transformed the cognitive routines of the FDA. In order words, reorienting the cognitive evaluation routines was a function of the ability to conceive a variety of noncognitive routines in the situated practices through reflection on prior routine accomplishments. This observation is further captured in the following quotes:

> As I said earlier, I believe that the way we are all able to review our work and suggest new ways to evaluate the product is very important if we want to keep up with the pace in the industry. For example, the new combinations of tree barks and other ingredients to produce alcoholic drinks means that we also have to redefine our product categorisation as well as the evaluation process to ensure that the products are safe. So, for us, even though the local bitters are also alcoholic drinks, we do the microbial test in addition to the ethanol, because they could still be contaminated. Sometimes we even do multiple testing. [Billy]

> The applicants have realised that they fail get approval because they have issues with the water they use in production. So now they use distilled purified bottled water to produce the samples. We have also noticed this, and we have decided to rely on the facility checks report from the enforcement unit to run alternative sample tests they may collect to verify the initial results, even though the guidelines and SOPs do not clearly state that we are required to do so. [Mina]

At the heart of this reflective action triggering change in the evaluation routines were the iterative conversations that were held about specific events or practices that posed inconsistency between the espoused cognitive routines and the situated occurrences. Here, the product evaluators were observed to engage in collective reflection through verbal actions (Edmondson et al., 2001), while situating a subject matter within emerging tensions between both (non)cognitive routines. Such conversational spaces facilitated the progressive unfolding of ideas on alternative conceptualisation and/or enactment of routines, which in turn opened up opportunities for change in the regulatory review process. The following quote from a regulatory officer puts this into perspective:

> When we look at how some of the evaluators at the FERD are using this risk-based approach to determine what products come to the laboratory or not, I think there is a need for us to have extensive conversation on the approach. The last time we met, we managed to agree on a few issues, and we were looking forward to them making the necessary changes. I, however, believe that more conversations will be held to resolve the challenges, as we have done before with several other procedures over the years. [Rose]

As the product evaluators discursively worked out ways to accomplish their situated roles and convey the intents or meaning of the products evaluation routines, they initiated a mutual adaption of both cognitive and noncognitive routines to the prevailing social and technological realities. In this respect, flexible mutation of the evaluation routines at the FDA had come to be dependent on a form of reflective monitoring that shifts between past and ongoing action patterns as well as the discursive frames that inform the future envisioned enactments. Informal conversational space was thus created when some form of change was perceived after reflection. The intended change then suffered rigorous

contestation as to whether it could affect the broader understanding of what the regulatory review process sought to achieve. Here, each participant provided their envisioned structure for executing the proposed routine, which was usually informed by their own reflection on the subroutine being discussed, hence extending the reflective space beyond the individual to a collective realm. Change was then achieved by creating a formal discursive space that reviewed the routine actors' mental maps for the trajectory of product evaluations as well as the proposed organizing practices for its performance. This thus established the codification process, which in turn characterised change in the cognitive evaluation routines of the FDA. The following quote from a regulatory officer underlines this observation:

> We were recently having discussions on why the applicants struggle to do the requirements we outline in our letters to them and realised that it is because they don't really understand what we ask of them in these letters. The conversation went up to the top [the CEO's office] and the head of legal, in consultation with the heads of unit, designed and trained us on the use of much simpler language to communicate with applicants. Even with that, there are times we realize that the client does not really get what we are saying in the letter, so we call, or we even invite them to come to the office, and we have a discussion to explain to their understanding. You know most of the applicant are not well educated, so it is very difficult for them to read and respond clearly to us. So, we have agreed to move a step further to call and explain to them the exact things we are asking of them. [Zoe]

This reflective practice was therefore observed to be pursued with an aligned integration of the participation of applicants whose socio-physical boundaries (Bucher & Langley, 2016) distance them from the actual performance of product evaluation routines. As such, the operational intent of effectively conveying the meaning of the product evaluations was undertaken with the observation of some contextual nuances that required the realisation of change in routines through discursive engagement with a non-participant in the routine enactment, but whose decoupled vision was affected by the execution of such routines. The data evidence further emphasise the high variation requirements that had to be fused to constitute a robust reflective framework to monitor the product evaluation

patterns. Here, it was observed that interactions with several actors of multiple interacting routines were established to co-create the reflective discourse. As such, the outcomes of the reflective exercise were seen to align with all other routine clusters that cumulatively constituted the regulatory review process. This was again revealed to be relevant to diminishing the influences discretionary control over the trajectory of product evaluations in this context, which posed threats to the legitimacy of the FDA within the broader regulatory landscape. The following quote by a regulatory supervisor subsumes this observation:

> We always use the existing body of knowledge we have about product categories to evaluate new products. And we know the product constituents once we see the product, but we still need to determine its composition scientifically. We run test to determine which contaminants is it predisposed, which microbial organism is it predisposed to. We re-examine our process and even the product categories to help come up with specific changes to the way we evaluate them. So, in this case, we discuss the emerging issues with the other departments, especially the laboratory and surveillance, so that we can all contribute to the change. This also helps to serve as some sort of check on each other and to remain guided by worldwide acceptable standards, and more importantly, to stay within the legislative instruments that set out our mandate as well as the legal regime that guides our day-today work here. [John]

In this regard, the noncognitive routine enactment, which has been proved to be efficient in the enactors' situated practice, was mobilised through the interactional reflective discourses to shape the adaptability of the cognitive evaluation routines. Staying within the guided regulatory framework remained an important aspect of this process. Surveillance on enacted routines therefore became constitutive in the process of ensuring stability and reorienting the existing patterns to the emerging dynamics of the NPI landscape. Reflective monitoring therefore underlined both the reproduction and transformation of the product evaluation routines. Though persistent, the cognitive routines set out the legitimate shared understanding of how routines were to be enacted, although they may come to be under threat from exogenous shocks and jolts. With the frame of reference itself being subject to non-constitutive change, the noncognitive routines once again emerged to salvage such chaotic events. The

diverse influence from multiple noncognitive routines shows how new evaluation patterns were constituted and actioned within the approved frames for executing product evaluation. The next section captures these arguments in detail.

5.5 Exogenous shocks and jolts

Although unanticipated events may be thought of as jeopardizing the execution of routines, such contingencies tend to yield ambiguous outcomes that offer opportunities for enactors to initiate new forms of routines in their situated practices. What was observed at the FDA was an archetypal case of bringing innovation to the fore, unveiled through novel ways of enacting product evaluation routines within the realm of organizing shocks caused by the Covid-19 pandemic. The pandemic was a disruptive external jolt that introduced chaos to the established systems of accomplishing situated tasks. The working conditions during this period meant that the co-working spaces that allowed collaborative practices to emerge and stimulate the conditions for enacting noncognitive routines were destabilized. This is because the health threat posed by the pandemic required that relatively fewer product evaluators could be present at the operational space to execute their situated roles. As one regulatory officer described:

> Right from the start of the pandemic, we were asked to observe the Covid-19 safety protocols that were proposed by the Ghana Health Service. So, it meant that less than half of the staff, including the evaluators, would have to be physically present here. And this was also the time we had loads of backlogs and were receiving a lot of new products, some of which were labelled as immune boosters to help fight the virus. And they were food products, so we couldn't move them to the drugs department to evaluate. It was a difficult one! [Lucy]

Nonetheless, the product evaluators demonstrated remarkable adaptive capability through the utilisation of such conditions to transform how the regulatory review process was organized in practice. The rich noncognitive realm of routine enactment enabled changes to the existing (and sometimes ad hoc) routines in order to provide stabilizing responses to the jolts caused by the pandemic and the

accompanying national lockdown. Effort was therefore made to ensure that the sorts of everyday situated practices that were drawn upon to sustain the intentions of the regulatory review framework adapted to the changing conditions. More importantly, given that durational elasticity for amending the cognitive routines would mean driving the review process to a halt, the focus here was on how the situated practices could be amended to address this problematic situation. Successfully pursuing this objective, the FDA demonstrated how radical shocks to coordinated and stable forms of organizing can be innovatively navigated without necessarily changing the cognitive routines of the organization. The concomitant outcome, therefore, was an opportunity for innovation in the noncognitive routines, which ensured consistency and stability of the intentions of the regulatory framework. As such, several of the situated tasks were accomplished outside of the work premises. A weekly rotation system was established where each regulator had to work every other week from home. A regulatory officer described this system, saying:

> We are now using a rotation system, so I am working from home and will return to the office next week. It's actually not too bad, because I still get the chance to call my colleagues to discuss issues or challenges I might be facing in evaluating a product. I came in today just to collect some samples. I usually carry the samples along when I would have to work on applications the following week, but I missed a few this time. I still meet my target though. [Bill]

In this regard, although there was a change in operational space for enacting situated activities, hence altering how they are enacted, the informant suggested that the benefits from collaborative practices in their coworking spaces continued to emerge. As such, the tacit knowledge that was shared to improve or accomplish the situated enactment of the evaluation routines created a means for navigating the new working conditions. Once the broader meaning, tools and competences had been maintained to execute the situated routines, a new normal was conceived and established. When asked about how the pandemic had affected the routines, a regulatory supervisor said:

> Well, aside from the health threat, the Covid-19 pandemic, to me, has been more beneficial because now it has taught us a new way of doing things. None of the

> evaluators here thought they could actually work from home, until it happened. Now I am saying that because of Covid, we can literally lock up this department office space and we can work from our home, globally, I mean everywhere. [John]

It was observed that the in-depth understanding of the demands of enacting the product evaluation routines which had pervaded the entire organization enabled the conception of possible alternative ways to navigate the ongoing challenge. Therefore, their awareness of the intentions of the situated practices, backed by the socio-cultural practices, allowed for the openness of routines to variations. A regulatory officer shared her experience in reviewing product advertisements and how evaluators had to alter their established practices in order to accommodate the challenges of the pandemic:

> Due to Covid and the many restrictions we have here, we have changed our approach to making decisions by deferring product ads straight away only when the concerns raised are based on the contents of the product. Before this, we could defer the ad based on grammatical errors or even font size. So now, in order to avoid delays in going back and forth with the ads, we call the clients. I think this has been very helpful because if calling the client to bring in the corrected versions rather than deferring or even rejecting for them to re-apply would help us to work within KPI, which is the number of days we're supposed to complete reviewing an ad, then it is a good way to make things easy in this time. So, yes, we simply call them, and they bring the correction, we approve for them. [Nora]

Preoccupied by the design of new ways to fulfil the aspirations and meanings of the organizing routines amid the perturbations caused by the pandemic, the product evaluators internalised their operational tensions in order to accommodate new forms of accomplishing task and fulfilling the objectives of the regulatory review process. Thus, in what was conceived as oppositional dualism (Rosales et al., 2022), which was informed by the distinct set of organizing principles, the everyday organizing routines at the FDA came to be mutually enabling in addressing the unanticipated problematic conditions. The following quote by a regulatory supervisor captures this observation:

> Despite the pandemic, we have made it a priority to ensure that we do our work accordingly. We are always and still looking for new ways of achieving our objectives as a regulatory agency. For instance, I think the current risk-based approach that we are using now was actually fast-tracked, in terms of the implementation, because of the pandemic. I'm saying this because it has been hanging for a while now and the debates surrounding it did not allow it to be fully operational and accepted across the entire food regulation chain. So, when we found ourselves in this pandemic, which was likely to make our job difficult, the new approach became an ultimate solution to help us to continue doing our work as expected, and even better. [Lucy]

Championing the combination of novel processes for achieving both situated and collective objectives, the FDA managed to contain the chaotic shocks caused by the Covid-19 outbreak. And as the set of new adaptive actions provided coherence and stability in the cognitive routines of the FDA, the ongoing patterns of routine enactment came to be reconstituted to provide new forms of organizing. In other words, as the product evaluators oscillated between the enactment of cognitive and noncognitive routines, to preserve the espoused meanings of the regulatory review process, a state of confidence was established to accept the new concrete expressions of situated routines. A regulatory officer shared his thoughts on how this new form of enacting situated routines could be an effective way of resolving challenges posed by resource constraints, while also signalling the potential for this to become an enduring part of the FDA's organizing practices:

> I think we've all become comfortable with the remote working. So, it is possible we can maintain this system even after the Covid-19 pandemic. Already the space available for all the workers is not enough, we don't have seats, desk, and computers for everyone to work. So, now that we're beginning to understand that this system is also efficient, it looks like in future, working from home will continue. [Ben]

While recognising the lasting tendencies of the existing working conditions, an integral element that allows for routine enactment across multiple working spaces to interconnect becomes instructive. Here, the role of technology in facilitating the effective enactment of new forms of organizing routines was observed to be utilized to allow the new forms of organizing to be feasible and easy to adapt (Kho

et al., 2019). Specifically, the FDA's use of application software interfaces to conduct product evaluations became the locus for enacting the adaptive forms of organizing routines. Thus, although the use of IT software had always been part of their day-to-day patterns of evaluating products, the unprecedent event created a necessary 'bang' to initiate its extensive application. Emphasizing the significance of such IT tools in the successful accomplishment of the situated adaptive practices, two informants said:

> What we've done to make working from home possible and also reduce delay in our processes is that we have deployed the Product Functionality System online. So once the evaluator has access to the internet, they can evaluate products and update their reports on the system. [Mina]

> The scientific part of our work which has seen significant changes is the risk-based approach. But now we are also reforming the processes which actually bring delays. So instead of the regional offices receiving applications and forwarding everything through transit to Accra for evaluation, after which we will communicate the decision to them, the online functionality system allows them to conduct the evaluations at their end and update the system online for the final decision to be made here. [Mike]

Also, it was observed that as part of the FDA's efforts to diffuse the technological competence of the evaluators situated at the head office to the other regional offices, an intensive training program was designed to achieve this objective. A regulatory supervisor who was part of this agenda highlighted:

> We're now training all FDA staff across the country to use the new software system. This is important because that is what we use here, and we have to integrate them into the system so that they'll also have access and be able to complete the registration process and give it status. There are new innovations and processes coming up that we also need to upgrade so that we can catch up with the trend, particularly when we know that the industry is operating very fast and is ahead of us. [John]

Employing modern technological tools as artefacts that complement the situated activities of evaluators, and as such improve the efficiency of the regulatory review process, the FDA is conceived

to be developing the competence needed to adequately regulate the emerging trends in product innovations for the market. However, since this technological artefact interacted with and influenced (or was influenced by) how routines were enacted in situated practice, it was further observed that upgrading the existing software system required the contribution of all evaluators to identify the core aspects that needed to be improved. In an interview conducted after a training session, a regulatory officer commented, when asked about how they expect the new software to operate:

> As most of the field officers suggested, they have issues with identifying whether there has been a new label for a product or not, so they often have to call the manufacturer or distributor. Some of the evaluators also talked about issues with the product categories and how they have been going about classifying them. We also heard comments on the confusion about who is responsible for what and so on. So, I think the new system [product evaluation and registration system] would have to capture all these concerns so that we don't have to come crying about these same problems. [Eric]

In this regard, it was observed that all actors within the product review process contributed to refining the new software prototype such that it was in congruence with the conditions of social practice that tended to shape their situated disciplines or roles. Here, the role of technology in facilitating the effective enactment of new forms of organizing routines was observed to be utilized to render such new forms persistent and durable (Pentland & Feldman, 2007). Thus, the emergent patterns of evaluation routines that were introduced through the adaptive responses to problematic situations, which were subsumed into the noncognitive routine enactment, found themselves infused into the cognitive evaluation routines through technological adoption. As a result, even the technological systems that served as cognitive prostheses to conveniently structure the situated routines came to be enmeshed in a socio-cultural milieu that forged the conditions of its application (Callon, 2021). This was quite well emphasised in the FDA's context, as technical experts who were imbued in the development of the IT software architecture had to draw on and replicate not only the cognitive patterns of product

evaluations, but also the tested adaptive practices that had sustained the intentions of the cognitive routines over time.

5.6 Chapter summary and conclusion

This chapter has sought to present empirical scrutinization of how noncognitive routine enactments identify, create, and inform innovative practices in regulatory review processes. It has provided a broad opening to acknowledging the network of socio-cognitive prostheses that intervene in the reformation of existing routine enactments. Specifically, the chapter has shed light on how the replication of regulatory standards exclusively adapts to the specific socio-cultural context, thereby leading to modifications. Thus, it was found that the regulatory evaluation routines at the FDA allowed for learning and replication of recognizable patterns of conducting product evaluations in order to be consistent with the changing conditions of the market selection environment. Yet the cultural repertories that enabled the execution of replicated forms in situated practice assimilated and nativized such routines to yield distinctive forms of organizing. The chapter further emphasised that product reviewers enacting noncognitive routines that infused their socio-cultural persuasions into the accomplishment of their situated task tended to portray the market-authorisation decisions as being informed by subjective judgements. However, this potential outcome was attenuated by influencing the perceptive evaluations of their audiences through collective enactment of internal and external deference. As such, the internal evaluative discourse was characterised by a deference obligation that the 'product review supervisor' (as superordinate) owed to the 'product evaluator' (as subordinate) to establish and signal the scientific objectivity of their preliminary decisions. Externally, a network of deference was also enacted through symbolic mentioning of affiliation with internationally recognised standard-setting institutions whose credibility was attested by the public, to signal validity and legitimise the context-specific forms of conducting regulatory reviews. Other strategic mechanisms, including the framing of the protracted review process as a way of ensuring scientific rigour or thorough scrutiny of products, were also adopted, since such practices resonated with the audience.

Offering primacy to the power of tacit knowledge imbued in the performance of noncognitive routines, the chapter went on to examine the impact of reflective monitoring on the existing pattern of product evaluation to negotiate change. This unveiled the underlying mechanism through which the evolving patterns of product evaluation were defined while sustaining the needs that were meant to be fulfilled to protect the legitimacy of the regulatory agency as a non-market selector. Regardless of this seemingly stable occurrence, the chapter further examined how jolts to the stable patterns of enactment may interrupt recursive interaction between the cognitive and noncognitive routines. Empirical observations were thus made on how the Covid-19 pandemic nurtured a tactic of compromise among the competing logics caused by distinctive tenets of situated roles. As such, the analysis provided in this chapter revealed how the product evaluators skilfully interpreted and navigated the contradictions embedded in the conceptions of their varying expertise to ensure the smooth running of the regulatory review process. Also, highlighting the need maintain stability in the organizational cognitive routines, the chapter explained how technology has come to play a critical role in achieving such intents. Specifically, the chapter highlighted the use of IT software to streamline operations at the FDA. However, such initiatives required the infusion of the situated adaptive action in order to efficiently capture the practical accomplishment of the product evaluation. As such, technology facilitating the effective enactment of new forms of organizing routines was observed to render the emergent patterns of evaluation routines that were introduced through the adaptive responses to problematic situations codified as part of the cognitive evaluation routines. In this regard, as conceptualized and empirically summarized as patterns of (non)cognitive enactments, routines themselves provide stability while the surrounding organizational structures and practices facilitate adaptation.

In conclusion, the situated enactment of regulatory evaluations has a great deal of socio-cultural contingency, which initiates noncognitive interventions that recursively emerge to define how change could be negotiated and lead to the identification of innovation in the regulatory review process. Therefore, the dynamics of the regulatory evaluation routines create a chaotic web of cultural repertoires, legitimacy-seeking, conversational and reflective spaces, and unanticipated occurrences,

which are altogether in constant flux. Thus, the noncognitive routines that are defined by the situated practice of the product evaluators are forged within a network of socio-cultural persuasion and scientific essence, which in turn provides the opportunity for creative and innovative ways of accomplishing the intentions of the regulatory review processes and framework.

CHAPTER SIX

Agility in evaluation routines: Navigating organizing constraints and enablement

This chapter presents a delineation of the underlying mechanism that define the evolutionary qualities of regulatory review processes within a rigidly cast evaluation framework. Specifically, the chapter provides a fine explication of the organizing routines that enabled or impeded change or adaption of regulatory review processes. This is espoused along the lines of organizing practices that establish asymmetrical capacity for executing situated actions, raise tensions within the interaction of distinct but complementary routine enactments, introduce frequent shifts and switches in organizing routines, and allow negotiation of change through co-opting and co-creation dynamics. The delineation of these theoretical themes is, however, preceded by an exposition of how the organizing practices of the FDA may shield this phenomenon within the system of social relations and organizing structures which characterise the paradoxical duality of inertia and change in routines. The final section summarises and concludes the chapter.

6.1 Duality of inertia and flexibility in evaluation routines

Situated actions underlying product evaluation routines (re)created the organizing structures of the FDA, which constrained and/or enabled adaptive responses that were reposed in noncognitive routine enactments. The regulatory review process, as observed in this context, was developed on existing coherent patterns that were systemised into a robust path for evaluating products. Since such established patterns had become internalised and shared among all enactors of the product evaluation routines, the organizing architecture that held these patterns into place underpinned the inertial qualities of the product evaluation routines to provide stability and consistency in the evaluation processes. Nonetheless, it was also observed that these structures provided the foundations for engaging in 'creative destructions' in situated enactments in order to sustain the relevance of the regulatory review process. This implies that the organizing architecture of the FDA sustained the

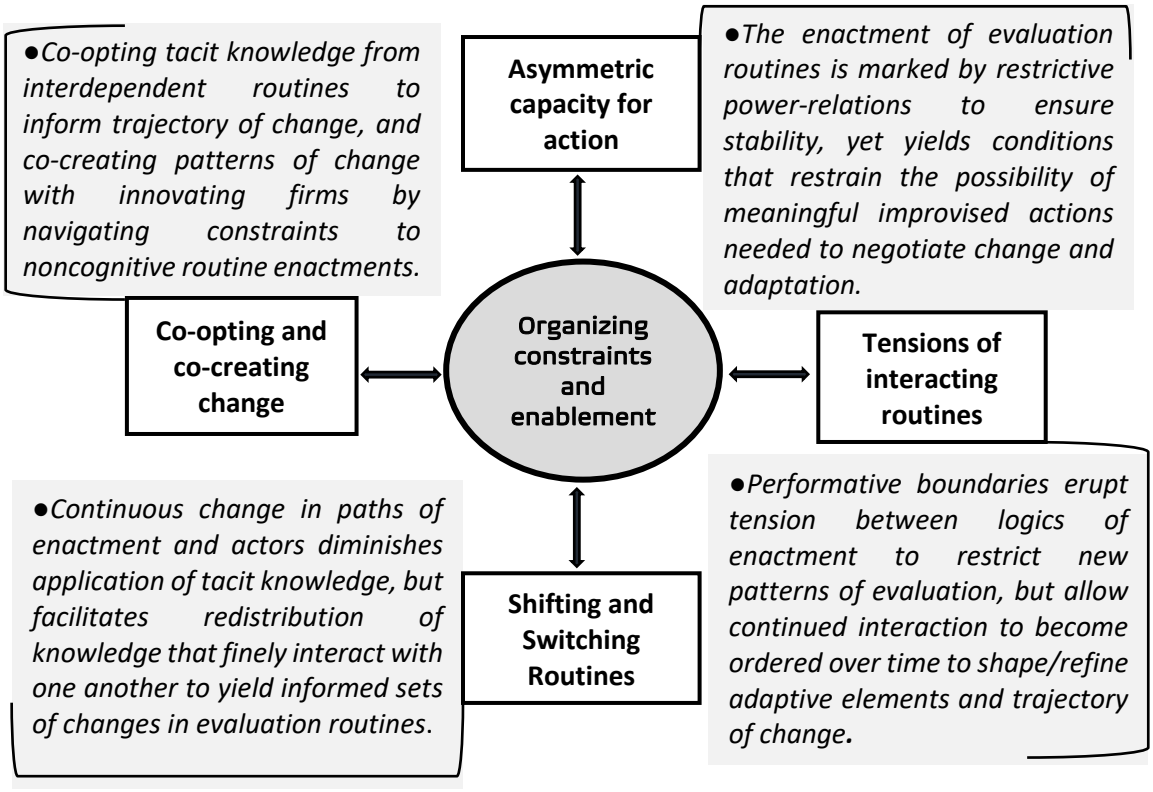
shared cognitive evaluation routines to establish order and (re)create patterns of action at every repeated instance. Yet, within this robust schema lay an organizing context which permitted change and agility as the shared cognitive routines became untenable in emergent dynamics. Thus, the regulatory review process at the FDA survived on a substrate of dual characteristics of routines as a set of stabilized patterns in recurrent form that were adaptive to new occurrences in the local material context (Dittrich & Seidl, 2018).

While observing the dual interplay of inertia and flexibility in the product evaluation routines at the FDA, the underlying practices that enabled (or impeded) the navigation of stability constraints were embedded within four main paths. First, the established organizing structure of the FDA recognized the performative boundaries of each routine enactor, which in turn limited the ability of product evaluators to independently initiate change in their situated practice. Thus, the enactment of evaluation routines was marked by the boundaries of hierarchical, structural features of the FDA. It was therefore observed that evaluation routines were executed along visible boundaries of authority, within which the product evaluator was restricted from investing in improvisations without the approval of an authoritative figure. Second, it was observed that the multiple interdependent routines, which were distributed and enacted over time and space (Feldman & Orlikowski, 2011), co-constitutively established the espoused patterns of the regulatory review process at the FDA. However, the constant interactions between the distinct clusters of routine enactors caused the eruption of operational frictions, which further created tensions that restricted creative improvisations, and sometimes enabled the same. The dynamics of interactions therefore provided a system of order in the chaotic outcomes of situated improvisations, while simultaneously shaping generative forms of adaptive responses that were initiated within the multiple situated interactive practices. Third, this structured pattern of organizing was designed to flexibly vary the routines and their enactors by switching and changing their situated roles. In this regard, although in-depth understanding of the situated practice was required to effectively enact noncognitive routines and alter existing practices to provide innovative approaches to navigate emerging challenges, this organizing practice restrained the

tendency to nurture deep-seated knowledge to inform change. Nonetheless, the cognitive coordination of embedded knowledge with new practical domains was also observed to provide the opportunity for redefinition of the situated practices and enactments.

Against this background, the adaptive qualities of the regulatory evaluation routines as observed at the FDA were nurtured through the navigation of the core capabilities and practices that are expected, and required, of a regulatory agency. Thus, although the rigorously established stable processes for product evaluation provided the basis for situating the FDA within a broader legitimacy dimension, defined by their ability to meet the primary goal of protecting public health and safety, such processes also needed to be navigated to develop new stable patterns in order to respond to emerging trends in the innovation landscape and the demands of the selection environment. While this may appear to solely emerge from within the organizing boundaries of the regulatory agency, the fourth path to agility was observed to emanate from shared insights among multiple routine logics and regular interactions between the FDA and innovating firms. Here, a shared interest in developing new patterns of situated actions that created a context for executing the network of evaluation routines underpinned the impetus for each enacted routine to offer possible ways through which the interdependent actions could co-evolve. As such, insights from all active routines in the regulatory review process were co-opted in the process of negotiation of change and agility in regulatory evaluation routines. Further playing out in the form of co-creation of evaluation routines, these interactions provided the means to minimise resistance to the assimilation of insights and knowledge on new products that were built on novel combinations of existing compositions or fundamentally new technologies. These collaborative efforts, which underlay the malleability of product evaluation routines, thus explain how the FDA was able to build a patterned change to bridge the knowledge gap in face new technological trajectories. The dynamic influence of these paths of constraints and emblements that (re)created organizing routines of the regulatory review process are depicted in Figure 6.1, below. The subsequent sections present the empirical characterisation of this mechanism in fine detail.

Figure 6.1: Summary of the mechanism underlying agility in evaluation routines



6.2 Asymmetric capacity for action

The sequence of relational activities that underpinned the organizing routines of the FDA was systematically defined along asymmetrically distributed lines of power and authority. Thus, the intended accomplishments of the product evaluators were reserved within their authorised boundaries of enactment, which in turn constrained their ability to engage in disruptive tactics to conceive new paths of evaluation in novel encounters (Cohen & Bacdayan, 1994). This implies that regardless of the intellectual grasp that a product evaluator might have about their situated practice to facilitate the enactment of noncognitive routines towards productive ends, the ability to accomplish such actions in its entirety was limited by the authoritative orders that they assumed. This observation was made explicit by a regulatory officer who, when asked why she did not immediately respond to new information that was useful in expediting the review process of a novel product, said:

> Because of my position and where I work, I don't have the power to do that. So, I hand it over to my boss. I just notify them that this is something I've seen and think this is how we should go about it, so what do they think about it. It delays the whole process but, you know, I'm not allowed to make such big decisions here [Mary]

As reflected in Mary's quote, the restricted order of enactment was defined by structured lines of engagement that has been established within the FDA. Noncognitive enactments were therefore perceived as discretionary and therefore were not considered to be a robust mode of enactment. While such tacit design and accomplishment of the evaluation routine might be operationally efficient in achieving the intentions and meanings of the regulatory review process, sorting out and implementing patterns of action that were not explicitly articulated in cognitive artifacts was perceived as strategic-level decision-making rather than situated manoeuvring. However, the implication of this organizing schema, which played out as a delay in the regulatory review process, found its justification in the ability to sustain stable, recognized patterns of product evaluation over time. As a regulatory supervisor put it:

> We know that sometimes the evaluators find new ways of evaluating the products which are not always clear in the guidelines. But we cannot just allow them to always adopt the new ideas they find; otherwise the FDA processes will not be clear [become ambiguous] and everyone will end up doing what they want. In fact, we might even end up doing things differently from what we have provided in the public domain, which will also affect our justifications for the decisions we make. So, this why it is important they seek approval from the supervisors before doing anything new. [Nora]

This formal boundary of authority, which was embedded in the accomplishment of product evaluation routines, provided a framework for coordinating the various situated practices that cumulatively defined the regulatory review process. Each line of engagement in this process terminated at an authoritative boundary which restricted interferences to control jolts that might erupt from the individual evaluator's narrowly informed creative actions. Nora's quote therefore suggests that the FDA considered its context of operation as one that required constant elimination of chaotic advances to the established patterns and standards of product evaluation. In this regard, given that a situated

action provides meaningful impetus for the subsequent ones (Kremser et al., 2019), permitting unbounded flexibility in enactments could harshly dilute the FDA's capabilities. And since such organizing capability was important to its legitimacy-seeking goals, efforts were made to cast its practices into more robust systems of organizing by stratifying the mode of enactment within the evaluation routines. Thus, the organizing routine of the FDA reinforced and deepened lines of authority by establishing an order of engagement which was described by the informants as 'levels of evaluation'. The following quote from a regulatory officer captures this:

> Our system here is according to levels. I may have an idea about how to go about the evaluation of a product, but I am not allowed to go ahead and do so: I can only inform my supervisor. At their level, they can make some of those decisions and it is acceptable. I must say sometimes it makes our work [processes] slow and complicated. [Dave]

This level of organizing thus provided limited room for the enactment of noncognitive routines. The somewhat agitating comments that the informants offered reveal a phenomenon where the patterned structure of fixed activities did not lend itself to operational flexibility. Thus, the capacity to bring into enactment acquired experiences and knowledge became restrained, thereby impeding agility. While adding to concerns about levels of enactment, Billy said:

> So, when it comes to the decision to do something different, it is always difficult at the evaluators' level. You may find that a product may not need to go for laboratory testing based on CoA, but it may be classified as high risk, so we still send it there. There are times that we might have to seek the advice of the heads of unit, especially for products that would undergo further processing, which will further reduce their microbial load. So, then they can decide, looking at the CoA and what we have found. It's always like we must complete the process and if we need to make any changes, then that change must be approved by a supervisor. [Billy]

The distinct capacity to initiate change at the various levels of enactment thus posed a challenge to establishing fit to the evolving present in lieu of new product designs and innovations. Furthermore, given that the product evaluator's decision to accept, defer or reject a product did not culminate the

regulatory review process, they took cognisance of the fact that their improvised accomplishments might not influence the final decision; neither might they trigger overall adjustment in the received patterns of product evaluations. As a regulatory officer highlighted:

> The decisions do change along the line. After all, the evaluator's decision is just a recommendation. The don't have much power in terms of the final decisions. All we do is to evaluate the products according to the guidelines and standards. If we think there is a way to improve certain aspects of the process, we can go ahead and do it, but it will depend on whether the unit head agrees with you or not, because they are going to defend the decision at the final evaluation meeting. Even at their level, they are not allowed to make some changes unless they have received approval from the CEO's office. This is important because you know we are working according to global standards. So, we must be careful the way we go about our work: otherwise, we might lose our accreditations and that will affect our reputation as well. [Zoe]

The organizing structures of the FDA were further cast in a relatively inflexible system which cut out conversational spaces for discursive struggles to (re)shape the patterns of enactment. Here, a Product Functionality System (PFM) which was designed to streamline and expedite their activities saw further upgrading (to Product Evaluation and Registration System), did not only side-line conversational spaces for change enactment, but also provide oversight over how consistency was maintained, and boundaries acknowledged, within and across routine enactors. Pat described this system by saying:

> The approach we use here when we have a novel product, and we do our research to find ways to evaluate them, is to have a discussion with the supervisors so that we all agree that is the best way to go about evaluating the product. But looking at the new IT systems that we are using – I mean the Product Functionality System, which is now being upgraded – we're only allowed to raise concerns about a product or bring new insights on board through the system. I think this makes it a bit difficult for us to hold discussion and agree, because it becomes more like we're just writing to each other. And it is not even a platform to engage in chatting: we just put the information there and wait for a response. So, for now it is only the meetings that we hold that helps us

> to discuss some of the issues or new ways we find. Because if we are to go strictly by the system…ah! Then we will be doing things like robots. [Pat]

While Pat highlighted the importance of conversational spaces to enact, validate and codify noncognitive routines, the emergent organizing structures and practices at the FDA tended to restrain the potential to engage in such discursive modes. In this regard, it was observed that the material artefacts designed to influence and mediate non-patterned activities eventually broke the relational engagements that often gave rise to adaptable paths to respond to situated cues. Here, the IT systems at the FDA were designed to constrain the persuasions of social configurations that might dominate in product evaluation routine enactments. However, the product evaluators conceived the system's rigid marking of limits to their *initiative-taking* endeavours as an impediment to the negotiation spaces through which new patterns were conceived, enacted, and maintained. A regulatory officer provided a critical analysis of this established practice:

> I think, and most of my colleagues share this concern, that the new IT system we are operating is likely to make our work more complex to do. The system is trying to capture all the product categories we have here as well as the various sub-categories. But we also know that regulation is dynamic, and therefore we cannot say that we have captured every single detail on the systems. Here is the case that we are being asked to send comments on novel products through the system, when before we could simply discuss, share ideas, and find ways to evaluate those products. I really wonder how they came to the idea that only the regulatory supervisors understand the process and can make changes. [Mina]

As the product evaluators became caged within a predefined order of enactment, adaptive forms of situated enactment became rather difficult to realise. The data evidence therefore suggests that these barriers to the actioning of noncognitive routines at the FDA drifted into what was observed to be a self-reinforcing practice that gave momentum to potentially re-enacting dysfunctional evaluation routines. In this respect, the regulatory review process was perceived to mismatch with the emerging dynamics of the innovation landscape, thereby causing operational lags as they struggled to define

astute evaluation standards for such NPIs. And given that the realm of practical enactment presents a maelstrom of interactions between what the cognitive routines prescribe and how the day-to-day situated encounters shape actual actions (Kremser & Sydow, 2022), the quest for stability preceded the potential innovative outcome from cognitive routine enactment. Yet, this complexity in enactment reserved the finely honed skills and knowledge required to respond to changing conditions (Nayak et al., 2020) and navigate the uncertainty with which the evaluation of novel products was approached. In this regard, restricting the flexible application of such tacitly acquired knowledge obstructed the product evaluation framework from nurturing sensitivity to the high-velocity innovation landscape. A regulatory supervisor put this into perspective:

> I can say with confidence that the guidelines and standards we have here are comprehensive because it is designed using the global regulatory standards. That is why we are well recognized in the world and have all the accreditations for that. But the most important thing we have to realise is that things are always different here and the evaluators who work on the product every day know what is actually going on. So, we should allow them to work from their experience sometimes, not always having to come to us before we approve for them to use new approaches they think are appropriate. And even with us, we don't always know what to do. And we don't always have the authority to change anything. What we do is provide justifications as to why this was evaluated this way and not the other. In the end, the reasons for our decision on a product is what we focus on, rather than how it was actually done. [Lucy]

While drawing attention to the significance of tacit knowledge that the product evaluators acquired from their situated practice, Lucy first emphasised the regulatory processes at the FDA being consistent with globally accepted standards and approaches. She narrowed her observations to the objective underlying the final regulatory decision taken on a product. The significance of her verbal expression therefore lies within her highlighting how conformity to the cognitive routines took precedence at the FDA. Situated enactment was thus expected, and efforts were made to ensure the same, to achieve a fit with the prescription within the cognitive representation of the evaluation routines. The preoccupation with adhering to the standard had informed the keen focus on establishing

boundaries for situated improvisations in order to resiliently maintain their reputational standing within the broader regulatory landscape. Consequently, the strict limits to the capacity to enact change in evaluation routines rendered the recursive relationship between cognitive and noncognitive routines problematic. The enactment of evaluation routines was profoundly marked by restrictive power-relations to ensure stability, but which yielded conditions that restrained any possibility of meaningful improvised action to negotiate change and adaptation (Rosales et al., 2022). The following quote by a regulatory supervisor, however, extends this observation by revealing how this phenomenon exists not only intra-routines but also inter-routines which collectively constitute the regulatory review process:

> At the client service level, once they record all the basic information about the product, they have to push it to our level. This will be at the level of the head of unit, who will give it a status as 'pending evaluation'. This is where the evaluators have assessed to the product and the system based on the reference number. Then we do all the evaluations, check, and verify all the details of the product, so that will be preliminary level. And this is where we become a client-to-laboratory-service department when we send the product for them to run their analysis. And after the evaluation, they push it to 'pending registration'. This means that it is out of the unit now, to the level of head of department. They compile the list of all the evaluated products for the period, maybe from beginning of the month to the end of the month, and call the meeting table to make the final decision. Sometimes we hold a pre-decision meeting where the evaluators, the heads of units, will hold a meeting to deliberate on the issue that we have raised. So sometimes there are issues that you have not seen, but through the meeting, they may see other issues [Billy].

Billy's description of the regulatory review process as constituting levels of evaluation further sheds light on the authority boundaries which characterised product evaluations at the FDA. Here, an improvised action at one level might trigger turbulence along the various levels of evaluation. This also had consequences for the final decision, which was why pre-decision meetings were held to ensure conformity to standards. Billy's quote further brings into focus the unique form of performative boundaries that exist between the multiple routines enacted at each level of evaluation. The interdependencies between relational activities that created the context for routine enactment for each

other became imperative for maintaining stability and ensuring flexibility. Thus, the asymmetrical capacity for action between routines faced some contesting intuitions that rendered the boundaries fluid and adjustable. The next theme explores this in detail.

6.3 Tensions of interacting routines

The regulatory review process at the FDA was observed to be actioned into life through the combination of distinct units or clusters of routines (Kremser et al., 2019; Kremser and Schreyögg, 2016). In this regard, the execution of product evaluation routines was enacted within a network of interlacing routines that created or extended the context of enactment for one another. Thus, the task of product evaluation at the FDA was not a single complex routine, but rather was distributed amongst subunits of enactments that provided partial or continued contribution to accomplish the regulatory review process. This complex web of interacting routines was, however, caught up within situated practices that were actioned by professionals/experts who had a distinct orientation to, or understanding of, the intentions of the regulatory review framework. Put starkly, multiple specialised blocks of closely interacting routines operated in combination to cumulatively frame the regulatory review process at the FDA. This implies that the experts at the general evaluation unit, the laboratory analysts, and 'field evaluators' at the post-market surveillance (PMS) and enforcement units, all had distinct orientations, perceptual values, logics, and dispositions, which were reduced to the somatic and cognitive resources defined by the disciplinary instincts of their situated practices. In this regard, all actors in the product evaluation process held an idealist view of how regulatory reviews should be conceived and enacted accordingly. The following quotes depict this observation:

> The work of the FDA really is about prioritizing our activities based on the risk that the products pose and our resources. This is the norm, even in the general global regulation: it is the risk which informs how we are to channel resource and efforts. [John]

> I think that in regulating products, comprehensive testing is really important. And of course, comprehensively evaluating products is not by adopting a risk-based approach because we want to know what really the products are and the emerging trends. [Jane]

> All we have to do as a regulatory body is to ensure that we are in control of the industry. We know the problems that exist, so our aim should be to intensify our surveillance and monitoring activities. Perhaps it should start from getting into the industry and finding out who the main players are. There are a lot of producers who submit high quality samples for evaluation but they're doing all kinds of unsafe mixtures. And it is important for us to know what is being offered for sale. We should be able to bring all of them under control to regulate their activities. So, as a regulatory body, we need to go out there and do some serious quality monitoring. [Eric]

This set of quotes, captured from informants at the FERD, the FDA laboratory and the PMS unit respectively, highlights a nuanced contradiction embedded in the understanding of their role routines. In this regard, it was observed that the organizing structures for product evaluation at the FDA involved the making of multiple cognitive patterns of role routine enactment that were informed by the conditions of the focal situated activity. The continuous *coupling up* of these distinct operational routines into a modular system of organizing created interactions that stirred up an inherent operational tension. In other words, the multiple idiosyncrasies of the routine enactors instigated a contestation of the situated practices of the 'other', and thus created operational tensions among the product evaluators. This was observed to arise within their operational spaces, with one attempting to impose their role perspective of the regulatory review framework on the 'others'. This phenomenon was particularly manifested in the informants' descriptions and understandings of the new risk-based approach to product evaluations that had recently taken prominence to shape the regulatory review process. A regulatory supervisor described the risk-based approach as follows:

> Historically we have resorted to more or less hard documentation and long list of evaluation requirements. Now, I think we have learned enough from the job, and that is why there is this paradigm shift in our way of working here when it comes to food evaluation and registration. We are currently using a new approach known as risk-based approach to food registration. [Mike]

Another informant highlighted the fundamental logic for the adoption of this new approach, with an effort to frame the scientific rigour underpinning the process.

> Fundamentally what the risk-based approach means is that we are applying science to the work we do. By science, I mean now, instead of strictly going by what the books, literature and standards tell us, we look at what the empirical data [are] telling us on the variable or parameters, which helps us to make decisions. For example, if we disaggregate the list of products, we have at minimum 18 product categories. For these categories, we have over two decades of data in terms of analysis that we have conducted and even received from different laboratories globally. The question then is, what is the data telling us about particular food composition? We find that we pick a product, and we can be 100% certain that some specific parameter will be okay based on the data we are having. In that sense, we need not run a test for that parameter. [John]

Indicating some form of dramatic shift in operational logics, the informants' keen interest in this new approach to product evaluation was observed to be underpinned by their situated framework of reasoning and envisioning of the regulatory review process. As both quotes are sourced from informants at the FERD, it is revealed that their expected consistency with the codified forms of conducting product evaluations was held within their shared conception of what their situated enactments must achieve and what ends the regulatory review framework as a whole ought to satisfy. However, the affected interest of the other routine enactors with different roles and orientation to the intentions of the regulatory review process, particularly that of the laboratory analysts, challenged these established interpretations at the FERD. A supervisor at the microbiological laboratory argued:

> We realise that there is a lot of subjectivity in the selection of parameters to test and application of the standard. There are instances where the standards state clearly what parameter we must test and verify, but the request that comes and those parameters are not included. Sometimes it appears they are oblivious of what the standards say. And when I ask, they tell me that they are working based on risk and that it is not every parameter that they request to be tested. So, in the end they decide to test only the ones

> that they think is relevant. I for one do not think this is the right approach. We must run detailed analysis of every single product. [Rose]

Rose revealed how she skilfully exploited the contradictions embedded in the new operational logics to cast the situated routines at the FERD as less desirable. As such, the ongoing contest over these new logics of evaluation was grounded in the notion that the established methods for evaluating products needed to be sustained in order to maintain the perception of scientific rigour and objectivity conceived by their clients and the general organizational audiences. In what seemed to be a counterargument and response to this contesting idea, a regulatory supervisor said:

> You know, regulation doesn't mean we should be static. We must continuously be using new information, knowledge, the emerging scientific processes, and even new evaluation standards from the various international regulatory bodies to do our work effectively. So here when we pick a particular parameter of interest, we start building data on it to get enough information in order take on an agenda to review the existing ones: that is, either to delete or add on. The risk-based approach is evidence of our efforts to improve the way things are done here. [Mike]

In this regard, the foregrounding of means to pursue the objectives of the regulatory review framework at the FDA was shaped by the encounter with opposing expertise in the collective accomplishment of the product evaluation routine. Thus, the interactions within multidisciplinary domains of executing crucial routines that were in partial fulfilment of the product review process created the opportunity for innovation in the conduct of the product evaluations. Nonetheless, the data further reveals that such new forms of organizing routines remained latent, being invoked only partially, until they had acquired legitimacy amongst all involved actors. Thus, there was a deliberate effort to capture the core values and intents encoded within the multidisciplinary expertise of the participating routine clusters. Particularly, the prevailing sub-cognitive patterns of routine enactments that cumulatively constituted the evaluative discourse at the FDA demanded that the practical intents of the situated enactment inform the tenets of the new product evaluation routines. A regulatory supervisor recounted how these approaches, competing for dominance in the product review process,

were made to settle within a consensual structure for organizing regulatory reviews by framing a cognitive legitimacy for the new logics of evaluation:

> What we are doing is about utilizing the data we have to improve on the work we do. This is in fact the basis of the risk-based approach. We did a trend analysis of all the parameters that borders on safety, particularly the microbiology. So, we pick a specific product and look at what the standards require. So, per the test we have run over a minimum of five years, we did a trend analysis, and we came to the conclusion that there are some products that over the years did not record any form of microbial deterioration or contamination. So, all those products fell within the low-risk category and therefore those parameters are no longer important to us. What this means is that we have moved them to what we call monitoring. And the monitoring implies that though we have deleted them from the main requirement as a prerequisite for registration, in terms of continuous safety monitoring of products on the market, we need to check them from time to time through the activities of the PMS. So, if PMS check and have issues of non-compliance, then the facility departments will pick them up. Where there is a need for industrial support, we support them to be able to come into compliance once again. It is as simple as that. [John]

This emphasis on the crucial role of the PMS in the survival of this new approach to evaluating products also suggests an encompassing legitimising strategy to ensure that the intents of the risk-based system resonated with the activities of the field officers. Thus, higher level routine enactment was constructed through attribution to and/or reinforcement of the core mandates of pre-existing schemas for enacting the situated routines. Satisfying this ecological uniqueness of the multiple disciplines that controlled the enactment of the evaluation routines thus created a way for the new form of organizing to become embedded within the situated assumptions of the multidisciplinary routine enactors. The objective therefore was to ensure that there was little contestation in the minds of the product evaluators in order to effectively execute the new modes of collective action. Yet, the strategic efforts to reshape the dominant reasoning that shaped the distinct principles of interpreting the regulatory review process, though they might be well received, continued to face probing and re-

examination. For instance, a field officer who found a locus for the operationalisation of the risk-based approach contended:

> I think the risk-based approach is in direction. After all, it is going to bring a lot of efficiency in terms of speed of product evaluations and registration. For us at the Enforcement unit, and of course as those as the PMS as well, we are ever ready to monitor those products on the market, and their various manufacturing and storage facilities, to ensure that they are conforming to the regulatory standards. But we also have to be careful with the way we are going by this whole approach, because anytime we go to the market we find new products, even these alcoholic drinks. They will assume that the products are low risk, but the manufacturers may be adding new ingredients which are unsafe. So, they may end up allowing unsafe products on the market. They must have very convincing sets of data to fully implement this. Otherwise, we are also going to struggle with doing a job here. [Ana]

This sentiment was shared among other laboratory officers, who found the new approach to be a progressive way of fulfilling the objectives of the regulatory review processes but had reservations about the conditions that were required to trigger such a huge change in the process. The following quotes illustrate these concerns:

> Now the decision to do risk-based testing must be based on knowledge. They should have been very familiar with a product, having analysed it, to be able to know that, okay, for this product, in this our local environment, this is the data that we have, and this are where the problems are. So, for example, we can say that they have a problem with yeast and mould. And therefore, if somebody submitted a cereal product, and you want to do a risk-based analysis, you will focus on the problem for the specific product and not the general concerns. But we realise that they are not informed by such data. [Josh]

> Well, risk-based approaches are good. In fact, it is a fantastic idea. I mean the science behind it is very good, but it's the underpinnings structure are what makes the risk-based decision credible. I have some issues with the way we are going about it because a risk-based decision is made based on data and based on scientific facts. If you don't have it, your decision will not be right. When you don't have the data, you don't have

> the scientific backing, so making a general conclusion then becomes problematic. For example, if we say that the level of aflatoxin in products A and if we look at the risk and we think it is low, so we should allow it to go, I will ask that you give me at least six years' data of that company showing that over the past six years, their records in that parameter has always been low. If you can show me that, then I think I mean that this is right. But if we don't have that data, then I don't think we should make that decision. And even with that, it'll mean that new products, from a specific company, that fall in the low-risk category would benefit from the approach. Not the general set of products in the category. [Dirk]

Regardless of this varying perception, forming a contradictory exposition on the new forms of organizing, the imperfectness of the conditions of practice allowed for the adoption of some sort of tactics of compromise (Mitzinneck & Besharov, 2019) in order to define a consensual path for conducting day-to-day product evaluations at the FDA. Highlighting how the FDA was able to muster the participation efforts of all routine enactors to ensure the successful implementation of the new approach to product evaluation, John, who seemed to be a key advocate of this new process, added:

> I think now we have all come to understand that this is the best way to go forward. A paradigm shift in the way we do things here. But I must say this, in order to get rid of any doubts, that when it comes to new products coming for registration, there's really nothing new in terms of products emerging. What the industry does is re-formulation of the existing products. But in terms of the product itself, is the same risk that we are predisposed to. So, there will always be issues with, say, aflatoxins and mycotoxins. Meaning that there will always be enough scientific basis to be able to make a clear decision on this. And I'm saying that through the empirical data we've gathered over the decades, we've gone through processes to legitimize that as a basis to regulate so there will always be a reference point. [John]

In this regard, although there was potential for this phenomenon of tension between interacting routines to destabilise the ordered patterns of evaluation routines, their continuous interaction rather tended to become ordered over time to shape how the product evaluation routines were executed. Settling these relational work tensions was, however, rooted in the ultimate objective to enhance the efficiency of the regulatory review framework. The interactional mode of these clusters of organizing

routines at the FDA was therefore found to be mutually recursive and coevolving with the awareness of, or at least an appreciation for, the possible nuances embedded in the distinctive objectives within the situated disciplines.

6.4 Shifting and switching routines

A reflective gaze on the data further reveals a unique phenomenon at the FDA which had a fundamental influence on how its organizing practices enabled or constrained noncognitive routine enactments. Here, the identifiable blocks of routines were restructured in response to emerging complexities of both the regulatory and innovation landscapes. This implies that the logics of situated routines, which oriented the enactor to a frame of reasoning and understanding of the intents of the regulatory review framework, experienced some form of operational turbulence. Thus, a regulatory officer imbued in the practical intents of their situated practice was introduced to a new set of routines that required an often-fundamental shift in logics in order to make sense of the new patterns. Although a switch in routine might not require an entirely contrasting orientation to a new set of regulatory intents, since the aggregated objective remained the same, the specific enactments within which an evaluator had developed competence and nurtured practical knowledge changed and offered one that the evaluator must learn anew. The following quotes illustrate this:

> When some of these structural changes are introduced, it is either we have to move to a totally new unit, or our work objective is changed. So, we always have to learn new things about new work roles. [Lucy]

> About a decade ago, we had a food safety management department, and that is where I was. We were in charge of the informal producers. But all that have changed and I'm now with the food enforcement department. We started with the food enforcement department having the post-market surveillance and consumer complaints under it. We also had advertisements being part of us, but that's moved to registration now. In fact, all these units have either been added to others or are now departments on their own. So now the enforcement unit is solely for inspectorates: that is, inspectorate of warehouses, manufacturing facility, both local and foreign. [Gabi]

The nature of the change in routines therefore triggered some cognitive burden for the evaluators, who had to relearn new aspects of the evaluation process. Lucy lamented that her previously acquired tacit knowledge had become contested and limited in application as she came to be situated within a new set of enactments. She therefore revealed the core relevance of tacit knowledge that manifested in noncognitive routine actions towards the successful accomplishment of the given task or role. For Gabi, her concern was about losing a holistic understanding of the evaluation process, as many of the interrelated tasks were being decoupled. This implies that the ability to enact noncognitive routines that create a convenient context for subsequent routines would become limited. As a result, any form of situated improvisation was enacted in isolation, as there was limited appreciation and consideration of subsequent or related routines, hence, having to face repulsion from related routines. Adhering to these organizing practices would thus create esoteric knowledge that would come to be harboured by the few enactors of the defined set of actions. Ultimately, the recurrent shift in focal enactments in a specific evaluation routine created a void in consistency, thereby limiting the ability to develop the impetus to initiate noncognitive routines. The following comment from a regulatory officer sheds light on this:

> I can see the FDA's effort to make the evaluation process simpler and more straightforward. That is why changes are always being made in order to break the whole process into smaller units and departments. So, some units that used to be one have been divided into two, new ones are created, and we the evaluators also get moved to other units and departments. What I have observed is that we continue to operate like we might struggle to have evaluators who have very good understanding of workings of a particular unit or department because they are always moving from place [routine] to another. And they might not be able to give proper recommendation as to how a particular unit or department can improve. [Billy]

While the change in organizing structures of the FDA was geared towards establishing a more flexible evaluation process, the legitimate concern raised by Billy hovered around the tendency to develop an archipelago of multiple interdependent routines. As a result, tacit knowledge became

remote from related actions, restrictive in creating context for subsequent routines, or even making fertile the conditions for receiving and continuing previously accomplished sets of enactments. The data evidence therefore suggests that the core characteristic of routines as adapting to emerging conditions, which was largely reposed in the situated accomplishment of its enactors, was rendered dysfunctional. Here, deeper learning to warrant such accomplishments was truncated through constant shifts and switches in routines, making the rooting of experiences into the cognitive crevices of the enactors problematic. Further insights revealed from the data suggest that the regulatory officers often relied on long association with co-enactors to build both social and cognitive bonds to negotiate adaptive forms of routines and practices (Danner-Schröder, 2021). Such ties provided significant avenues of engagement to allow knowledgeable routine actors to re-engage the discursive frames underlying their situated activities. Thus, the operational intents, as well as the mechanised means of fulfilling those aims, came to redefined through the constant interactions with evaluators who had devoted considerable time and energy to nurturing the otherwise implicit canons of a specific task. As a regulatory officer put it:

> We work as a team. So, if we are always [constantly] having people move around, it makes it difficult to discuss the issues we face in detail. The longer one stays with us the more they understand our work really well, so I think it is important that they stay for a long time to know what really goes on here. [Ana]

This quote extends the socio-cognitive relevance of a stable co-working space to shed light on the inextricability of cognitive interdependency in the accomplishment of routines. Thus, the close-knit relationships that existed between routine enactors over time engendered confidence that spurred the evaluators to hold the belief that each 'team member' was imbued in the situated practices that defined their task (Turner & Rindova, 2012). The regulatory officers therefore placed emphasis on shared experiences that nurtured common sentiments about the existing patterns of actions and the potential trajectories of change in the routines. In this regard, changing the enactors or the set of routines itself was perceived as an impeding condition that limited their ability to co-enact with one another. This

suggests that the product evaluators relied on an often-distributed tacit understanding of situated tasks to provide cues for their actions as well as design modes of change and improvisation. While this reveals a somewhat collective effort by a set of routine actors to accomplish the intents of the situated roles, the key emphasis they made here was that the ability to cooperate with one another was dependent on the extent to which one was engaged in enacting those set of routines. Thus, a continuous enactment of routines was perceived to have cognitive benefits that contributed to the negotiation of change and adaption of the evaluation routines. The following quote by a regulatory officer puts this in perspective:

> I, for example, used to work at the lab [laboratory] and I was moved to FERD. I must say initially it was quite challenging. I could see that the staff here know a lot about the products. They are able to place the products into categories and tell how they should be evaluated and even whether to take a product to the lab or not. I mean, these are usually products that there are no clear guidelines. So, I was always asking around for help and reading the guidelines. And, you know, when they are discussing something new that they have seen and think it could be useful, I could barely contribute. [Zoe]

Nonetheless, this switching and shifting of routines as a form organizing strategy of the FDA did not entirely proffer gloom and doom for the regulatory review process. The data evidence suggests that such practices provided opportunities for deep-seated knowledge to be transferred across all aspects of the evaluation process. When asked about why evaluators were moved to other units, particularly those from completely different departments, a regulatory supervisor said:

> Usually, it is because some of the staff have different interest and have acquired some special skill or training that are needed elsewhere. Sometimes it is because we need to change our processes [structures] here to meet standard requirement and their skill will no longer be needed at the existing unit, so they need to be moved to another appropriate department. [Gabi]

While explaining the logics of change in the organizing structures of the FDA, Gabi's remarks highlight the importance of maintaining the FDA's repute and legitimate position within the regulatory

landscape. It is thus significant that changes in the organizing architecture were made in order to keep up with emerging trends. Gabi continued:

> I also used to be stationed at the laboratory, but at the time, we were doing pretty much everything, including the post-market activities. So, when it was time for the agency to upgrade and receive accreditation, we had to break us into the various departments. I was considered competent to help and be part of the enforcement and surveillance unit, and I brought all my experiences to the field. [Gabi]

Against this background, it is observed that the evaluation routines were, in themselves, subject to change, given the contextual contingencies. The situated actors therefore played an all-important role in seeing to the realisation of such change, particularly given that the FDA's organizing routines were in an evolving pathway towards establishing a definite framework for evaluating products. Thus, the transfer of knowledge and expertise became relevant in creating a network of competencies that finely interacted with one another to constitute a robust set of regulatory evaluation routines and practices. Re-situating the product evaluators in new routines therefore served as a significant mechanism for redistributing knowledge for developing a complementary set of practices. The following comment from a regulatory officer underlines these observations:

> When we are evaluating the products, we usually look at the values on the CoA and cross-check to see if those values match with the ones that have been recorded in the lab and see if they are okay or not. And then another thing too is you may check if it's to undergo further processing. Also, we now rely on the idea that if the product will undergo further processing, for example cooking, or will be mixed with more alcohol [for the local bitters], then we can consider how much of the microbial counts are likely to be reduced in that process. You know, all this understanding comes from the fact that some of the staff here have previously worked at the laboratory before coming here so they understand the science behind the whole process. [Dan]

The data evidence thus suggests that switching and shifting routines and their enactors aided in the transfer of core fundamentals of the regulatory review framework. Therefore, these organizing practices not only underpinned the deployment of shared patterning, but also allowed the assimilation

of noncognitive actions by all actors of the evaluation routines. Furthermore, they served as an avenue to understand the perceptual orientation of the multiple blocks of routines that combined to fulfil the operational meanings of the regulatory review process. And although this variation in the routines and their enactors was not initiated to develop identical frames for conceiving how product evaluation was to be conducted, such arrangements provided a common place of relational understanding that rendered the situated action congruent. In this regard, given that processual nature of the evaluation routines at the FDA, defining a compatible set orientation to the intentions of the regulatory review process nurtured the ability to trigger and influence change in the related routines. What was observed at the FDA was that regulatory officers' broader understanding of all aspects of the evaluation process aided their ability to anticipate the responses from enactors of interrelated routines. Thus, they were able to initiate noncognitive routines that took into account the interpreting frames that were existent in other routines in order to equally support the improvised action in those routines. Armed with this nurtured skill and experience, actors who had gained experience served as a reliable source of insights and monitoring of the noncognitive enactments. The following quotes put this into perspective:

> I have always said that it is important that everyone understand what is going on at other units and departments. It really helps because then you are aware of how the things we do here will affect their activities as well. We have a number of officers who have come from other departments: you can see from when they are defending how they have evaluated the product using the guidelines that they have a holistic view of the entire process here. [Mike]

> We sometimes run into situations where there are no clear standards for a product, so it becomes really difficult to know what sub-category to place it and of course what test is required in addition to basic ones. What I do is that we ask one of the evaluators who has experience from the microbiology laboratory, so sometimes if I need help, I can discuss with her, and she'll guide me as to what to do. She even sometimes explains how a particular test is done and why a product might not require additional tests after the standard ones are complete. [Joan]

As the data evidence suggests, the distributive nature of the practical knowledge that was deployed through the restructuring of organizing routines at the FDA helped to provide harmony and stability in evaluation routines as well as to inform change and adaption of the regulatory review process. In addition, an important insight that emerged from this phenomenon, and the data at large, was that the dynamics that triggered change in evaluation routines were co-created through the interaction between the multiple actors from distinct but related blocks of routines. Here, the tension that existed between multiple routines, and which shaped and refined elements of change, did not inform the trajectory of change. Rather, it was observed that there was a deliberate effort by the product evaluators to adaptively enact noncognitive routines in a way that corresponded to the activities in related routines. Thus, the transferable insights from the multiple routines came to shape the direction of change and adaptation in a focal routine. In addition, in conditions of the product evaluators' interaction with the innovating landscape, a co-creation dynamic prevailed. The next theme captures this phenomenon in detail.

6.5 Co-opting and co-creating change

Patterns of situated actions at the FDA exhibited evolutionary qualities as product evaluators became familiarised with ongoing practice across routines. In this regard, the relational action and interactivity with actors who were imbued in different operational intents provides insights as to when and how change should be (re)negotiated to enhance the adaptive qualities of the regulatory review framework. As such, through the discursive interactions, and often through the acquisition of practical experience from engaging in multiple routines, the product evaluators were allowed access to information regarding the logics that underpinned the various routine clusters. Thus, the organizing practices that enabled this form of interaction between the multiple actors formed the basis for deliberate interrogations into innovative ways through which a focal routine could be adjusted to create a more convenient context for the enactment of other related routines. It was therefore the willingness of actors of a given set of routines to draw on their tacit knowledge, which was shaped by understanding of

logics embedded in related routines, to engage in noncognitive routine enactments that would anticipatively ignite change in the product review process. The following quote underlines this observation:

> We know that the QA [Quality Assurance] is always in talk with the head of laboratory to ensure that we have the capacity to run a particular test that is being asked for as well as discuss which test is appropriate for the nature of product described. But sometimes when the products come in, we can see that when we do only the test requested for our clients [referring to FERD], they are likely to come back for some additional tests. So, when this happens, our head, who has more experience in regulation and even represents the FDA on the standard-setting committee, can recommend that we should test for A or B in addition to the original request. So, in that case, it makes it easier for the clients to make their credible decisions and speeds up the process. [Josh]

The following comment by a regulatory supervisor who had prior experience from the laboratory also sheds light on this phenomenon:

> I do have conversations with some of my former colleagues at the laboratory and they tell me a lot about the challenges they face and how our activities can improve to help make their work a bit easy. For instance, with the new risk-based approach, a lot of discussions went on to ensure that the change … won't cause further challenges for the those at the laboratory and even the post-market surveillance team. So, yes, we do get information from other departments to ensure that we are all on the same page. [Lucy]

Furthermore, the data revealed a co-evolving pattern of enactment that occurred through an alignment of situated actions within and between related routines. The blocks of evaluation routines developed a cohesive interaction that facilitated a relational process of negotiating change across routines. Consequently, deep-seated knowledge became migratory as it travelled across multiple action domains to proactively construct the foundational elements that facilitated and characterised the co-evolving pattern of the multiple interdependent routines. As the organizing practices at the FDA continued to provide space for such conditions to emerge, change in the patterns of action became both

relational and processual. Thus, change in the evaluation routines was evocative in the socio-cultural repertoires that allowed and galvanised relational actions. A regulatory officer commented on this:

> We just had a training session … where we were being introduced to a new software program that we will need to do our work. It was done together with the enforcement team because they will also need the same software to verify products when they go to the industries to check their factories and warehouses. [Tom]

Tom emphasised how the cohesive relationship between the set of routines at the FERD and the food safety enforcement unit established a co-constitution of adaptive forms of action in their situated practices. More importantly, his quote makes apparent the extent to which the relational enactment of routines was defined through their shared technological system for fulfilling distinct but related intents of the situated actions within either department. In this regard, although the regulatory officers at the FERD were experiencing a form of change in the paths of executing the evaluation routines, this change was not fulfilled in isolation. Rather, it drew in actors of the interdependent routines to fully institute and formalise the emergent form of enactment. Further insights from this observation are revealed through the following quote:

> Although we are making changes to our processes at the FERD, we're also looking to ensure that this change runs across the entire operations. That is why the software that has been introduced contains all our activities, from the client service desk all the way to surveillance and enforcement. You know, we cannot just make the change here without considering how the other departments we work with can benefit from it or even help to ensure that the system change becomes efficient. Moving forward, I think we might even have to add the laboratories to the system. Also, the applicants' views should be taken on board when we do the next update. [Billy]

Change in a specific routine at the FDA was therefore expected to have a 'bullwhip effect' across the entire range of routine clusters that constitute the regulatory review process. In this regard, the noncognitive routines were cast within a complementary network of relational enactments that co-existed to shape and inform the nature and direction of change in regulatory reviews. However, the regulatory framework, standard and cumulative activities were not developed and executed

exclusively without assimilating the commercial interest of the innovating firms or the benefits that the public may accrue from products. The continuous morphing of the regulatory evaluation routines was therefore tied to the ability to accumulate insights from the market selection environment. At the FDA, this was observed to be a rather implicit display of efforts to respond to industry needs. Here, deliberate and explicit systems were not designed to rein in these insights as the product passed through the product review process. Rather, situated improvisations provided the opportunity to responsively capture the critical information needed to refine the patterns of product evaluation. A regulatory supervisor made an important observation:

> When dealing with the clients, they sometimes explain to us why it is difficult to meet a specific criterion or do a particular test. They even complain about the whole process in terms of the documentation and requirements. So, what we do is, we are able to tell them how to go about it. But most importantly, their complaints inform us on the things that we, as regulators, can also change to help the process. [Mike]

This quote highlights how the navigation of regulatory uncertainty became entangled in the complex repertoires and routines that sequentially defined the paths of product evaluation. Yet, it also sheds light on the value of the direct interactions between the FDA and the innovating firms in shaping the patterns of evaluation. As a result, there was inherent interdependency between the FDA and the innovating firms through which the shaping of regulatory evaluation routines towards adaptive ends was consummately achieved. A regulatory officer provided further reflection on how this practice enabled the FDA to remain up-to-the-minute on the emerging trends in the industry:

> Some of the information we get from the clients are very helpful to the way we evaluate products here. Not long ago, we evaluated some of the bitters that had very good test results on the CoA from one credible institution that the FDA recommends, but when we took to our laboratory, it failed some key microbial tests. It was not until recently that we found out from one of the applicants who we were keen on getting the products reviewed as quickly as possible that they mix some other ingredients with the products which minimizes the microbial count over a period of time. And beyond that period, the test may record high volumes of microbes. So now we are looking into the

> particular ingredient to see whether it is safe and how long it remains active in the product for, so we can decide on how much time we should wait before testing them. [Mel]

In addition to what was observed to be a revolutionary episode in this quote, it reveals that the knowledge gap between the FDA and the innovating firms could be bridged. Therefore, this quote underlines the regulatory effort to capitalise on evaluators' interactions with the innovation landscape to inform change. Here, Mel provides insights into the adaptive responses which she claimed lay in the ability to amend the evaluation routines to include defining a 'fallow period' before running the various tests on the products. This is indeed important information that ignited situated practices that were not explicitly defined in the cognitive routines, but rather in the socially informed noncognitive enactments that provided the conversational space for such intuitive revelations to emerge. A regulatory supervisor also shared some key insights on the co-optation and creation of outcomes:

> We realised the applicants always want a contact number to call us on. So, the client service always gives them the one for the front desk, which is simply for them to call in and get updates on the status of their product. But that is not really what they want to hear or know. They usually need further explanations on what to do next, how to respond to our earlier feedbacks, or what exactly we are requesting of them to add to their submitted documents. And the problem here is that we as evaluators are not allowed to call any applicant directly. So, what have found is that when they phone in, we have asked the client service desk to take their details, call them back and tell them they are going to speak to one of FDA agents and then they connect the call to us. In this way we are able to directly answer their questions and explain things to them. [Pat]

In this regard, a new set of situated actions was introduced to the set of enactments in the product evaluation routines through the iterative interactions with the clients. The noncognitive enactments therefore included telephone communication to address impediments to achieving the intentions of the regulatory review framework. Although this had not been fully codified within the cognitive routines of the FDA, the creative navigation of organizing constraints enabled an adaptive

response to an emergent situation. As such, the data suggests that the organizing routines of the FDA, which aimed to attenuate the potential influence from applicants on the product evaluators through preconditioning mechanisms, limited the applicants' ability to communicate directly with the evaluators to gain clarity on the regulatory requirements. Yet, given that the local context for executing the regulatory review framework was characterised by critical challenges such as limited access to clear and accurate information on the nuances of the product innovation domains, as well as a continuously evolving regulatory requirement, it was practical for the product evaluators to adopt this unconventional approach. Thus, the navigation of the contact-restricted organizing practices played out in the form of maintaining the core intents of such constraints but also enabling the ability to conceive enacted complexity through unanimous but direct interaction with the applicants. Again, this approach to gathering key information to improve the evaluation process was deemed efficient by a regulatory officer, who said:

> When our officers engage with the client, they are able to help them get through our process and we also benefit from the knowledge that we get about the industry and how they understand our work here, so that we can either strengthen or improve our work. Especially, those on the field who do the surveillance, those at the port and the enforcement unit. They get the first-hand experience of what the industry is doing, as well as how the market is responding. All this helps us to improve our work. [John]

Against this background, the direct engagement with innovating firms allowed the FDA to acquire deeper insights into the industry responses and reactions to their evaluation processes. Having in mind the tendency for the industry to equally manoeuvre the regulatory systems to its favour, access to what John described as "first-hand information" remained critical to the FDA's legitimate role as a market intermediary that controls the flow of NPIs to the selection environment. Thus, the emergent qualities of the evaluation routines were realised through adaptation towards the realised conditions of the innovating firms. As such, the co-creation mechanism was relevant to establishing congruence between what the industry perceives the product evaluation to achieve and the actual intentions for

which the regulatory framework was putatively developed. A regulatory supervisor emphasised the importance of ingesting the experience of the innovating firm to conceive change in evaluation routines:

> I believe that if we allowed the industry to tell us about the challenges they encounter with our work and even how they recognize the role of the FDA as important or not, it will help us to know what to explain to them and how we can improve our work to make things easier for them. Also, I think when they are able to voice out their challenges and suggest solutions, we would be able to make appropriate change, and they will all be willing to bring their work into compliance with the standards and requirements. [Mike]

Therefore, the co-creation mechanism expanded the scope of possible conceptions of agility from which the FDA could construct and legitimise patterns of change. The array of insights that emerged from the industry would become the foundation for defining a local rationale for product evaluations, which were, however, not markedly antithetical to the established standards that conferred a reputable position to the FDA within the broader regulatory landscape. Thus, as the FDA juggled the primary objective of ensuring public safety while at the same time encouraging the innovation outputs, a well-formed system of engagement with the industry was deemed relevant to meeting the needs of the fast-evolving innovation landscape. The organizing practices that impeded this important path to agility were nonetheless manoeuvred by the product evaluators through their noncognitive enactments. which emerged to ensure both stability and flexibility in evaluating products.

6.6 Chapter summary and conclusion

Against the background of insights from the empirical data, which suggest a navigation of the organizing structures of the FDA to negotiate stability and change in regulatory review processes, this chapter has sought to provide a fine-grained explication of the organizing routines that impeded and enabled noncognitive enactments in regulatory evaluation routines. More importantly, it provided both a theoretical specification and an empirical characterisation of how cognitive routines that have proved to be efficient in the evaluation of products became the established system of enacting routines such

that the prevailing practices tend to impede further emergence and execution of noncognitive routines in creating change in the patterns of evaluation. However, attuning to a 'Janusian thinking' on the epistemic interpretation of this phenomenon, the chapter has provided a delineation of how this robust system of ensuring stability in evaluation routines also constituted a frame of manoeuvring that satisfied the stable intents of the regulatory framework as well as the agility in organizing routines. The underlying mechanism for achieving adaptive ends of the regulatory reviews was subsumed in the noncognitive enactments that allowed creative actions to flourish.

The explication of these dynamics began by first defining the enacted complexities of situated practices within the paradoxical dynamics of inertia and flexibility in evaluation routines. Following this, the chapter captured in detail the organizing contingencies within such situated dynamics that occurred to co-constitutively (re)create the patterns of product evaluation. This was subsumed in the practice of aligning situated actions with the codified processes, which were enforced through the well-defined authoritative boundaries and capacities for execution. Thus, the enactment of noncognitive routines was bounded within a set of situated capacities that determined the ability of a product evaluator to develop and implement improvised forms of actions in the face of emerging contextual cues. Providing further explication on the organizing contingencies that impeded and enabled the domination of noncognitive routine enactment in defining the emergent qualities of the product evaluation routines, the chapter went forth to unveil the dynamic outcomes of the operational tensions between interacting routines. Therefore, a fine-grained explanation of how competing conceptions of the core objective of the regulatory review framework could be achieved to systematically shape new forms of product evaluation routines.

Furthermore, the chapter sought to explain how the practice of switching routine enactors as well as the nature of routines to be executed came to limit the ability to nurture tacit knowledge for noncognitive enactments. However, within these organizing constraints lay the ability to transfer logics of the multiple interdependent routines in order to align the patterns of change. Finally, through the

switches and shifts in routines emerged the ability to nurture collaborative knowledge that minimised the tensional relationships that existed among interacting routines to engender new forms of executing situated routines that were informed by the multidisciplinary routine enactments. The chapter has thus provided an understanding of how cognitive legitimacy was constructed through the constant interaction of distinct clusters of situated routines that collectively constituted the regulatory review process of the FDA. In what appeared to be a never-ending sharing of logics to accomplish the regulatory evaluation routines, the discursive space for engaging influenced the conception of trajectories of change in the situated routines. Thus, it was revealed that this process facilitated the ability to co-opt logics that were relevant to defining change in a specific routine. These organizing practices, however, extended beyond the organizing boundaries of the FDA to included interaction with the innovating firms. As the innovating landscape expected experiences of the regulatory review processes to inform the patterns of change, the FDA conceived that taking on board insights from the industry was a way to establish an up-to-date, rigorous evaluation process that would attract compliance. In conclusion, the dynamics of the regulatory evaluation routines involved the creation of a web of mutually enabling relationship between stability and change. Thus, the emergent outcomes of organizing routines, subsumed in a complex multiple enactment of routines, cumulatively constitute how the regulatory review process was maintained as stable and dynamic.

CHAPTER SEVEN
Discussion and Conclusion

Regulatory reviews have come to dominate contemporary discourse on innovation management and the strategic survival of firms in today's high-velocity market (Gao & McDonald, 2022; Polidoro, 2020; Roca & O'Sullivan, 2022). Several studies have sought to provide important insights into how the regulatory review process is inextricable from the new product commercialisation process, as the technical and scientific evaluations conducted on products effectively serve as a means to ensure that product innovations conform to approved standards and safety requirements (Olson, 2008; Rindova et al., 2005; Wiegmann and Roca, 2021). Amongst these standards are the efficacy and safety concerns that need to be mitigated to protect public health, as well as the challenges posed by market failure (Gao & McDonald, 2022; Guidi et al., 2020; Prieger, 2002; Sherman et al., 2017). More importantly, regulatory reviews are deemed essential to mitigate the challenges resulting from the asymmetrically distributed nature of information within existing markets (Downer, 2011; Polidoro, 2020). As a result, regulatory agencies sustain their role as non-market stakeholders whose activities determine the transition of new products from the laboratory to the market. Their activities tend to shape the dynamics of market conditions to influence the success of innovations, since they signal product quality and safety to the market (Kessler and Chakrabarti, 1996; Polidoro, 2020, 2013), determine the speed at which new products are introduced and commercialized in the market (Chorniy et al., 2021; Polidoro, 2020), and frame categories for new products to the selection environment (Tharchen & Garud, 2022).

However, this thesis argued that research on regulatory reviews to date has only managed to provide insights into the phase-gate scientific analysis that underlies regulatory decisions and the constellation of non-market strategies that innovation firms adopt to influence regulatory review processes. While some studies have focused and emphasised on the significance of the role regulatory agencies in safeguarding public health and safety (Carpenter, 2004; Hargadon & Douglas, 2001; Polidoro, 2020; Sherman, 2017), others have drawn attention to the delays, cost, uncertainty and

knowledge gaps between regulatory agencies and innovating firms as impediments to the new product commercialisation process (Blind, 2017; Gao & McDonald 2022; Kwon et al., 2022; Polidoro, 2013; Prieger, 2007). Yet, there remains limited understanding of how regulatory agencies organize and (re)structure their evaluation processes and frameworks, and adapt to the changing needs of the innovation landscape and markets. More importantly, little attention has been paid to how context-specific dynamics may serve as the influential contingency that underpin differential categorisations of products and distinct strategic frames to establish regulatory agencies' legitimate interactions in the market selection environment and define the local rationale for conducting product evaluations. These insights, as argued in this thesis, have long remained scarce. It was further argued in this thesis that this is largely due to the extant literature being replete with studies that are developed in stable and well-established contexts and industries where rules are clearly described, standards are explicitly defined, and socio-cultural persuasions and normative controls have minimal influence on regulatory agencies. Thus, understanding of how situated actions and socio-cultural and cognitive constructs cumulatively influence and shape the regulatory review process and decisions in highly volatile and turbulent contexts, where institutions are weak and markets are underdeveloped, remains scant.

Against this background, this thesis has set out to provide both theoretical understanding and empirical characterisation of how the everyday adaptive practices of product evaluators, which are socio-cognitively defined, contribute to efforts to (re)define the regulatory review process and adjust the regulatory frameworks to respond to new markets, production processes and the changing market contexts within which the technologies underpinning products are developed. The thesis focused on providing insights into the dynamics of regulatory review processes by drawing on the concept of routines as a theoretical frame to conceive the interdependent activities that constitute regulatory review processes. Specifically, it explored the context-specific contingencies influencing the conduct of regulatory reviews by drawing attention to the meanings, competences, and socio-material artifacts through which logical adaptation in regulatory review processes can be conceived. Thus, abstracting regulatory review processes as patterns of actions and practices that are bounded by both scientific

testing rules and social, organizational, and cognitive factors (Cohen, 2007; Feldman, 2000; Pentland and Rueter, 1994), which are 'enacted' into life by multiple and situated performative accomplishments by product evaluators, the thesis viewed regulatory activities through the conceptual optics of the *practice perspective* of routines (Feldman & Orlikowski, 2011; Parmigiani and Howard-Grenville, 2011). The onto-epistemological positioning of the thesis was, however, meant to capture Cowley and colleagues' notion that "cognition is everywhere in the organization and that it becomes very difficult to disentangle it from organisational human activities" (2017, p. 326). Therefore, a conceptual distinction between organizational cognition and that of individual agents' tacit knowledge, which does not lend itself to codification, was emphasised (Nayak et al., 2020, p. 282). As such, the thesis conceived the regulatory review process as constituting (non)cognitive routines which subsume both recognizable codified patterns of organizing and tacitly honed skills and knowledge that are brought to fore in the review of a product.

In providing empirical expositions to characterise these conceptualisations and fill existing lacunae in the literature, the thesis carved its contribution from an agile regulatory agency embedded in a setting where markets and institutions remain underdeveloped, thereby creating the impetus for continuous change and adaption in response to dynamism in both innovation and regulatory landscapes. This context was deemed fruitful for understanding how the dynamic interplay between (non)cognitive routines and the influences of socio-cultural artefacts (scarce or abundant) and repertories may come to define the process of regulatory review of NPIs. Moreover, the enactment of noncognitive routines in this context was perceived to yield variations that are assimilated into the regulatory agency's cognitive routines, thereby helping to account for the mechanism through which change, and adaption of regulatory review frameworks is realised. Focusing in on the regulatory evaluation routines making up the review process for new alcoholic beverage applications, the context provided a fertile ground to observe and explicate how social practices and the dispositional mindsets of product evaluators about alcohol consumption cumulatively influence the evaluation routines and decisions. In this regard, the thesis rendered priority to observing regulatory officers in their effortful

enactment of routines in their situated practices, which are guided by documented procedures and codified processes, while unveiling their experiences and tacit knowledge through the verbal accounts of their purposeful everyday actions. In this vein, documentary materials on cognitive routines of the FDA were initially analysed, which provided an optical prism through which to observe their practical enactment. The observational data thus revealed how organizing structures, social practices, and situated improvisations led to some actions which were either fairly distinct from the espoused process or, more importantly, not initially codified in the cognitive representational documents. This thus informed the lines of questioning and discussions that were held during the thirty-one semi-structured interviews with regulatory officials and evaluators across all blocks of interdependent routines executed at the various departments and units involved in the regulatory review process. The inductive analysis of the qualitative data revealed three main findings, each providing both theoretical and empirical responses to the three important questions that this study sought to answer.

7.1 Regulatory evaluation routines as a cognitive affair

The first set of findings provided insights into the active cognition involved in the enactment of regulatory evaluation routines (Lazaric, 2021). More importantly, it unpacked how the patterned sequence defined as organizational cognitive routines interacted with the creative enactment of the routines by active agents in ways that were conceived as the noncognitive routines in regulatory review processes. In this regard, a fine balance was achieved between the organizational cognitive routines and the situated practices that yield noncognitive routine enactments to explicate the mechanism through which (non)cognitive routines co-constitutively form the complementary substrates upon which the patterns of organizing at the regulatory agency become implicated in the processes of (re)negotiating organizing reality and change. Specifically, the findings suggests that in the context of regulatory reviews at the FDA, the organizational cognitive routines were a representation of the knowledge structures about what repetitive patterns of evaluation ought to be enacted. Meanwhile, the

noncognitive routines were cast within a deep structure of the product evaluators' minds, and were repetitively expressed in the situated enactment of the cognitive evaluation routines. The theoretical specification of this phenomenon was captured as an interplay between differing cognitive demands to successfully enact and accomplish the intention of product evaluation routines at the FDA. Rooted in the experiences of all actors across the bundles of routines within the regulatory review process, the findings emphasised how frequency in routine enactment and tacit knowledge gathered from prior engagement in multiple clusters of organizational routines helped to refine the FDA regulatory officers', supervisors', and laboratory analysts' competences in executing their situated tasks. Thus, the tacitly honed knowledge that enabled adaptive responses in unfamiliar events was an accumulation of in-depth understanding of the logics and intentions of the cognitive patterns of product evaluation.

Interestingly, given that legal and scientific justifications underpinned the decisions that emerged from the enactment of routines, the findings revealed that the regulatory review process did not allow for mere trial-and-error experimentation with new routines without the involvement of cognitive representations. As such, the intentions of the routines were somewhat preestablished but were only creatively imagined in the enactment of the noncognitive routines. This, however, suggests that although established rules, standards, and codified guidelines in the broader regulatory framework continued to drive such actions, the enactment of these cognitive patterns in the situated practice often required the immediate design of new routines to allow for situational sensitivity and affordances. Furthermore, the findings provided an explication of the process through which such tacit knowledge, skills and improvised forms of enactment become codified into the cognitive routines of the organization. In this regard, the situated experiences that enabled product evaluators to effectively navigate the evaluation of novel products, and sometimes novel conditions, was extracted and absorbed into the cognitive evaluation routines to provide much more efficient patterns of action. Laying this observation parallel to the interaction that exists between declarative and transaction memory (Cowley et al., 2017; Miller et al. 2012), the findings have underlined that the organizing structures of regulatory agencies are designed to ensure that the effective creative responses of the

evaluators served as a modification tool that sustain the intention of the cognitive evaluation routines in dynamic conditions. The mechanism through which this knowledge-gathering activity was purposefully initiated to encode the noncognitive routines into the organizational cognitive routines is thus quintessential to defining the regulatory review process at any material moment.

Nonetheless, as these interactions went on to label the content and sequence of product evaluations, creative destruction emerged in some of the existing cognitive patterns of product evaluations. The findings thus revealed that the cognitive aspect of the evaluation routines that guide situated enactments is sometimes rendered inefficient; hence, those routines were found to have experienced decay and elimination from the codified routines. In this respect, the recursive interactions between the (non)cognitive routines informed patterns of change in the organizing routines of the FDA. This was further reflected in aspects of the findings which revealed that the evolutional trajectories of the organizing routines of the empirical context were bounded in a set of endogenous mechanism that triggered, defined, and established the adaptive qualities of routines and structural change in patterns of organizing through the cognitive bandwidths of the product evaluators. In essence, the duality of stability and change which is conceived by the concept of routine dynamics (Feldman et al., 2016) is reposed in both identifiable action patterns that are coded in artefactual materials to inform situated practices, and skilled adaptive actions of the routine participants in the bid to sustain the relevance and intentions of the organizing routines (Feldman, 2000; Feldman & Orlikowski, 2011; Feldman & Rafaeli, 2002; Nayak et al., 2020). The dynamics of product evaluation routine enactment therefore underline that the cognitive realm of routine conceptualisation that dialectically captures the relational and mutually enabling aspects of routines becomes relevant in unpacking the active cognitive interactions between rules and learned practice, which provide stability in coordinating day-to-day organizational activities (Danner-Schröder, 2021; Garud & Rappa, 1994; Geiger, 2022).

7.2 Innovation in the regulatory review process

The findings further unveiled how noncognitive routine enactments identified, created, and informed innovative practices in regulatory review processes. Thus, a broad opening was offered to acknowledge when a socio-cognitive prosthesis intervenes to re-form the existing product evaluation routines. Narrowing in on the specific mechanism through which this was achieved, the findings suggest that replication of widely recognized regulatory standards, rules, and guidelines exclusively adapted to the specific conditions of the socio-cultural context within which their enactments were unleashed. Put starkly, it was found that although the organizing routines of regulatory agencies allow for the transfer of recognizable patterns for conducting product evaluations to varying regulatory contexts, the cultural repertoires that enable social structure to spell out the institutional configuration that shifts absorption of the transferred patterns from replication toward adaptation. Thus, the execution of replicated forms of evaluation routines in situated practice assimilate and nativize such routines to yield distinctive forms of organizing in order to be consistent with the changing or novel conditions of the market selection environment within the applied context. It was therefore clearly espoused in the findings that the broader cultural norms that define social practices establish a set of contextualised knowledge that informed the situated logics for enacting the regulatory evaluation routines. This, for example, led to situations where the context of products development yielded distinct product categorisations (Tharchen & Garud, 2022), which were informed by the local perception of what the product is and how it is consumed (Akyeampong, 1995). Complementary to this categorisation condition lies what the thesis captures as an extension of regulatory decisions beyond scientific logics. This was found to exist such that the evaluation of products is narrowly construed in somewhat socio-religious persuasion about the use and abuse of products, particularly that of alcohol beverages in the social context. Thus, in addition to the scientific evaluation of product constituents at the FDA, a perceived social dynamic that exhorted some products to be transubstantiated to satisfy certain superstitious objectives required tactful analysis that drew in other non-scientific connotations, such as product naming, which eventually influenced the final regulatory decisions.

Against this background, the findings suggested that the unique elements of the context within which regulatory reviews are conducted is rooted in the organizing practices of the regulatory agency, playing out in the form of relational thinking among the product evaluators. The accomplishment of the regulatory review process is thus found to be confined in a network of common socio-cultural meanings by which product reviewers understand and enact their situated roles accordingly. However, given that such practices might provoke tensions in the market selection environment and the broader regulatory landscape, the regulatory agency observed in this study drew on other institutional policies as a form of local mediation to confer legitimacy to such socio-cultural controls. Specifically, within the conceptualisation that there were noncognitive routines that were enacted in product review processes, the socio-cultural persuasions that were infused into the execution of situated tasks tended to portray the market-authorisation decisions as being informed by subjective judgements. The strategic measures to attenuate such perceptive evaluations of the organizing routines as normative systems were effortfully orchestrated through collective enactment of external deference. As such, the evaluative discourse within the regulatory agency cultivated symbolic interaction with overarching or peer regulatory bodies whose association shielded them from 'legitimacy threat' (Hiatt & Park, 2013), and who were particularly important for signalling the robustness of the regulatory review framework and specific actions. This was further found to be expressed within a network of deference (Jourdan et al., 2017) that was enacted through symbolic mentioning of standardizing institutions – such as the WHO, ISO, Codex Alimentarius, ANAB, and the like – whose credibility resonated with the market selection environment. The symbolic mentioning of affiliations with and accreditations from these internationally recognised standard-setting institutions conferred credibility to decisions elicited by the regulatory agency to certify them as robust and valid, and to legitimise the context-specific forms of evaluating products. The interaction between these institutions and the culturally held ideals that underpinned the situated enactment and contextual interpretation of the regulatory review process thus created innovative ways to refine and realign practices with established regulatory guidelines and evaluation standards. Adopting such standards, however, not only contributed to the efforts to render

credibility to the FDA's product evaluation processes, but also signalled quality and efficacy for products it approved to other jurisdictional markets.

Furthermore, drawing attention to the power of tacit knowledge that are infused in noncognitive routine performances to enact change in evaluation routines, the findings revealed how reflective monitoring of the existing pattern of product evaluation serve as a diagnostic tool to ascertain avenues to negotiate change and provide adaptive solutions accordingly. This unveiled the underlying mechanism through which the evolving patterns of product evaluation are defined while sustaining the needs that are meant to be fulfilled to protect the legitimacy of the regulatory agency as a non-market selector. Here, a conscious attempt was made at the FDA to understand how best cognitive routines can be made to fit the local variations while, at the same time, identifying what could be endorsed beyond their bounded social setting. Hence, conversational spaces were created to conceive some form of change based on the evaluators' own experiences and reflections on the subroutine being discussed. The reflective outcomes on the evaluation process were thereafter infixed in the ongoing patterns of evaluation, while establishing supervisory actions to contain the new logics of action within the core boundaries and tenets of the evaluation framework. Through this practice, the product evaluators were able to navigate the constraints of pre-existing routines to alter their situated actions and refine the cognitive routines. Yet, in addition to this imperfect system of organizing, which received continuous efforts to conceive innovative ways of achieving the intentions of the regulatory review processes, came a daunting response to environmental jolts and technological shocks. The findings further made clear how the Covid-19 pandemic set the scene to nurture a tactic of compromise among the competing logics caused by the distinctive tenets of situated roles. As such, the product evaluators skilfully interpreted and navigated the contradictions embedded in the conceptions of their varying expertise, to ensure the smooth running of the regulatory review process. Moreover, the regulatory agency introduced new avenues for conducting product evaluations remotely. The significant role of technology, although initially disorienting to product evaluators, came to streamline operations at the regulatory agency.

7.3 Configuring change through 'clustering' and co-creation mechanisms

While the thesis continues to hold on to the notion that "change is not the rare, episodic phenomenon … but, rather, it is endemic to [organizations]" (Brown and Eisenhardt, 1997, p. 1), it was found that the constantly fluxing and transforming organizing routines in the context of regulatory reviews is marked by a dual condition of *impediments* and *enablement*. The configuration of change in the context of the FDA encountered cognitive routines that had proved to be efficient in the evaluation of products and thus had become the established system for enacting situated patterns of actions. Such routines came to underpin the shared internalised practices that tended to impede further emergence of innovative practices through the execution of noncognitive routines, in the process creating change in the patterns of evaluation. Thus, the organizing practice of the regulatory agency sustained a shared cognitive evaluation routine to establish order and (re)create patterns of action at every repeated instance, thereby characterising the stable patterns of product evaluations. This finding further emphasised the efforts made by the regulatory agency to ensure stability in evaluation routines as a core aspect of their operational objective (Food Standards Agency, 2022). Yet, as evident in the innovation literature, regulatory evaluations often struggle in the face of innovations that emerge from within a non-existing technological domain or completely novel fields (Kwon et al., 2022; Polidoro, 2020). In this respect, the robust schema for evaluating products often becomes untenable when applied to novel products and contexts, thereby challenging the notion that regulatory agencies are 'all-powerful and all-knowing' (Gao & McDonald, 2022, p. 31). In this regard, agility becomes imperative in ensuring that the regulatory review process is sustained as both stabilized patterns in recurrent form and adaptive to new occurrences in the innovation landscape and the local material context.

The regulatory agency studied in this thesis demonstrated how this was achieved through efforts to maintain patterns and practices which offered avenues to creatively conceive new evaluation routines. As the findings reveal, the power to engage in what was conceived as a potential disruption to the routines is cast within a hierarchically structured authority that created boundaries of enactment. Thus, the lines of authority at the regulatory agency limited the application of tacit knowledge to

navigate newly emerging conditions. This is subsumed in the practice of aligning situated actions with the codified processes which were enforced through the well-defined authoritative boundaries and capacities for execution. Also, given that there was a tendency for discursive modes to emerge and trigger collective conception of innovation in the review process as product evaluators co-enacted their situated routines, all forms of communication were redirected through the IT platform, which restricted such interactions. This led to conditions where the enactment of noncognitive routines was bounded within a situated capacity that determined the ability of a product evaluator to develop, engage with others and implement improvised forms of actions in the face of emerging contextual cues, thereby ensuring stability. Nonetheless, as the mechanism for achieving adaptive ends in the regulatory reviews remain embedded in the noncognitive enactments that allowed creative actions to flourish, a deliberate effort by the agency to conceive new modes of enactment encountered tensions between interacting routines. The findings suggest that the competing conceptions of how the core objective of the regulatory review framework could be achieved served to systematically shape new forms of product evaluation routines. Thus, as the multiple clusters of evaluation routines interact, operational tensions among product evaluators are triggered, with the intention of maintaining the patterned activities in their situated roles. This leads to conditions where the conceived path to agility in product evaluation routine evolve with the awareness of, and appreciation for, the possible nuances embedded in the distinctive objectives within multiple situated disciplines. Hence, the multiple clustering of interdependent routines (Kremser et al., 2019), paradoxically, provide avenues to shape and streamline imagined change in order to maintain rigour and achieve operational intents.

While this system of routine clustering (Kremser & Schreyögg, 2016) provided a means of shaping emergent new patterns, a practice of switching routine enactors as well as the nature of routines to be executed was found to limit the ability to nurture tacit knowledge to inform such co-evolving dynamics in order to ensure stability in espoused routines. Thus, product evaluators were introduced to new sets of enactments that required fundamental shifts in logics in order to make sense of the new patterns. Again, within these organizing constraints also laid the innovative tendencies

where logics, knowledge and capabilities honed by the enactors were transferred across the multiple interdependent routines in order to align the patterns of change. Here, the findings suggest that the re-situating of product evaluators in new routines underpinned the mechanism of enriching relational knowledge to develop a complementary set of practices. Thus, the tenets of one routine cluster informs how new patterns in another, to enable or impede the creation of context for enactment. As a result, imagining adaptive ends in the evaluation process becomes complementary. Further explication presented on this phenomenon also revealed an understanding of how change is constructed through the constant interaction of distinct clusters of situated routines that collectively constitute the regulatory review process. Thus, rather than igniting tensional relations that could become ordered over time, a co-optation dynamic emerged where varying practices across the interdependent routines were effortfully assimilated into a focal routine. This was found to be a strategic approach to nurturing collaborative knowledge that not only helped to minimise tensional relationships that existed among interacting routines, but also absorbed market-informed changes that had occurred in other related routines. Through this never-ending sharing of logics to accomplish the regulatory evaluation routines, change in addressing emerging challenges come to establish discursive spaces for engaging and influencing the conception of trajectories of change in situated evaluation routines. These organizing practices, however, extended beyond the organizing boundaries of the FDA to include interaction with the innovating firms, which followed the co-creation of regulatory evaluation routines (Gao & McDonald, 2022). The direct interactions between regulatory officers and innovating firms seeking commercial approval for their products is rendered a fundamental avenue to capture core insights relevant to bridging knowledge gaps and responding to market dynamics.

7.4 Research contributions

Insights from the findings in this thesis present four main contributions to the discourse on regulatory reviews. First, the study offers a fine-grained understanding of the activities of regulatory agencies by breaking down and delineating the regulatory review of NPI as a sequence of patterned activities that

constitute the building-blocks of the espoused process for evaluating products— which survives on a flow of situated actions enacted by product evaluators. Specifically, the characterisation of regulatory review processes as a bundle of routines has provided detailed insights into the contents, sequence, and practices that underlie the product evaluations. In this regard, the thesis has demonstrated how the mutually enabling set of codified patterns in the form of organizing structures and the actual accomplishment of product evaluation (Feldman et al., 2019) interactively define the organizing practices that portray what regulatory reviews are conducted and how. Furthermore, as a response to calls to examine the connections between structures and agency influencing regulatory decision-making (Guidi et al., 2020), this dual characterisation of regulatory reviews underlines how micro-situated practices of the atomic individual who engages in the day-to-day evaluation of product at a regulatory agency shape the aggregated patterns of enactment that define the regulatory review process. More importantly, although the regulatory review process is explicitly labelled as codified guidelines, procedures, and standards, the thesis has underlined the cognitive underpinnings of the specific activities that are involved in the product evaluation process. Unpacking these as 'patterned orders' (Geiger, 2022) undergirding and sustaining the espoused sequence of evaluating products has helped to extend understanding on how individual evaluators' interpretation of the underlying logics of the product review process come to be rooted in the cognitive skills that are sealed away in their tacit knowledge. This analysis thus extends the discourse of regulatory reviews beyond the known phase-gate process to account for how the situated activities, actual performances, and tacit knowledge of product evaluators constitute a set of cognitive constructs that emerge, are enacted, evolve, or discontinue in the process of characterising the regulatory review of NPIs.

Second, the thesis has pointed out how context-specific dynamics yield distinctive practices that define a local rationale for evaluating products yet remain conforming to the established standards and rules within the broader regulatory landscape. Observing how the conduct of regulatory review in a peripheral context paradoxically plays out as a 'coherence in contradiction' (Derrida, 2007), this thesis contributes to the literature by unveiling how specific contexts present varying frames for enacting

regulatory reviews and engaging performative processes through which evaluation standards are adopted and assimilated into a socio-organizational context. Thus, the uniqueness of the context within which NPIs are conceived and developed also ignites regulatory responses that are actioned within distinct norms, categories, vocabularies, shared assumptions and meaning systems. As such, while the prototypical description of regulatory agencies may fall solely within the broader scientific analysis of products, often defined by the internationally recognized regulatory institutions, the actual implementation of regulatory review frameworks develops sensitivity to the context within which they operate and hence present patterns that are not fully subsumed by widely labelled norms. This further offer important contributions to the burgeoning discussions in the literature on how regulatory agencies frame different categories for a product based on jurisdictional conditions, thereby influencing consumption patterns in a focal market (Ozcan & Gurses, 2018; Tharchen & Garud, 2022). In this respect, the core insight presented here underlines that regulatory review processes are not exclusively defined by their putatively scientific contents and sequences of evaluations, but also rooted in a series of context-adaptive mechanisms that allow the accommodation of social preferences to inform organizing practices that guide regulators towards achieving the primary intents of the regulatory review framework. Nonetheless, although such contextual contingencies inflict normative and socio-cultural persuasions, which are rendered dominant in defining how products are evaluated, the preoccupation of regulatory agencies to protect public health and safety takes an overriding interest, acting as an invisible guide in ensuring reliable outcomes from the review process and decisions thereof.

Third, this thesis helps to define how the internal dynamics of organizing at regulatory agencies inform patterns of change and order of adaption. Specifically, it has elucidated how the artefact-embedded (non)cognitive evaluation routines accomplish analytically distinguishable but functionally constitutive purposes in the process of negotiating change or adaptation, or defining inertia in regulatory agencies and their product review processes, thereby offering deeper insight into the mechanisms through which regulatory agencies themselves evolve and improve the services they

offer to the public. As was unveiled in the study context, the dynamic configuring change and redefinition of the existing coherent sequence of product evaluations to minimize regulatory cost, uncertainty and delay rests in an interactive web of mutually enabling relationships between organizing structures, clusters of routines and their co-evolving patterns to define both stability and change in regulatory review processes. Therefore, the emergent outcomes of organizing routines of regulatory agencies, as subsumed in complex multiple enactments of routines, cumulatively constitute how the regulatory review process remains both stable and dynamic. This illuminates how the learning regulators (Carpenter, 2004), within the contingencies of organizing, come to refine their evaluation processes through a constitutive mode of conversion which exists between the acquired tacit knowledge of the regulatory officers and scientifically-bounded schemas for evaluating products. Since the unconscious and inarticulable tacit knowledge underlies the effective performance of organizations (Nayak et al., 2020), a social domain that establishes discursive spaces for product evaluators to share their experiences facilitates the distribution of shared meanings and tacit knowledge that are required to coherently enact the evaluation routines. This further enhances the combination of discrete pieces of codified guidelines and process to – at least in part – articulate the core foundations of their tacit knowledge to provide grounds for conceiving innovative ways of evaluating products. As these spaces trigger discursive struggles between actors of the multiple clusters of product evaluation routines, they develop useful orientation towards assuming a motivated cognition which identifies emergent struggles between scientific constructs and socio-organizational conditions as well as the situated intents of the interdependent routines in order to imagine new patterns of action that are consummately shared and accepted to reframe the regulatory review process.

Fourth, prior research has often focused on strategies such as claims-making and framing through media and public advocacy (Carpenter, 2002; Gurses & Ozcan, 2015; Keidan, 2007; Pollman & Barry, 2016), political persuasions (Carpenter, 2004; Dorobantu et al., 2017), and other forms of indirect soft power tactics (Hiatt & Park, 2013), as influential tools for driving regulatory agencies towards facilitating the commercialisation of new products – a system which often results in regulatory capture

(Bonardi et al., 2005). This thesis, however, has presented an important point of departure in the understanding of how direct *regulator–innovator* interactions effectuate shared reasoning to influence regulatory review processes. Thus, instead of discursive and power struggles, resistance and the often-confrontational episodes that seem to characterise the existing ways of signalling and enforcing change in regulatory review processes, the thesis has drawn attention to collaborative efforts between innovating firms and regulatory agencies toward bridging knowledge gaps to ensure that regulatory review frameworks are responsive to the dynamics of the innovation landscape. As was well resonated in the findings of the thesis, innovating firms expect their experiences of the regulatory review processes to inform decisions to establish up-to-the-minute rigorous evaluation processes that would attract support and compliance within the broader innovation landscape. Thus, the equivocality that often engulfs the regulatory review process for new products innovations is disentangled through co-creation logics that seek to narrow the knowledge gaps (Gao & McDonald, 2022). Knowledge gathered through such collaborative efforts facilitates the creative navigation of organizing constraints, eliminates regulatory uncertainty, and enables adaptive responses of regulatory agencies to the evolving innovation landscape. This interdependent relationship therefore underpins the ability of regulatory agencies to develop deeper knowledge of the technology on which new products are developed in order to expedite evaluation processes and boost innovation (Polidoro, 2020). Although unconventional, the thesis has drawn this regulator-innovator nexus to the centre-stage, labelling it as a pragmatic approach to developing expertise and limiting knowledge deficit on emerging new products.

7.5 Theoretical implications

The thesis has important implications for the theory of routines as applied in contemporary management research. To begin with, while explicating the inextricably intertwined sets of espoused recurrent action patterns and the actual situated enactments that constitute routines, a clear effort is made to emphasise the active cognition involved in the enactment of routines. In this regard, the thesis

has taken a cognitivist turn (Nayak et al., 2020) to underscore routines as the neural structure of organizations that transcends into the active nodes of competence, and through which elements of dynamism and improvisation are expressed in practice in order to successfully accomplish the goals and intentions of the routine. This implies an analytical view of the organization as an entity that holds its own storage of routines in the form of codified representations of rules, guidelines, and procedures. Thus, this explicitly stored knowledge is by nature the cognition of the organization, which actively informs how situated actions are to be accomplished, thus yielding the observation of recurrent action patterns (Becker, 2005; Cohen et al., 1996; Lazaric, 2021; Secchi & Cowley, 2021). However, exposure to the realm of actual enactment also wields unique cues that require the routine *actors* to draw on their deep-seated knowledge to navigate emergent impediments to accomplish the intentions of organizational routines (Dittrich & Seidl, 2018). Therefore, what is observational in the enactment of routines often cannot be traced to representations of the recurrent action patterns. As Cohen and Bacdayan (1994, p. 556) would argue, "routines partially reside in an organizational unconscious" – which presents an analytical distinction between the organizational cognition and the actor's cognition, or what has been labelled here as the noncognitive routines of the organization. While this fundamental interrelatedness as a core element of routines has been captured in the existing literature, which borrows its conceptual vocabulary from Latour's (1986) *ostensive* and *performative* aspects (see Feldman & Pentland, 2003), this thesis, invoking the need to establish cognitive grounds of routine (Lazaric, 2021), has situated the concept of routines in a much more succinct dialectical expression that highlights the characteristic of routines as effortful accomplishments that are cognitively bound.

Furthermore, the thesis draws attention to a routine not as a mere abstraction of behavioural patterns of organizations but rather as a lived experience. This is to say that the sustainability of the routinized character of most organizational activity in the day-to-day conduct of agents is "grounded in practical consciousness" (Giddens, 1984, p. 60). In this regard, the thesis has emphasised that the active (re)creation of organizational routines is socially negotiated through time and space, such that the routine itself encompasses core elements of social practices, including material artefacts,

competences, and meanings inflicted by socio-cultural persuasions (Dittrich, 2021; Feldman, 2022; Shove et al., 2012). This conception places emphasis not just on the aesthetic specifics to which the recognizable patterns of action in one domain must be made to adapt for survival, which are largely rooted in intra-organizational, industry and socio-political differences (Friesl & Larty, 2013; Szulanski & Jensen, 2004), but also sets out, in novel fashion, how native customs establish, beforehand, a cognitive orientation for the routine actors. The existing orientations become the actor's engrained perceptual frames for conceiving *how* tasks are to be accomplished and define *what* action patterns are undertaken in their situated practice. Thus, although thoughtful intelligent agents may conceive the dynamics of a specific context and embed the same in the replication of efficient design routines (Winter & Szulanski, 2001), this custom-rooted rationale of the atomised routine actor interferes to diffract the actual routine enactment from its original conception. This implies that in the study of routines across cultural settings, actual adaptions which shape and define the ultimate patterns of action in a given context do not exist prior to exposure of routines to that specific context, rather, it is an ex-post phenomenon. In this regard, the socio-cognitive orientation of the individual routine actors is very significant in understanding varying expressions of routines in localised contexts (Cohendet & Llerena, 2003). This adds to the recent proposition to set the routine actor at the centre-stage of routine study (Danner-Schröder, 2021), as their social-cognitive preferences critically shape the specific nature and characterisation of routines.

Lastly, the thesis contributes to the recent 'dynamic turn' in the study of routines to account for how specific actions taken in the enactment of routines (re)create patterns to define organizational stability and change (Danner-Schröder & Geiger, 2016; Feldman et al., 2021;). Specifically, insights from the thesis suggest that the underlying mechanism which characterises the generative feature of routines exists as a motif of developing organizational competencies through stability while, at the same time, nurturing sensitivity to emergent cues. This implies that although situated actions, relationality and interdependencies of enactment, and socio-material artefacts all co-shape the evolutionary qualities of routines, the core embedded intentionality of these features in establishing stable patterns is to ensure

that routines are enacted as designed. Thus, the duality of inertia and flexibility, as was observed in this context of this study, was fundamentally aimed at enacting recognizable patterns as predetermined and established. This further implies that the operational context and/or nature of the industry within which an organization is located may impose essences of conformity and consistency across all active players, thereby driving cumulative efforts towards specific intended patterns of action. While this may seem to breed a rather contentious and risky emulsification of the immiscible capabilities and practice onto-epistemologies of routines (Feldman et al., 2021), the significance of this discovery-oriented latticework of the thesis lies in the tactful translation, rather than contrast-widening, of insights from both perspectives. This helps to provide a more nuanced approach to routine study which highlights how the blending of commonalities from these contesting perspectives may become relevant to conceiving new ways of observing and accounting for the dynamics of routines.

7.6 Implications for innovation management

The thesis presents new ways of understanding the role of regulatory agencies in innovation, which in turn has several implications for innovation management. First, attention is drawn to an important but often overlooked, or even contested, view on whether regulatory agencies could become active agents who purposefully help to pre-empt innovation failure. While prior literature has focused on swaying market actors' perceptual evaluations and habits that inhibit the penetration of NPIs into the market (Joachim et al., 2018), this thesis complements the extant emphasis in the literature on the influence of non-market stakeholders in shaping market perceptions and evaluations, and hence the success of new products on the market (Polidoro, 2020; Rindova et al., 2005). Regulatory agencies reserve the role as non-market actors whose activities help to mitigate the challenges of information asymmetry, and hence offer a guaranteed avenue or means of evaluating the safety and, often, the efficacy of NPIs. Specifically, what was revealed in the context of the study is the utilisation of the regulatory review process as fundamental means of assessing the underpinning technology of NPIs through a prolonged evaluation process, which tends to assuage safety doubts about the commercialised products. The

regulatory agency was therefore found to play a significant role in the success of new products that encounter existing *para-competitors* whose products are imported from 'well-defined' regulatory environments. Here, the accreditation acquired by the regulatory agency in the context, coupled with their rigorous evaluation processes, cumulatively shaped the market perception about the locally designed products as equally safe or even superior. More importantly, the activities of regulatory agency (re)create the context within which those products have value, as they continually (re)frame product categories and articulate the value of NPI to consumers to enhance their commercial success on the market (Tharchen & Garud, 2022; Zhu et al., 2017). Thus, although the regulatory agencies do not engage in market-based exchange with innovating firms, their influence on the consumers' choice of products makes apparent their power to control the success of innovations. This thus implies that anticipating evolving patterns of regulatory activities to identify, specialise and capture market niches that regulators may be keen to satisfy is critical to mitigating the risk of innovation failure.

Second, regulatory agencies occupy liminal space in the transition of NPIs from the innovation laboratory to the market and even between markets. This situates them in a position where they become entangled in an intermediary role (Stewart & Hyysalo, 2008), focusing on satisfying the commercial interest of innovating firms while at same time protecting public health and safety. In this regard, the regulatory agency engages in post-market surveillance activities to monitor continuous safety compliance in order to maintain this critical balance. Over and above this established knowledge on the workings of regulatory agencies, this thesis signals how this operational width extends to include the capturing of information on emerging variant usage of the commercialised products as they encounter market conditions. This overlooked role of the regulatory agency is, however, critically important to innovation firms' market information-gathering efforts, as the spectrum of product usage defined by consumers tends to create disparity between the innovating firms' intended use and the actual market use of an NPI. This is because products that are commercialised on the market hybridise under the conditions and preferences of the selection environment, thereby extending the scope of the product to include unanticipated segments or demands of the market (Cattani, 2006). Nonetheless,

innovating firms often fail to capture this core variation in product usage. Yet, for the regulator, ensuring that all products consumed on the market remain safe and, in the context of the present study, do not have transubstantiated value, lead them to discover these forms of variations. Thus, acknowledging the potential for a wide range of consumer usage that a product can assume helps to offer opportunities for innovating firms' NPI development initiatives to move towards the frontiers of technological pre-adaptation, and to optimise widespread and varied use of products to expand product categories via incremental innovations (Davis & Tomoda, 2017; Shluzas & Leifer, 2014). In this respect, regulatory agencies remain ever more important in innovating firms' efforts to identify potential trajectories of *product speciation* in order to define the flexible configuration of NPIs (McKinley et al., 2014).

Third, the existing insights on the strategies adopted by innovating firms to drive regulatory efforts to commercialise products have tended to rely on a somewhat tensional relationship between these key players in the innovation process. On the contrary, the findings presented in this thesis suggest a more collaborative approach. It is quite telling to observe that regulatory agencies actually rely on insights from the innovating firms to understand novel technologies and to be responsive to lingering concerns, which may help to improve the regulatory review process. Thus, bridging knowledge gaps, learning to understand regulatory focus and requirements, and having an interactive process that allows innovating firms to signal uncertainty costs to the regulator all help to collectively achieve a robust and efficient regulatory review framework. Moreover, the regulator has nurtured competencies in conceiving and drawing the socio-cultural dynamics that distinguish the use of products in one context from another and thus enabling the creation of an important knowledge base that is relevant for innovating firms to incorporate into their new product designs. The configurations in distinct modes of macro and socio-political instruments to influence and shape the context of consumption are all reposed in the mandate of the regulatory agency. This therefore suggests that the competing interest and resistance approach highlighted in the existing literature is often untenable (Gao & McDonald, 2022), as the regulatory agencies hold discretionary powers and the political

influence needed to carry out those strategies could become difficult to muster (Gao & McDonald, 2022; Grandy & Hiatt, 2020). Thus, fostering this dependency relationship works in the interest of innovating firms, since they are able to directly engage with regulatory agencies to co-create patterns of product evaluation. More importantly, the ability to build a collaborative bond helps to build a stronger regulator-innovator nexus where access to core regulatory information and focus could yield distinct capability for the innovating firm, which is necessary to gain strategic advantage (Helfat, 2021).

7.7 Policy implications

For policymakers, insights from this thesis suggest a need to continuously intervene in the dynamics of socio-cultural practices that seem to take prominence in the regulatory review process. This is important, as the local frames tend to dilute the scientific rigour which is putatively the underlying basis for regulatory decisions. Specifically, efforts from both government and oversight institutions should focus on designing policy measures that interfere in the product evaluator's webs of beliefs and habits of action that may potentially sway the *practice meanings* (Shove et al., 2012) and intentions of the regulatory review framework. Within this system of organizing product reviews, we risk having the *socio-cultural-artefacts-informed means* (D'Adderio, 2014) influencing the intended *ends* of the regulatory review process. This is not to argue that the social practices which inform situated improvisations that are expressed in the creation, modification and redefinition of means to achieve the core intents of product regulation lose their centrality in ensuring both stability and flexibility in the regulatory review process. Rather, the proposition put forward here is that there is a need for policy measures that would control the range and scope of influence of such practices on the regulatory review process, as we seek to develop a more robust and legitimate product evaluation framework.

In addition, policies within the broader regulatory landscape could adopt a *catalytic* orientation. This implies delving into the operational intents of regulatory review process to emphasise active intermediation and speeding up of innovations. In this respect, the activity patterns of regulatory

agencies are to intervene and ease the process commercialising innovations with the aim of encouraging innovative efforts and intensifying competition, which improves the utility of consumers in the market selection environment. This would, however, require a shift in the dynamic interactions between regulators and the innovation firms in order to design bespoke regulatory frameworks. This could also be in the form of policies that require regulatory agencies to have *entrepreneurs-in-residence* from innovation hubs, who will help to responsively configure new ways of evaluating emerging new products that present equivocality to existing regulatory review frameworks and processes. These individuals will therefore serve to provide up-to-the-minute information on the new conceivable trajectories of the innovation landscape in order to minimise the prolonged learning process embedded in the product evaluation process and to build a more proactive regulatory agency. This will thus make significant the role of regulatory agencies as contributing to a web of stakeholder roles and relationships that is geared towards fostering innovation, and hence minimise existing opposition tensions between the regulatory landscape and innovation domains.

7.8 Limitations and future research opportunities

Despite the significant contributions offered by this thesis, a number of limitations should be acknowledged, which also lend themselves to exploitation by future research. To begin with, the focus on methodological individualism focused the analysis narrowly on situated routines enacted by the product evaluators and their improvisational acts to achieve the putative ends of the regulatory review process. Thus, the finding specifically drawn to unveil the interactions and mechanisms through the noncognitive routine enactment come to shape the codified cognitive routines of the regulatory agency. In this regard, in accounting for change and adaptivity to changing contexts and events, the study assumed the evaluators' dispositions and cognitive bandwidths as the overarching boundary within which new forms of organizing were imagined and executed. This conceptualisation, however, relegates the role of regulatory administrative managers (e.g., the Chief Executive Officer and board members) in influencing the intentionality of the change and the trajectory evolution in regulatory

framework to the periphery. Specifically, the study ignored the role of executive management, middle-level managers, and regulatory supervisors in informing the conception and actualisation of patterns of change in evaluation routines. To the extent that this was achieved, the analysis only managed to highlight these dynamics as occurring after the patterns of change had been imagined by the product evaluator. Thus, although the ability of noncognitive routines to sustain the intentions of the regulatory framework is fundamental to the legitimisation of action, the substrate logics that informed how, which, and what creative routines should be absorbed into the cognitive routines remain unaccounted for. In lieu of the hierarchical nature of the organizing structure observed in the context of this study, future research could go forth to investigate the influence of administrative agents' and supervisors' frames of cognition in informing change and the mechanism through which new routines are conceived, as well as how they define the conditions under which some noncognitive routines are side-lined while others are legitimised and codified.

Furthermore, a key observation in the context of the regulatory agency studied in this thesis was how discursive frames of its situated roles unleashed differential intents and understandings of the regulatory review process. Hence, although unexplored in the thesis, discourse was observed to be the rule that determines what constitutes the evaluation routines that underpin regulatory framework. The choice of rationality of the regulatory officers who are imbued in the practical expectations of their role in the product review process was informed by the discursive formations that bound the situated practices of their specific routine cluster. More importantly, properties of language and interaction at the regulatory agency produced a system of organizing where the linguistic forms signalled relational differences, provided hierarchical alignment of organizational members, sanctioned legitimate actions, and enacted powerful versus powerless actors or domination (Fairhurst & Putnam, 2004; Phillips et al., 2004). In this regard, the mechanism through which change and adaptation of the regulatory review process is conceived is potentially implicated in the dynamic interplay between multiple discourse-embedded (re)constructions of routines. This implies that the discursive means by which tensions between interdependent routines arise to signal and/or prompt change could serve as an important

avenue for future research to elucidate how the interactions of multiple routines help to accomplish analytically distinguishable but functionally constitutive purposes in the process of negotiating patterns of change in regulatory evaluation routines, both within the agency and with external agents, including innovating firms and oversight institutions. Thus, this thesis advocates that future scholars should draw on discursive practices as a metatheoretical lens to offer alternative interpretations to clarify and account for the relationally negotiated patterns of change in regulatory review processes.

In addition, the analytical insights presented in this thesis are solely drawn from the perspective of the regulator, without any empirical sensitivity to that of the innovating firms. Thus, the thesis lacks insights on what perceptual evaluations innovating firms enact to position the role of the regulatory agency as central to the commercial success of their products. Specifically, what was quite intriguing is the regulatory agency basing a decision to approve an alcoholic beverage on denotations of the product labelling, which underlines how normative standards – rather than the notions of solely scientific logics – inform regulatory decisions. In this regard, given that there are varying socio-cultural elements that control the formation of evaluation standards and guidelines in a given context, insights on why and how the innovation landscape or industry enacts meaning-making on these dynamics to continuously frame the legitimacy of the regulatory agency in such contexts would be a significant contribution to knowledge. Such enquiries could also need to shed light on the innovating firms' specific frames of interpretation that underlie the recognition of cultural conventions (Gray et al., 2015) in regulatory reviews as important to their order of engagement with the market, and more broadly, how their meaning-making frames reinforce the enactment of deference in the bid to establish legitimacy and trust for their new products (Jourdan et al., 2017).

Finally, theoretical efforts were made in the thesis to conceive routines not as static 'things' that are rigid in character, but rather as being composed of dynamic practice-informed situated enactments of multiple actors (Feldman et al., 2016, 2021). This conceptualisation of routines places emphasis on the actors as "knowledgeable and often reflective" (Feldman et al., 2016, p. 506), thereby dissolving

contentions about the cognitive resources required in the accomplishment of situated tasks in routines. Engaging and extending this theoretical sentiment, the thesis situated the analysis of actions that constitute the regulatory review process as a routine into a more cognitive-oriented frame, while allowing the analysis to emerge as a metatheory to unpack the active cognition involved in the internal dynamics of routine. Nonetheless, this endeavour to place routine within an active cognitive structure may be prone to problems of *reification* (Lukács, 2017). Thus, although the focus of the analysis was drawn directly from the actors involved in routine enactment, the extensive characterisation of the routine as a form of memory, actively learning and unlearning, and exhibiting dynamic evolving qualities as humans interact with routines, risked imposing an ontology of routine as a detached concept independent of its origin of enactment. Put starkly, in the attempt to define new theoretical specification for routines in order to fit the empirical context observed in this study, there was a seemingly innocuous tendency to give form to the experiences and observations by conceiving them as constructs that distinctively congeal those experience into "'thingness'" (Wenger, 1999, p. 58). This is particularly evident in the study's attempt to conceive routines as being actively present in the dual domains of organizational cognition and that of the actors', yet independent of each other and only interact in event of contestation in practical delivery. Although this abstraction becomes both critical and convenient in unpacking the role of cognition in the enactment of routines at the regulatory agency, and even helped to show the co-construction of both (non)cognitive patterns of enactment, this endeavour remains prone to posing conceptual ambiguity, which would require future research to draw on the insights presented in this thesis as a cautionary landmine to offer further empirical and theoretical assessment that would be devoid of tendencies of reification.

7.9 Conclusion

Thus far, the discourse on the regulatory review of NPIs has only offered understanding of the phase-gate regulatory review process, strategies to allow innovating firms to navigate regulatory constraints, and re-conceptualisation of the role of regulatory agencies as innovation intermediaries – all within

stable and well-defined contexts. This has led to limited insights into the internal dynamics of regulatory activities and processes, adaptive responses to the innovation landscapes and market conditions, and socio-cultural contingencies of context which establish local rationales for conducting regulatory review of NPIs. In this thesis, these lacunae are filled by drawing a *routine–practice* perspective of routine theory to unpack the dynamics of how micro-situated practices of the atomised individual who engages in the day-to-day evaluation of new products come to shape and influence the regulatory review process in an agile regulatory context. Thus, the interaction between the (non)cognitive aspects of product evaluation routines that define the regulatory review process (re)create stability in activity patterns and yield innovative practices that underlie the adaptive capabilities needed to sustain the intention of the product evaluation framework in a constantly evolving innovation landscape. More importantly, the thesis has established that the situated enactment of regulatory evaluations has a great deal of socio-cultural contingency, which initiates noncognitive interventions that recursively emerge to define how change could be negotiated and lead to the identification of innovation in the regulatory review process. The constant navigation of organizing constraints by the product evaluators thus defines the regulatory review process as the making of a chaotic web of scientific logics, cultural repertoires, unanticipated occurrences, improvisations, and legitimacy-seeking – all bounded in the enactments of cognitive and noncognitive routines.

References

Abernathy, W. J., & Clark, K. B. (1985). Innovation: Mapping the winds of creative destruction. *Research Policy*, *14*(1), 3-22.

Abraham, J. (2002). The pharmaceutical industry as a political player. *The Lancet*, *360*(9344), 1498-1502.

Adams, R., Bessant, J., & Phelps, R. (2006). Innovation management measurement: A review. *International Journal of Management Reviews*, *8*(1), 21-47.

Aime, F., Johnson, S., Ridge, J. W., & Hill, A. D. (2010). The routine may be stable but the advantage is not: Competitive implications of key employee mobility. *Strategic Management Journal*, *31*(1), 75-87.

Akyeampong, E. (1995). Alcoholism in Ghana—A socio-cultural exploration. *Culture, Medicine and Psychiatry*, *19*(2), 261-280.

Akyeampong, E. K. (1996). *Drink, power, and cultural change: A social history of alcohol in Ghana, c. 1800 to recent times*. AbeBooks.

Alexander, L., & Van Knippenberg, D. (2014). Teams in pursuit of radical innovation: A goal orientation perspective. *Academy of Management review*, *39*(4), 423-438.

Ali, A. (1994). Pioneering versus incremental innovation: Review and research propositions. *Journal of Product Innovation Management*, *11*(1), 46-61.

Alleman, J., & Rappoport, P. (2002). Modelling regulatory distortions with real options. *The Engineering Economist*, *47*(4), 390-417.

Alvesson, M., Hardy, C., & Harley, B. (2008). Reflecting on reflexivity: Reflexive textual practices in organization and management theory. *Journal of Management Studies*, *45*(3), 480-501.

Arora, H., & Tosti, A. (2017). Safety and efficacy of nail products. *Cosmetics*, *4*(3), 24.

Ashforth, B. E., & Fried, Y. (1988). The mindlessness of organizational behaviors. *Human Relations*, *41*(4), 305-329.

Aspelund, A., Berg-Utby, T., & Skjevdal, R. (2005). Initial resources' influence on new venture survival: A longitudinal study of new technology-based firms. *Technovation*, *25*(11), 1337-1347.

Atuahene-Gima, K., Slater, S. F., & Olson, E. M. (2005). The contingent value of responsive and proactive market orientations for new product program performance. *Journal of Product Innovation Management*, *22*(6), 464-482.

Avent-Holt, D. (2012). The political dynamics of market organization: Cultural framing, neoliberalism, and the case of airline deregulation. *Sociological Theory*, *30*(4), 283-302.

Aversa, P., Huyghe, A., & Bonadio, G. (2021). First impressions stick: Market entry strategies and category priming in the digital domain. *Journal of Management Studies*, *58*(7), 1721-1760.

Baldacchino, L., Ucbasaran, D., & Cabantous, L. (2022). Linking experience to intuition and cognitive versatility in new venture ideation: A dual-process perspective. *Journal of Management Studies*. https://doi.org/10.1111/joms.12794

Baldwin, C. Y., & Clark, K. B. (2000). *Design rules: The power of modularity* (Vol. 1). MIT press.

Baldwin, C. Y., & Clark, K. B. (2006). Architectural innovation and dynamic competition: The smaller "footprint" strategy. *Harvard Business School, Boston, MA*.

Banbury, C. M., & Mitchell, W. (1995). The effect of introducing important incremental innovations on market share and business survival. *Strategic Management Journal*, *16*(S1), 161-182.

Baraka Policy Institute (2016). National alcohol policy. Available at: http://barakapolicy.org/wp-content/uploads/2021/10/GHANA-NATIONAL-ALCOHOL-POLICY-1.pdf. [Accessed 15 December].

Becker, M. C. (2004). Organizational routines: A review of the literature. *Industrial and Corporate Change*, *13*(4), 643-678.

Becker, M. C. (2005). The concept of routines: some clarifications. *Cambridge Journal of Economics*, *29*(2), 249-262.

Becker, M. C. (Ed.). (2008). *Handbook of organizational routines*. Edward Elgar Publishing. https://doi.org/10.4337/9781848442702.00006

Bergek, A., Berggren, C., Magnusson, T., & Hobday, M. (2013). Technological discontinuities and the challenge for incumbent firms: Destruction, disruption or creative accumulation?. *Research Policy*, *42*(6-7), 1210-1224.

Berndt, E. R., Gottschalk, A. H., Philipson, T. J., & Strobeck, M. W. (2005). Industry funding of the FDA: effects of PDUFA on approval times and withdrawal rates. *Nature Reviews Drug Discovery*, *4*(7), 545-554.

Biney, R. P., Agyei, P. E. O., Ameyaw, E. O., Afortude, J. K., Henneh, I. T., Obese, E., ... & Ekor, M. (2020). Effects of three herb-based alcoholic beverages manufactured in Ghana on sperm characteristics and reproductive hormones in rats. *Scientific African*, *7*, e00316.

Blanche, C., & Cohendet, P. (2019). Remounting a ballet in a different context: A complementary understanding of routines transfer theories. In M. S. Feldman, L. D'Aderio, K. Dittrich., & P. Jarzabkowski (Eds.), *Routine dynamics in action: Replication and transformation* (pp. 11-30). Emerald Publishing Limited.

Blind, K., Petersen, S. S., & Riillo, C. A. (2017). The impact of standards and regulation on innovation in uncertain markets. *Research Policy*, *46*(1), 249-264.

Blind, K. (2016). The impact of regulation on innovation. In J. Edler, P. Cunningham, A. Gök., & P. Shapira (Eds.), *Handbook of innovation policy impact* (pp. 450-482). Edward Elgar Publishing.

Boghossian, J., & David, R. J. (2021). Under the umbrella: Goal-derived category construction and product category nesting. *Administrative Science Quarterly*, 00018392211012376.

Bonardi, J. P., Hillman, A. J., & Keim, G. D. (2005). The attractiveness of political markets: Implications for firm strategy. *Academy of Management Review*, *30*(2), 397-413.

Bower, J. L., & Christensen, C. M. (1995). Disruptive technologies: Catching the wave. *Harvard Business Review*, *73*(1), 43-53.

Bucher, S., & Langley, A. (2016). The interplay of reflective and experimental spaces in interrupting and reorienting routine dynamics. *Organization Science*, *27*(3), 594-613.

Burger-Helmchen, T., Laperche, B., Schiavone, F., & Stefani, U. (2020). Financing novelty: New tools and practices to induce and control innovation processes. *European Journal of Innovation Management*. https://doi.org/10.1108/EJIM-03-2020-333.

Breckenridge, A., Feldschreiber, P., Gregor, S., Raine, J., & Mulcahy, L. A. (2011). Evolution of regulatory frameworks. *Nature Reviews Drug Discovery*, *10*(1), 3-4.

Brown, A. D., & Thompson, E. R. (2013). A narrative approach to strategy-as-practice. *Business History*, *55*(7), 1143-1167.

Brown, S. L., & Eisenhardt, K. M. (1997). The art of continuous change: Linking complexity theory and time-paced evolution in relentlessly shifting organizations. *Administrative Science Quarterly*, 1-34.

Callon, M. (2021). *Markets in the making: Rethinking competition, goods, and innovation*. Princeton University Press.

Cannon-Bowers, J. A., & Salas, E. (2001). Reflections on shared cognition. *Journal of Organizational Behavior*, *22*(2), 195-202.

Cardador, M. T., Hill, P. L., & Salles, A. (2021). Unpacking the status-leveling burden for women in male-dominated occupations. *Administrative Science Quarterly*, 00018392211038505.

Carpenter, D. P. (2002). Groups, the media, agency waiting costs, and FDA drug approval. *American Journal of Political Science*, 490-505.

Carpenter, D., Chernew, M., Smith, D.G., Fendrick, A.M., 2003. Approval times for new drugs: Does the source of funding for FDA staff matter? The amount of resources devoted to FDA review, not the source of funding, was likely the principal driver behind shrinking approval times since 1980. Health Affairs 22 (Suppl1), W3–618.

Carpenter, D. P. (2004). Protection without capture: Product approval by a politically responsive, learning regulator. *American Political Science Review*, *98*(4), 613-631.

Carpenter, D., Zucker, E. J., & Avorn, J. (2008). Drug-review deadlines and safety problems. *New England Journal of Medicine*, *358*(13), 1354-1361.

Carpenter, D., Chattopadhyay, J., Moffitt, S., & Nall, C. (2012). The complications of controlling agency time discretion: FDA review deadlines and postmarket drug safety. *American Journal of Political Science*, *56*(1), 98-114.

Cattani, G. (2006). Technological pre-adaptation, speciation, and emergence of new technologies: how Corning invented and developed fiber optics. *Industrial and Corporate Change*, *15*(2), 285-318.

Cohendet, P., & Llerena, P. (2003). Routines and incentives: The role of communities in the firm. *Industrial and Corporate Change*, *12*(2), 271-297.

Chen, K. M., & Liu, R. J. (2005). Interface strategies in modular product innovation. *Technovation*, *25*(7), 771-782.

Chia, R., & Tsoukas, H. (2003). Everything flows and nothing abides: Towards a "rhizomic" model of organizational change, transformation and action. *Process Studies*, *32*(2), 196-224.

Chorniy, A., Bailey, J., Civan, A., & Maloney, M. (2021). Regulatory review time and pharmaceutical research and development. *Health Economics, 30*(1), 113-128.

Chou, Y. C., Chuang, H. H. C., & Shao, B. B. (2016). The impact of e-retail characteristics on initiating mobile retail services: A modular innovation perspective. *Information & Management*, *53*(4), 481-492.

Chown, J. (2021). The unfolding of control mechanisms inside organizations: Pathways of customization and transmutation. *Administrative Science Quarterly*, *66*(3), 711-752.

Clark, S. M., Gioia, D. A., Ketchen Jr, D. J., & Thomas, J. B. (2010). Transitional identity as a facilitator of organizational identity change during a merger. *Administrative Science Quarterly*, *55*(3), 397-438.

Christensen, C. M., McDonald, R., Altman, E. J., & Palmer, J. E. (2018). Disruptive innovation: An intellectual history and directions for future research. *Journal of Management Studies*, *55*(7), 1043-1078.

Cohen, M. D. (2007). Reading Dewey: Reflections on the study of routine. *Organization Studies*, *28*(5), 773-786.

Cohen, M. D., Burkhart, R., Dosi, G., Egidi, M., Marengo, L., Warglien, M., & Winter, S. (1996). Routines and other recurring action patterns of organizations: Contemporary research issues. *Industrial and Corporate Change*, *5*(3), 653-698.

Cohen, M. D., & Bacdayan, P. (1994). Organizational routines are stored as procedural memory: Evidence from a laboratory study. *Organization Science*, *5*(4), 554-568.

Cohen, W. M., & Levinthal, D. A. (1990). Absorptive capacity: A new perspective on learning and innovation. *Administrative Science Quarterly*, 128-152.

Collins, H. M. (2005). What is tacit knowledge? In T. R. Schatzki, K. K. Cetina, & E. von Savigny (Eds.), *The practice turn in contemporary theory* (pp. 115-128). London, UK: Routledge.

Collis, D. J. (1994). Research note: how valuable are organizational capabilities? *Strategic Management Journal*, *15*(S1), 143-152.

Cowley, S. J., Vallée-Tourangeau, F., & Vallée-Tourangeau, F. (2017). *Cognition beyond the brain*. Springer International Publishing.

Cunliffe, A. L. (2003). Reflexive inquiry in organizational research: Questions and possibilities. *Human Relations*, *56*(8), 983-1003.

Cyert, R. M., & March, J. G. (1963). *A behavioral theory of the firm*. Prentice-Hall.

D'Adderio, L. (2008). The performativity of routines: Theorising the influence of artefacts and distributed agencies on routines dynamics. *Research Policy*, *37*(5), 769-789.

D'Adderio, L. (2014). The replication dilemma unravelled: How organizations enact multiple goals in routine transfer. *Organization Science*, *25*(5), 1325-1350.

Danneels, E. (2002). The dynamics of product innovation and firm competences. *Strategic management journal*, *23*(12), 1095-1121.

Danner-Schröder, A. (2021). Without actors, there is no action: How interpersonal interactions help to explain routine dynamics. *Review of Managerial Science*, *15*(7), 1913-1936.

Danner-Schröder, A., & Geiger, D. (2016). Unravelling the motor of patterning work: Toward an understanding of the microlevel dynamics of standardization and flexibility. *Organization Science*, *27*(3), 633-658.

Datta, A., Mukherjee, D., & Jessup, L. (2015). Understanding commercialization of technological innovation: Taking stock and moving forward. *R&D Management*, *45*(3), 215-249.

Davis, C., & Tomoda, Y. (2018). Competing incremental and breakthrough innovation in a model of product evolution. *Journal of Economics*, *123*(3), 225-247.

de Rond, M., Lok, J., & Marrison, A. (2021). To catch a predator: The lived experience of extreme practices. *Academy of Management Journal*, *65*(3). https://doi.org/10.5465/amj.2020.1492

Denyer, D., Tranfield, D. and van Aken, J.E. (2008). Developing design propositions through research synthesis. *Organization Studies, 29*, 393–413.

Denyer, D. & Tranfield, D. (2009). Producing a systematic review. In, D.A. Buchanan & A. Bryman (Eds), *The Sage Handbook of Organizational Research Methods* (pp. 671–689). Sage.

Derrida, J. (1967/2007). Structure, sign, and play in the discourse of the human sciences. In Derrida, J., *Writing and Difference*, 278-93.

DiMasi, J. A., & Manocchia, M. (1997). Initiatives to speed new drug development and regulatory review: the impact of FDA-sponsor conferences. *Drug information journal: DIJ/Drug Information Association*, *31*, 771-788.

Dimasi, J. A. (2002). The value of improving the productivity of the drug development process. *Pharmacoeconomics*, *20*(3), 1-10.

DiMasi, J. A., Hansen, R. W., & Grabowski, H. G. (2003). The price of innovation: New estimates of drug development costs. *Journal of Health Economics*, *22*(2), 151-185.

DiMasi, J. A., & Faden, L. (2009). Factors associated with multiple FDA review cycles and approval phase times. *Drug Information Journal*, *43*(2), 201-225.

DiMasi, J. A., Feldman, L., Seckler, A., & Wilson, A. (2010). Trends in risks associated with new drug development: success rates for investigational drugs. *Clinical Pharmacology & Therapeutics*, *87*(3), 272-277.

Dimitri, N. (2010). The economics of priority review vouchers. *Drug Discovery Today*, *15*(21-22), 887-891.

Dionysiou, D. (2021). Pragmatism & Routine Dynamics. In Feldman, M. S., Pentland, B. T., Rerup, C., & Seidl, D. Cambridge Handbook of Routine Dynamics. Cambridge: Cambridge University Press, pp. 62–70

Dittrich, K., & Seidl, D. (2018). Emerging intentionality in routine dynamics: A pragmatist view. *Academy of Management Journal*, *61*(1), 111-138.

Dittrich, K., Guérard, S., & Seidl, D. (2016). Talking about routines: The role of reflective talk in routine change. *Organization Science*, *27*(3), 678-697.

Dorobantu, S., Kaul, A., & Zelner, B. (2017). Nonmarket strategy research through the lens of new institutional economics: An integrative review and future directions. *Strategic Management Journal*, *38*(1), 114-140.

Dosi, G., Nelson, R. R., & Winter, S. G. (Eds.). (2000). *The nature and dynamics of organizational capabilities*. Oxford University Press.

Dosi, G., Faillo, M., & Marengo, L. (2008). Organizational capabilities, patterns of knowledge accumulation and governance structures in business firms: An introduction. *Organization Studies, 29*(8-9).

Downer, J. (2010). Trust and technology: The social foundations of aviation regulation. *The British Journal of Sociology*, *61*(1), 83-106.

Downer, J. (2011). On audits and airplanes: Redundancy and reliability-assessment in high technologies. *Accounting, Organizations and Society*, *36*(4-5), 269-283.

Downing, N. S., Aminawung, J. A., Shah, N. D., Braunstein, J. B., Krumholz, H. M., & Ross, J. S. (2012). Regulatory review of novel therapeutics—comparison of three regulatory agencies. *New England Journal of Medicine*, *366*(24), 2284-2293.

Downing, N. S., Zhang, A. D., & Ross, J. S. (2017). Regulatory review of new therapeutic agents—FDA versus EMA, 2011–2015. *New England Journal of Medicine*, *376*(14), 1386-1387.

Dowuona-Hammond, C. (2018). Consumer law and policy in Ghana. Journal of Consumer Policy, 41(4), 333-354.

Dranove, D., & Meltzer, D. (1994). Do important drugs reach the market sooner? *The RAND Journal of Economics*, *25*(3), 402-423.

Dutta, S., Zbaracki, M. J., & Bergen, M. (2003). Pricing process as a capability: A resource-based perspective. *Strategic Management Journal*, *24*(7), 615-630.

Edmondson, A. C., Bohmer, R. M., & Pisano, G. P. (2001). Disrupted routines: Team learning and new technology implementation in hospitals. *Administrative Science Quarterly*, *46*(4), 685-716.

Ellwood, P., Grimshaw, P., & Pandza, K. (2017). Accelerating the innovation process: A systematic review and realist synthesis of the research literature. *International Journal of Management Reviews*, *19*(4), 510-530.

Emerson, R. M., Fretz, R. I., & Shaw, L. L. (2011). *Writing ethnographic fieldnotes*. University of Chicago Press.

Epstein, S. (1996). *Impure science: AIDS, activism, and the politics of knowledge* (Vol. 7). University of California Press.

Ettlie, J. E., Bridges, W. P., & O'keefe, R. D. (1984). Organization strategy and structural differences for radical versus incremental innovation. *Management Science*, *30*(6), 682-695.

Fairhurst, G. T., & Putnam, L. (2004). Organizations as discursive constructions. *Communication Theory*, *14*(1), 5-26.

Farny, S., Kibler, E., & Down, S. (2019). Collective emotions in institutional creation work. *Academy of Management Journal*, *62*(3), 765-799.

Feldman, M. S. (2000). Organizational routines as a source of continuous change. *Organization Science*, *11*(6), 611-629.

Feldman, M. S. (2003). A performative perspective on stability and change in organizational routines. *Industrial and Corporate Change*, *12*(4), 727-752.

Feldman, M. S. (2004). Resources in emerging structures and processes of change. *Organization Science*, *15*(3), 295-309.

Feldman, M. S. 2016. Past, Present, and Future. In J. Howard-Grenville, C. Rerup, A. Langley, & H. Tsoukas (Eds.), *Organizational Routines: How They Are Created, Maintained, and Changed* (23-46). Oxford: Routledge.

Feldman, M. S., & Orlikowski, W. J. (2011). Theorizing practice and practicing theory. *Organization Science*, *22*(5), 1240-1253.

Feldman, M. S., & Pentland, B. T. (2003). Reconceptualizing organizational routines as a source of flexibility and change. *Administrative Science Quarterly*, *48*(1), 94-118.

Feldman, M., & Pentland, B. (2008). Routine dynamics. In D. Barry & H. Hansen (Eds.), *The SAGE handbook of new approaches in organization and management* (pp. 302–317). Sage.

Feldman, M. S., & Pentland, B. T. (2022). Routine dynamics: Toward a critical conversation. *Strategic Organization*, 14761270221130876.

Feldman, M. S., Pentland, B. T., D'Adderio, L., & Lazaric, N. (2016). Beyond routines as things: Introduction to the special issue on routine dynamics. *Organization Science*, *27*(3), 505-513.

Feldman, M. S., Pentland, B. T., D'Adderio, L., Dittrich, K., Rerup, C., & Seidl, D. (2021). What is routine dynamics? In M.S. Feldman, B. T. Pentland, L. D'Adderio, K. Dittrich, C. Rerup, & D. Seidl, (Eds.), *Cambridge Handbook of Routine Dynamics* (pp. 1-18). Cambridge University Press.

Feldman, M. S., & Rafaeli, A. (2002). Organizational routines as sources of connections and understandings. *Journal of Management Studies*, *39*(3), 309-331.

Fiaveh, D. Y. (2020). Masculinity, male sexual virility, and use of aphrodisiacs in Ghana. *The Journal of Men's Studies*, *28*(2), 165-182.

Finkel, M. J. (1980). The FDA's classification system for new drugs: An evaluation of therapeutic gain. *New England Journal of Medicine*, *302*(3), 181-183.

Fixson, S. K., & Park, J. K. (2008). The power of integrality: Linkages between product architecture, innovation, and industry structure. *Research Policy*, *37*(8), 1296-1316.

Fleming, J. J. (2015). The decline of venture capital investment in early-stage life sciences poses a challenge to continued innovation. *Health Affairs*, *34*(2), 271-276.

Food and Drugs Authority (2021a). Corporate profile. Available at: https://fdaghana.gov.gh/about-us.php. [Accessed 25 Oct 2021].

Food and Drugs Authority (2021b). FDA Act. Available at: https://fdaghana.gov.gh/fda-act.php. [Accessed 12 October].

Food and Drugs Authority (2021c). Press release. Available at: https://fdaghana.gov.gh/press-release.php. [Accessed 5 October].

Food and Drugs Authority (2021d). Annual Reports. Available at: https://fdaghana.gov.gh/anual-reports.php. [Accessed 5 December].

Food and Drugs Authority (2016). Guidelines for Advertising Food. Available at: https://fdaghana.gov.gh/images/stories/pdfs/downloads/food%20guidelines/REVIEWED%20GUIDELINES%20FOR%20THE%20ADVERTISEMENT%20OF%20FOODS-28-1-16-FINAL-FINAL.pdf. [Accessed 29 December].

Food Standards Agency (2022). Consistency in regulatory work. Available at: https://www.food.gov.uk/research/cutting-edge-regulator/consistency-in-regulatory-work. [Accessed 20 December 2022].

Foucart, R., & Li, Q. C. (2021). The role of technology standards in product innovation: Theory and evidence from UK manufacturing firms. *Research Policy*, *50*(2), 104157.

Friedman, M. A., Woodcock, J., Lumpkin, M. M., Shuren, J. E., Hass, A. E., & Thompson, L. J. (1999). The safety of newly approved medicines: do recent market removals mean there is a problem?. *Jama*, *281*(18), 1728-1734.

Friesl, M., & Larty, J. (2013). Replication of routines in organizations: Existing literature and new perspectives. *International Journal of Management Reviews*, *15*(1), 106-122.

Gajendran, T., Brewer, G., Gudergan, S., & Sankaran, S. (2014). Deconstructing dynamic capabilities: the role of cognitive and organizational routines in the innovation process. *Construction Management and Economics*, *32*(3), 246-261.

Gans, J. S., & Ridley, D. B. (2013). Innovation incentives under transferable fast-track regulatory review. *The Journal of Industrial Economics*, *61*(3), 789-816.

Gao, C., & McDonald, R. (2022). Shaping nascent industries: Innovation strategy and regulatory uncertainty in personal genomics. *Administrative Science Quarterly*, 00018392221112641.

Garber, S., Gates, S. M., Keeler, E. B., Vaiana, M. E., Mulcahy, A. W., Lau, C., & Kellermann, A. L. (2014). Redirecting innovation in US health care: Options to decrease spending and increase value. *Rand Health Quarterly*, *4*(1).

Garcia, R., & Calantone, R. (2002). A critical look at technological innovation typology and innovativeness terminology: A literature review. *Journal of Product Innovation Management*, *19*(2), 110-132.

Garud, R., & Rappa, M. A. (1994). A socio-cognitive model of technology evolution: The case of cochlear implants. *Organization Science*, *5*(3), 344-362.

Gavetti, G., & Levinthal, D. (2000). Looking forward and looking backward: Cognitive and experiential search. *Administrative Science Quarterly*, *45*(1), 113-137.

Geiger, D. (2022). Routine dynamics and paradox: A revised research agenda. *Scandinavian Journal of Management*, *38*(4), 101244.

Gersick, C. J., & Hackman, J. R. (1990). Habitual routines in task-performing groups. *Organizational Behavior and Human Decision Processes*, *47*(1), 65-97.

Ghana Health Service (2020a). Guidelines for international flight operations on COVID-19 safety at the Kotoka International Airport. Available at: https://www.ghs.gov.gh/covid19/other-releases.php. [Accessed 27 December].

Ghana Health Service (2020b). Ministerial directive on wearing masks in public places. Available at: https://www.ghs.gov.gh/covid19/press-releases.php. [Accessed 28 December]

Ghana Statistical Service (2015). *Integrated Business Establishment Survey (IBES): Report of the fifth round (V) Accra*.

Ghana Statistical Service (2021a) Press release: Population and housing census. Available at https://census2021.statsghana.gov.gh/ [Accessed 5 December].

Ghana Statistical Service (2021b). Population and housing Census: Age and sex distribution. Available at: https://census2021.statsghana.gov.gh/bannerpage.php?readmorenews=mtq1mtuyodeymc43mdc1&2021-phc-general-report. [Accessed 28 December].

Giddens, A. (1984). *The constitution of society*. Polity Press.

Gieringer, D. H. (1985). The safety and efficacy of new drug approval. *Cato Journal*, *5*(1), 177-201.

Gioia, D. A. (1992). Pinto fires and personal ethics: A script analysis of missed opportunities. *Journal of Business Ethics*, *11*(5), 379-389.

Gioia, D. A., Corley, K. G., & Hamilton, A. L. (2013). Seeking qualitative rigor in inductive research: Notes on the Gioia methodology. *Organizational Research Methods*, *16*(1), 15-31.

Gioia, D. A., Price, K. N., Hamilton, A. L., & Thomas, J. B. (2010). Forging an identity: An insider-outsider study of processes involved in the formation of organizational identity. *Administrative Science Quarterly*, *55*(1), 1-46.

Giudici, A., Reinmoeller, P., & Ravasi, D. (2018). Open-system orchestration as a relational source of sensing capabilities: Evidence from a venture association. *Academy of Management Journal*, *61*(4), 1369-1402.

Goffman, E. (1956). The nature of deference and demeanor. *American Anthropologist*, *58*(3), 473-502.

Grabowski, H. G., Vernon, J. M., & Thomas, L. G. (1978). Estimating the effects of regulation on innovation: an international comparative analysis of the pharmaceutical industry. *The Journal of Law and Economics*, *21*(1), 133-163.

Grabowski, H., Wang, Y.R., 2008. Do faster Food and Drug Administration drug reviews adversely affect patient safety? An analysis of the 1992 Prescription Drug User Fee Act. The Journal of Law and Economics 51 (2), 377–406.

Grandy, J. B., & Hiatt, S. R. (2020). State agency discretion and entrepreneurship in regulated markets. *Administrative Science Quarterly*, *65*(4), 1092-1131.

Gray, B., Purdy, J. M., & Ansari, S. (2015). From interactions to institutions: Microprocesses of framing and mechanisms for the structuring of institutional fields. *Academy of Management Review*, *40*(1), 115-143.

Guba, E. G., & Lincoln, Y. S. 2005. Paradigmatic controversies, contradictions, and emerging confluences. In N. K. Denzin & Y. S. Lincoln (Eds.), *The SAGE handbook of qualitative research* (3rd edition, pp. 191–215). Sage.

Guidi, M., Guardiancich, I., & Levi-Faur, D. (2020). Modes of regulatory governance: A political economy perspective. *Governance*, *33*(1), 5-19.

Gurses, K., & Ozcan, P. (2015). Entrepreneurship in regulated markets: Framing contests and collective action to introduce pay TV in the US. *Academy of Management Journal*, *58*(6), 1709-1739.

Habib, T., Kristiansen, J. N., Rana, M. B., & Ritala, P. (2020). Revisiting the role of modular innovation in technological radicalness and architectural change of products: The case of Tesla X and Roomba. *Technovation*, *98*, 102163.

Haines, F. (2017). Regulation and risk. In Drahos P. (Ed.), *Regulatory Theory: Foundations and Applications* (pp. 181-196). ANU Press.

Hargadon, A. B., & Douglas, Y. (2001). When innovations meet institutions: Edison and the design of the electric light. *Administrative Science Quarterly*, *46*(3), 476-501.

Heidenreich, S., & Kraemer, T. (2016). Innovations—doomed to fail? Investigating strategies to overcome passive innovation resistance. *Journal of Product Innovation Management*, *33*(3), 277-297.

Helfat, C. E. (2021). What does firm shaping of markets really mean. *Strategy Science*, *6*(4), 360-370.

Helfat, C. E., & Winter, S. G. (2011). Untangling dynamic and operational capabilities: Strategy for the (N) ever-changing world. *Strategic Management Journal*, *32*(11), 1243-1250.

Henderson, R. M., & Clark, K. B. (1990). Architectural innovation: The reconfiguration of existing product technologies and the failure of established firms. *Administrative Science Quarterly*, *35*(1), 9-30.

Hiatt, S. R., & Park, S. (2013). Lords of the harvest: Third-party influence and regulatory approval of genetically modified organisms. *Academy of Management Journal*, *56*(4), 923-944.

Hibbert, P., Coupland, C., & MacIntosh, R. (2010). Reflexivity: Recursion and relationality in organizational research processes. *Qualitative Research in Organizations and Management, 5*(1), 47-62.

Hirai, Y., Kinoshita, H., Kusama, M., Yasuda, K., Sugiyama, Y., & Ono, S. (2010). Delays in new drug applications in Japan and industrial R&D strategies. *Clinical Pharmacology & Therapeutics*, *87*(2), 212-218.

Hodgson, G. M., (2008). The concept of a routine. In Becker, M. C. (Ed.), *Handbook of Organisational Routines* (15-28). Edward Elgar.

Hodgson, G. M., & Knudsen, T. (2004). The firm as an interactor: Firms as vehicles for habits and routines. *Journal of Evolutionary Economics*, *14*(3), 281-307.

Hoerr, R. A. (2011). Regulatory uncertainty and the associated business risk for emerging technologies. *Journal of Nanoparticle Research*, *13*(4), 1513-1520.

Hofman, E., Halman, J. I., & Van Looy, B. (2016). Do design rules facilitate or complicate architectural innovation in innovation alliance networks? *Research Policy*, *45*(7), 1436-1448.

Howard-Grenville, J. A. (2005). The persistence of flexible organizational routines: The role of agency and organizational context. *Organization Science*, *16*(6), 618-636.

Howard-Grenville, J., & Lodge, J. (2021). Context, Embeddedness and Routine Dynamics. In M. Feldman, B. Pentland, L. D'Adderio, K. Dittrich, C. Rerup, & D. Seidl (Eds.), *Cambridge Handbook of Routine Dynamics* (pp. 229-243). Cambridge University Press. https://doi.org/10.1017/9781108993340.020

Hutchins, E. (2014). The cultural ecosystem of human cognition. *Philosophical Psychology*, *27*(1), 34-49.

Ichimaru, K., Toyoshima, S., & Uyama, Y. (2010). PMDA's challenge to accelerate clinical development and review of new drugs in Japan. *Clinical Pharmacology & Therapeutics*, *88*(4), 454-457.

Ishibashi, T., Kusama, M., Sugiyama, Y., & Ono, S. (2012). Analysis of regulatory review times of new drugs in Japan: association with characteristics of new drug applications, regulatory agency, and pharmaceutical companies. *Journal of Clinical Pharmacy and Therapeutics*, *37*(6), 657-663.

Jacobides, M. G. (2005). Industry change through vertical disintegration: How and why markets emerged in mortgage banking. *Academy of Management Journal*, *48*(3), 465-498.

Jarzabkowski, P., Lê, J., & Balogun, J. (2019). The social practice of coevolving strategy and structure to realize mandated radical change. *Academy of Management Journal*, *62*(3), 850-882.

Joachim, V., Spieth, P., & Heidenreich, S. (2018). Active innovation resistance: An empirical study on functional and psychological barriers to innovation adoption in different contexts. *Industrial Marketing Management*, *71*, 95-107.

Joe, D. (2021). Bitters take over: Here is a list of all the bitters in Ghana. Available at: https://www.nsemwoha.com/bitters-take-over-here-is-a-list-of-all-the-bitters-in-ghana/. [Accessed 29 December]

Jolly, V. K. (1997). Commercializing New Technology. *Harvard Business School Press, Boston, MA*.

Jones, N. (2003). Competing after radical technological change: The significance of product line management strategy. *Strategic Management Journal*, *24*(13), 1265-1287.

Jourdan, J., Durand, R., & Thornton, P. H. (2017). The price of admission: Organizational deference as strategic behavior. *American Journal of Sociology*, *123*(1), 232-275.

Kaitin, K. I., Phelan, N. R., Raiford, D., & Morris, B. (1991). Therapeutic ratings and end-of-phase II conferences: initiatives to accelerate the availability of important new drugs. *Journal of clinical pharmacology*, *31*(1), 17-24.

Kaitin, K. I., Manocchia, M., Seibring, M., & Lasagna, L. (1994). The new drug approvals of 1990, 1991, and 1992: trends in drug development. *The Journal of Clinical Pharmacology*, *34*(2), 120-127.

Kaitin, K. I., & Cairns, C. (2003). The new drug approvals of 1999, 2000, and 2001: Drug development trends a decade after passage of the Prescription Drug User Fee Act of 1992. *Drug Information Journal*, *37*(4), 357-371.

Kaitin, K. I., Manocchia, M., Seibring, M., & Lasagna, L. (1994). The new drug approvals of 1990, 1991, and 1992: Trends in drug development. *The Journal of Clinical Pharmacology*, *34*(2), 120-127.

Keidan, J. (2007). Sucked into the Herceptin maelstrom. *British Medical Journal*, *334*(7583), 18-18.

Kesselheim, A.S., Wang, B., Franklin, J.M., Darrow, J.J., 2015. Trends in utilization of FDA expedited drug development and approval programs, 1987-2014: cohort study. British Medical Journal 351, h4633. https://doi.org/10.1136/bmj.h4633.

Kessler, E. H., Bierly, P. E., & Gopalakrishnan, S. (2000). Internal vs. external learning in new product development: Effects on speed, costs and competitive advantage. *R&D Management*, *30*(3), 213-224.

Kessler, E. H., & Chakrabarti, A. K. (1996). Innovation speed: A conceptual model of context, antecedents, and outcomes. *Academy of Management Review*, *21*(4), 1143-1191.

Kho, J., Spee, P. A., & Gillespie, N. (2019). Enacting relational expertise to change professional routines in technology-mediated service settings. In M. S. Feldman, L. D'Aderio, K. Dittrich, K., & P. Jarzabkowski (Eds.), *Routine Dynamics in Action: Replication and Transformation* (Research in the Sociology of Organizations, vol. 61, pp. 191-213). Emerald Publishing Ltd. https://doi.org/10.1108/S0733-558X20190000061010.

Kim, L. (1998). Crisis construction and organizational learning: Capability building in catching-up at Hyundai Motor. *Organization Science*, *9*(4), 506-521.

Kim, S. (2021). Frame restructuration: The making of an alternative business incubator amid Detroit's crisis. *Administrative Science Quarterly*, *66*(3), 753-805.

Kivimaa, P., Boon, W., Hyysalo, S. and Klerkx, L., 2019. Towards a typology of intermediaries in sustainability transitions: A systematic review and a research agenda. *Research Policy*, *48*(4), pp.1062-1075.

Kiwan, L., & Lazaric, N. (2019). Learning a new ecology of space and looking for new routines: Experimenting robotics in a surgical team. . In M. S. Feldman, L. D'Aderio, K. Dittrich, K., & P. Jarzabkowski (Eds.), *Routine Dynamics in Action: Replication and Transformation* (Research in the Sociology of Organizations, vol. 61, pp. 173-189). https://doi.org/10.1108/S0733-558X20190000061009.

Klonoff, D. C. (2020). The new FDA real-world evidence program to support development of drugs and biologics. *Journal of diabetes science and technology*, *14*(2), 345-349.

Knudsen, T. (2008). Organizational routines in evolutionary theory. In Becker, M. C. (Ed.), *Handbook of Organisational Routines* (pp. 125-151). Edward Elgar.

Koerner, M. M. (2014). Courage as identity work: Accounts of workplace courage. *Academy of Management Journal*, *57*(1), 63-93.

Kremser, W., & Blagoev, B. (2021). The dynamics of prioritizing: How actors temporally pattern complex role–routine ecologies. *Administrative Science Quarterly*, *66*(2), 339-379.

Kremser, W., Pentland, B. T., & Brunswicker, S. (2019). Interdependence within and between routines: A performative perspective. In M. S. Feldman, L. D'Aderio, K. Dittrich, & P. Jarzabkowski (Eds.) *Routine Dynamics in Action: Replication and Transformation* (pp. 79-98). Emerald Publishing Limited.

Kremser, W., & Schreyögg, G. (2016). The dynamics of interrelated routines: Introducing the cluster level. *Organization Science*, *27*(3), 698-721.

Kremser, W., & Sydow, J. (2022). When Practices Control Practitioners: Integrating self-reinforcing dynamics into practice-based accounts of managing and organizing. *Organization Theory*, *3*(3), 26317877221109275.

Kuzma, J., & Besley, J. C. (2008). Ethics of risk analysis and regulatory review: From bio-to nanotechnology. *Nanoethics*, *2*(2), 149-162.

Kwon, S., Youtie, J., Porter, A., & Newman, N. (2022). How does regulatory uncertainty shape the innovation process? Evidence from the case of nanomedicine. *The Journal of Technology Transfer (2022)*, 1-41. https://doi.org/10.1007/s10961-022-09980-8

Laar, A. K., Redman, B. K., Ferguson, K., & Caplan, A. (2020). Institutional approaches to research integrity in Ghana. *Science and Engineering Ethics*, *26*(6), 3037-3052.

Latour, B. (1986). The powers of association. In J. Law (ed.), *Power, action and belief* (pp. 264-280). Routledge and Kegan Paul.

Lazaric, N. (2021). Cognition and routine dynamics. In M. Feldman, B. Pentland, L. D'Adderio, K. Dittrich, C. Rerup, & D. Seidl (Eds.), *Cambridge handbook of routine dynamics* (pp. 255-265). Cambridge University press.

Leifer, R., O'Connor, G. C., & Rice, M. (2001). Implementing radical innovation in mature firms: The role of hubs. *Academy of Management Perspectives*, *15*(3), 102-113.

Lettl, C., Herstatt, C., & Gemuenden, H. G. (2006). Users' contributions to radical innovation: Evidence from four cases in the field of medical equipment technology. *R&D Management*, *36*(3), 251-272.

Lerner, J., & Nanda, R. (2020). Venture capital's role in financing innovation: What we know and how much we still need to learn. *Journal of Economic Perspectives*, *34*(3), 237-61.

Lewin, A. Y., Massini, S., & Peeters, C. (2011). Microfoundations of internal and external absorptive capacity routines. *Organization science*, *22*(1), 81-98.

Liberti, L., McAuslane, N., Patel, P., Breckenridge, A., Eichler, H. G., & Peterson, R. (2013). Regulatory Review: How Do Agencies Ensure the Quality of Decision Making? Centre for Innovation in Regulatory Science Workshop on Regulatory Review: How Do Agencies Ensure the Quality of the Decision? 24–25 January 2013 Beijing, China. *Clinical Pharmacology & Therapeutics*, *94*(3), 305-308.

Locke, K., & Velamuri, S. (2009). The design of member review: Showing what to organization members and why. *Organizational Research Methods*, *12*(3), 488-509.

Locke, K. (2001). *Grounded theory in management research*. Sage.

Louis, M. R., & Sutton, R. I. (1991). Switching cognitive gears: From habits of mind to active thinking. *Human Relations*, *44*(1), 55-76.

Luginaah, I., & Dakubo, C. (2003). Consumption and impacts of local brewed alcohol (*akpeteshie*) in the Upper West region of Ghana: A public health tragedy. *Social Science & Medicine*, *57*(9), 1747-1760.

Lukács, G. (2017). Reification and the Consciousness of the Proletariat. In *Karl Marx* (pp. 3-25). Routledge.

Lumpkin, G. T., & Dess, G. G. (1996). Clarifying the entrepreneurial orientation construct and linking it to performance. *Academy of Management Review*, *21*(1), 135-172.

Magnusson, T., Lindström, G., & Berggren, C. (2003). Architectural or modular innovation? Managing discontinuous product development in response to challenging environmental performance targets. *International Journal of Innovation Management*, *7*(1), 1-26.

Manders, B., de Vries, H. J., & Blind, K. (2016). ISO 9001 and product innovation: A literature review and research framework. *Technovation*, *48*, 41-55.

Mantere, S., & Ketokivi, M. (2013). Reasoning in organization science. *Academy of Management Review*, *38*(1), 70-89.

Massa, F. G., & O'Mahony, S. (2021). Order from chaos: How networked activists self-organize by creating a participation architecture. *Administrative Science Quarterly*, 00018392211008880.

McDermott, C. M., & O'Connor, G. C. (2002). Managing radical innovation: An overview of emergent strategy issues. *Journal of Product Innovation Management, 19*(6), 424-438.

McKinley, W., Latham, S., & Braun, M. (2014). Organizational decline and innovation: Turnarounds and downward spirals. *Academy of Management Review*, *39*(1), 88-110.

McNamee, L. M., Walsh, M. J., & Ledley, F. D. (2017). Timelines of translational science: From technology initiation to FDA approval. *PLoS One*, *12*(5), e0177371.

Merrill, R. A. (1984). Food and Drug Administration regulation: An unnecessary barrier to new product innovation. *Food, Drug, Cosmetic Law Journal*, *39*(1), 113-119.

Michel, A. (2011). Transcending socialization: A nine-year ethnography of the body's role in organizational control and knowledge workers' transformation. *Administrative Science Quarterly*, *56*(3), 325-368.

Miettinen, R., & Virkkunen, J. (2005). Epistemic objects, artefacts and organizational change. *Organization*, *12*(3), 437-456.

Miller, D. J. (2021). Corporate renewal through internal innovation: The four 'R's of corporate bricolage. *Strategic Management Review*, *2*(2), 323-354.

Miller, K. D., Pentland, B. T., & Choi, S. (2012). Dynamics of performing and remembering organizational routines. *Journal of Management Studies*, *49*(8), 1536-1558.

Miner, A. S., Ciuchta, M. P., & Gong, Y. (2008). Organizational routines and organizational learning. In Becker, M. C. (Ed.), *Handbook of Organisational Routines* (pp. 152-186). Edward Elgar.

Mitchell, W., & Shaver, J. M. (2003). Who buys what? How integration capability affects acquisition incidence and target choice. *Strategic Organization*, *1*(2), 171-201.

Mitzinneck, B. C., & Besharov, M. L. (2019). Managing value tensions in collective social entrepreneurship: The role of temporal, structural, and collaborative compromise. *Journal of Business Ethics*, *159*(2), 381-400.

Mol, A. (2008). *The logic of care: Health and the problem of patient choice*. Routledge.

Moore, D. A., Oesch, J. M., & Zietsma, C. (2007). What competition? Myopic self-focus in market-entry decisions. *Organization Science*, *18*(3), 440-454.

Munir, K., Ansari, S. and Brown, D. (2021). From Patañjali to the "Gospel of Sweat": Yoga's remarkable transformation from a sacred movement into a thriving global market. *Administrative Science Quarterly*, *66*(3). doi:10.1177/0001839221993475

Nayak, A., Chia, R., & Canales, J. I. (2020). Noncognitive microfoundations: Understanding dynamic capabilities as idiosyncractically refined sensitivities and predispositions. *Academy of Management Review*, *45*(2), 280-303.

Nelson, R. R., & Winter, S. G. (1982). *An evolutionary theory of economic change*. Belknap Press.

Nickerson, J. A., & Zenger, T. R. (2004). A knowledge-based theory of the firm—The problem-solving perspective. *Organization Science*, *15*(6), 617-632.

Oerlemans, L. A., Knoben, J., & Pretorius, M. W. (2013). Alliance portfolio diversity, radical and incremental innovation: The moderating role of technology management. *Technovation*, *33*(6-7), 234-246.

Orlikowski, W. J. (2007). Sociomaterial practices: Exploring technology at work. *Organization Studies*, *28*(9), 1435-1448.

Olson, M. K. (1995). Regulatory agency discretion among competing industries: Inside the FDA. *Journal of Law, Economics and Organization*, *11*(2), 379-405.

Olson, M. K. (1997). Firm characteristics and the speed of FDA approval. *Journal of Economics & Management Strategy*, *6*(1), 377-401.

Olson, M. K. (2000). Regulatory reform and bureaucratic responsiveness to firms: The impact of user fees in the FDA. *Journal of Economics & Management Strategy*, *9*(3), 363-395.

Olson, M. K. (2004). Managing delegation in the FDA: Reducing delay in new-drug review. *Journal of Health Politics, Policy and Law*, *29*(3), 397-430.

Olson, M. K. (2008). The risk we bear: The effects of review speed and industry user fees on new drug safety. *Journal of Health Economics*, *27*(2), 175-200.

Ono, S., Yoshioka, C., Asaka, O., Tamura, K., Shibata, T., & Saito, K. (2005). New drug approval times and clinical evidence in Japan. *Contemporary Clinical Trials*, *26*(6), 660-672.

Orlikowski, W. J. (2007). Sociomaterial practices: Exploring technology at work. *Organization Studies*, *28*(9), 1435-1448.

Orlikowski, W. J., & Scott, S. V. (2015). Exploring material-discursive practices. *Journal of Management Studies*, *52*(5), 697-705.

Osei-Bonsu, E., Appiah, P. K., Norman, I. D., Asalu, G. A., Kweku, M., Ahiabor, S. Y., ... & Boadu, S. (2017). Prevalence of alcohol consumption and factors influencing alcohol use among the youth in Tokorni-Hohoe, Volta Region of Ghana. *Science Journal of Public Health*, *5*(3), 205-214.

Ozcan, P., & Gurses, K. (2018). Playing cat and mouse: Contests over regulatory categorization of dietary supplements in the United States. *Academy of Management Journal*, *61*(5), 1789-1820.

Papachristos, G., & van de Kaa, G. (2020). A system dynamics model of standards competition. *IEEE Transactions on Engineering Management*, *68*(1), 18-32.

Park, W. Y., Ro, Y. K., & Kim, N. (2018). Architectural innovation and the emergence of a dominant design: The effects of strategic sourcing on performance. *Research Policy*, *47*(1), 326-341.

Parmigiani, A., & Howard-Grenville, J. (2011). Routines revisited: Exploring the capabilities and practice perspectives. *Academy of Management Annals*, *5*(1), 413-453.

Peng, D. X., Schroeder, R. G., & Shah, R. (2008). Linking routines to operations capabilities: A new perspective. *Journal of Operations Management*, *26*(6), 730-748.

Pentland, B. T., & Feldman, M. S. (2005). Organizational routines as a unit of analysis. *Industrial and Corporate Change*, *14*(5), 793-815.

Pentland, B. T., & Feldman, M. S. (2007). Narrative networks: Patterns of technology and organization. *Organization Science*, *18*(5), 781-795.

Pentland, B. T., & Feldman, M. S. (2008). Designing routines: On the folly of designing artifacts, while hoping for patterns of action. *Information and Organization*, *18*(4), 235-250.

Pentland, B. T., Feldman, M. S., Becker, M. C., & Liu, P. (2012). Dynamics of organizational routines: A generative model. *Journal of Management Studies*, *49*(8), 1484-1508.

Pentland, B. T., & Rueter, H. H. (1994). Organizational routines as grammars of action. *Administrative Science Quarterly*, 484-510.

Phillips, N., Lawrence, T. B., & Hardy, C. (2004). Discourse and institutions. *Academy of Management Review*, *29*(4), 635-652.

Pickering, A. (2010). *The mangle of practice*. University of Chicago Press.

Polidoro Jr, F. (2013). The competitive implications of certifications: The effects of scientific and regulatory certifications on entries into new technical fields. *Academy of Management Journal*, *56*(2), 597-627.

Polidoro Jr, F. (2020). Knowledge, routines, and cognitive effects in nonmarket selection environments: An examination of the regulatory review of innovations. *Strategic Management Journal*, *41*(13), 2400-2435.

Pollman, E., & Barry, J. M. (2016). Regulatory entrepreneurship. *Southern California Law Review*, *90*, 383-448.

Prieger, J. E. (2002). Regulation, innovation, and the introduction of new telecommunications services. *Review of Economics and Statistics*, *84*(4), 704-715.

Prieger, J. E. (2007). Regulatory delay and the timing of product innovation. *International Journal of Industrial Organization*, *25*(2), 219-236.

Prieger, J. E. (2008). Product innovation, signaling, and endogenous regulatory delay. *Journal of Regulatory Economics*, *34*(2), 95-118.

Ranchordás, S. (2014). Innovation-friendly regulation: The sunset of regulation, the sunrise of innovation. *Jurimetrics*, *55*(2), 201-224.

Ravasi, D., & Schultz, M. (2006). Responding to organizational identity threats: Exploring the role of organizational culture. *Academy of Management Journal*, *49*(3), 433-458.

Reckwitz, A. (2002). Toward a theory of social practices: A development in culturalist theorizing. *European Journal of Social Theory*, *5*(2), 243-263.

Regnstrom, J., Koenig, F., Aronsson, B., Reimer, T., Svendsen, K., Tsigkos, S., ... & Vamvakas, S. (2010). Factors associated with success of market authorisation applications for pharmaceutical drugs submitted to the European Medicines Agency. *European Journal of Clinical Pharmacology*, *66*(1), 39-48.

Reichert, J. M., Chee, J., & Kotzampaltiris, C. S. (2001). The effects of the Prescription Drug User Fee Act and the Food and Drug Administration Modernization Act on the development and approval of therapeutic medicines. *Drug Information Journal*, *35*(1), 85-94.

Rerup, C., & Feldman, M. S. (2011). Routines as a source of change in organizational schemata: The role of trial-and-error learning. *Academy of Management Journal*, *54*(3), 577-610.

Ridley, D. B., Grabowski, H. G., & Moe, J. L. (2006). Developing drugs for developing countries. *Health Affairs*, *25*(2), 313-324.

Rindova, V. P., Williamson, I. O., Petkova, A. P., & Sever, J. M. (2005). Being good or being known: An empirical examination of the dimensions, antecedents, and consequences of organizational reputation. *Academy of Management Journal*, *48*(6), 1033-1049.

Rivkin, J. W. (2000). Imitation of complex strategies. *Management Science*, *46*(6), 824-844.

Roca, J. B., & O'Sullivan, E. (2020). The role of regulators in mitigating uncertainty within the Valley of Death. *Technovation*, 102157. http://doi.org/10.1016/j.technovation.2020.102157.

Rosales, V., Gaim, M., Berti, M., & e Cunha, M. P. (2022). The rubber band effect: Managing the stability-change paradox in routines. *Scandinavian Journal of Management*, *38*(2), 101194.

Rosenblatt, M., Austin, C. P., Boutin, M., Chin, W. W., Galson, S. K., Jain, S. H., ... & Woodcock, J. (2016). Innovation in development, regulatory review, and use of clinical advances: a vital direction for health and health care. *NAM Perspectives*, *6*.

Rothwell, R., & Gardiner, P. (1985). Invention, innovation, re-innovation and the role of the user: A case study of British hovercraft development. *Technovation*, *3*(3), 167-186.

Rubera, G., & Kirca, A. H. (2012). Firm innovativeness and its performance outcomes: A meta-analytic review and theoretical integration. *Journal of Marketing*, *76*(3), 130-147.

Sarpong, D., Appiah, G., Bi, J., & Botchie, D. (2018). In direct breach of managerial edicts: a practice approach to creative deviance in professional service firms. *R&D Management*, *48*(5), 580-590.

Sarpong, D., & Maclean, M. (2019). Moving on up? Exploring the career journeys of skilled migrants in the professions. *The International Journal of Human Resource Management*, *32*(14), 3004-3032.

Sarpong, D., Maclean, M., & Eyong, J. E. (2020). Cross-state mobility of European naturalised third-country nationals. *European Urban and Regional Studies*, *27*(1), 50-69.

Schatzki, T. R (2001). Introduction: Practice theory. In Schatzki, T. R., Knorr-Cetina, K., & Von Savigny, E. (Eds.). *The practice turn in contemporary theory* (pp. 1-14). Routledge.

Schilling, M. A. (2000). Toward a general modular systems theory and its application to interfirm product modularity. *Academy of Management Review*, *25*(2), 312-334.

Scott, J. W. (1991). The evidence of experience. *Critical Inquiry*, *17*(4), 773-797.

Secchi, D., & Cowley, S. J. (2021). Cognition in organisations: What it is and how it works. *European Management Review*, *18*(2), 79-92.

Shen, W., Lin, C. L., & Marcus, A. (2013, May). Using traceability links to identifying potentially erroneous artifacts during regulatory reviews. In *2013 7th international workshop on traceability in emerging forms of software engineering (tefse)* (pp. 19-22). IEEE.

Sherman, R. E., Davies, K. M., Robb, M. A., Hunter, N. L., & Califf, R. M. (2017). Accelerating development of scientific evidence for medical products within the existing US regulatory framework. *Nature Reviews Drug Discovery*, *16*(5), 297-298.

Shluzas, L. M. A., & Leifer, L. J. (2014). The insight-value-perception (iVP) model for user-centered design. *Technovation*, *34*(11), 649-662.

Shove, E., Pantzar, M., & Watson, M. (2012). *The dynamics of social practice: Everyday life and how it changes*. Sage.

Slater, S. F., & Mohr, J. J. (2006). Successful development and commercialization of technological innovation: Insights based on strategy type. *Journal of Product Innovation Management*, *23*(1), 26-33.

Slater, S. F., Mohr, J. J., & Sengupta, S. (2014). Radical product innovation capability: Literature review, synthesis, and illustrative research propositions. *Journal of Product Innovation Management*, *31*(3), 552-566.

Stewart, J., & Hyysalo, S. (2008). Intermediaries, users and social learning in technological innovation. *International Journal of Innovation Management*, *12*(03), 295-325.

Strauss, A., & Corbin, J. M. (1997). *Grounded theory in practice*. Sage.

Suchman, L. A. (1987). *Plans and situated actions: The problem of human-machine communication*. Cambridge University Press.

Sutton, R. I., & Callahan, A. L. (1987). The stigma of bankruptcy: Spoiled organizational image and its management. *Academy of Management Journal*, *30*(3), 405-436.

Swidler, A. (2001). What anchors cultural practices. In T. R. Schatzki, K. Knorr-Cetina, & E. Von Savigny (Eds.). *The practice turn in contemporary theory* (pp. 74-92). Routledge.

Szulanski, G. (1996). Exploring internal stickiness: Impediments to the transfer of best practice within the firm. *Strategic Management Journal*, *17*(S2), 27-43.

Szulanski, G., & Jensen, R. J. (2004). Overcoming stickiness: An empirical investigation of the role of the template in the replication of organizational routines. *Managerial and Decision Economics*, *25*(6-7), 347-363.

Tampah-Naah, A. M., & Amoah, S. T. (2015). Consumption and drinking frequency of alcoholic beverage among women in Ghana: A cross-sectional study. *BMC Public Health*, *15*(1), 1-10.

Taylor, J. R., & Van Every, E. J. (2000). *The emergent organization: Communication as its site and surface*. Routledge.

Teece, D. J. (2007). Explicating dynamic capabilities: the nature and microfoundations of (sustainable) enterprise performance. *Strategic Management Journal*, *28*(13), 1319-1350.

Teece, D. J. (2012). Dynamic capabilities: Routines versus entrepreneurial action. *Journal of Management Studies*, *49*(8), 1395-1401.

Tharchen, T., & Garud, R. (2022). The differential categorization of novel products by institutional actors across places: The case of e-cigarettes in the US and the UK. *Strategic Organization*, 14761270221124022.

Thomas, L. G. (1990). Regulation and firm size: FDA impacts on innovation. *The RAND Journal of Economics*, *21*(4), 497-517.

Tranfield, D., Denyer, D., & Smart, P. (2003). Towards a methodology for developing evidence-informed management knowledge by means of systematic review. *British Journal of Management*, *14*(3), 207-222.

Tripsas, M. (1997). Unraveling the process of creative destruction: Complementary assets and incumbent survival in the typesetter industry. *Strategic Management Journal*, *18*(S1), 119-142.

Tsoukas, H. (2021). Process theorizing and routine dynamics. In Feldman, M. S., D'Adderio, L., Pentland, B. T., Dittrich, K., Rerup, C., and Seidl, D. (Eds), *Cambridge Handbook of Routine Dynamics* (pp. 37-48). Cambridge University Press.

Tsoukas, H., & Chia, R. (2002). On organizational becoming: Rethinking organizational change. *Organization Science*, *13*(5), 567-582.

Turkson, F. E., Amissah, E., & Gyeke-Dako, A. (2020). The role of formal and informal finance in the informal sector in Ghana. *Journal of Small Business & Entrepreneurship*, *34*(3), 1-24. https://doi.org/10.1080/08276331.2020.1724002.

Turner, S. F., & Rindova, V. (2012). A balancing act: How organizations pursue consistency in routine functioning in the face of ongoing change. *Organization Science*, *23*(1), 24-46.

Tyner, K., & Sadrieh, N. (2011). Considerations when submitting nanotherapeutics to FDA/CDER for regulatory review. In McNeil, S.E. (Ed.), *Characterization of nanoparticles intended for drug delivery* (pp. 17-31). Humana Press.

Ulrich, K. (1995). The role of product architecture in the manufacturing firm. *Research Policy*, *24*(3), 419-440.

Vaccaro, A., & Palazzo, G. (2015). Values against violence: Institutional change in societies dominated by organized crime. *Academy of Management Journal*, *58*(4), 1075-1101.

Vernon, J. A., Golec, J. H., Lutter, R., & Nardinelli, C. (2009). An exploratory study of FDA new drug review times, prescription drug user fee acts, and R&D spending. *The Quarterly Review of Economics and Finance*, *49*(4), 1260-1274.

Veryzer Jr, R. W. (1998). Discontinuous innovation and the new product development process. *Journal of Product Innovation Management*, *15*(4), 304-321.

Vesey, J. T. (1991). The new competitors: they think in terms of 'speed-to-market'. *Academy of Management Perspectives*, *5*(2), 23-33.

Vogel, D. (1990). When consumers oppose consumer protection: The politics of regulatory backlash. *Journal of Public Policy*, 449-470.

Vromen, J. J. (2006). Routines, genes and program-based behavior. *Journal of Evolutionary Economics*, *16*(5), 543-560.

Wang, Y., Gao, J., & Wei, Z. (2021). The double-edged sword of servitization in radical product innovation: The role of latent needs identification. *Technovation*, 102284.

Wenger, E. (1999). *Communities of practice: Learning, meaning, and identity*. Cambridge university press.

Weick, K. E. (2009). Organized impermanence: An overview. In Weick, K. E. (Ed.) *Making sense of the organization: The impermanent organization* (vol. 2, pp. 3-8). John Wiley & Sons.

Weick, K. E., & Roberts, K. H. (1993). Collective mind in organizations: Heedful interrelating on flight decks. *Administrative Science Quarterly*, *38*(3), 357-381.

Whiteman, G., & Cooper, W. H. (2016). Decoupling rape. *Academy of Management Discoveries*, *2*(2), 115-154.

Wiegmann, P. M., & Roca, J. B. (2021, July). Balancing quality and speed in the market approval of diagnostic tests: Experiences of South Korea, the UK, and the US. *JAMA Health Forum*, *2*(7), pp. e211333-e211333.

Winter, S. G. (2003). Understanding dynamic capabilities. *Strategic Management Journal*, *24*(10), 991-995.

Winter, S. G., & Szulanski, G. (2001). Replication as strategy. *Organization Science*, *12*(6), 730-743.

World Health Organization (2020). COVID-19 public health emergency of international concern. Available at: https://www.who.int/publications/m/item/covid-19-public-health-emergency-of-international-concern-(pheic)-global-research-and-innovation-forum. [Accessed 26 December 2021]

Wright, A. (2019). Embodied organizational routines: Explicating a practice understanding. *Journal of Management Inquiry*, *28*(2), 153-165.

Wright, A. L., Meyer, A. D., Reay, T., & Staggs, J. (2021). Maintaining places of social inclusion: Ebola and the emergency department. *Administrative Science Quarterly*, *66*(1), 42-85.

Wrubel, R. P., Krimsky, S., & Anderson, M. D. (1997). Regulatory oversight of genetically engineered microorganisms: Has regulation inhibited innovation? *Environmental Management*, *21*(4), 571-586.

Yuan, B., & Zhang, Y. (2020). Flexible environmental policy, technological innovation and sustainable development of China's industry: The moderating effect of environment regulatory enforcement. *Journal of Cleaner Production*, *243*, 118543.

Yu, D., & Hang, C. C. (2010). A reflective review of disruptive innovation theory. *International Journal of Management Reviews*, *12*(4), 435-452.

Zbaracki, M. J., & Bergen, M. (2010). When truces collapse: A longitudinal study of price-adjustment routines. *Organization Science*, *21*(5), 955-972.

Zhao, Y. L., Erekson, O. H., Wang, T., & Song, M. (2012). Pioneering advantages and entrepreneurs' first-mover decisions: An empirical investigation for the United States and China. *Journal of Product Innovation Management*, *29*, 190-210.

Zhu, Q., Sarkis, J., & Lai, K. H. (2017). Regulatory policy awareness and environmental supply chain cooperation in China: A regulatory-exchange-theoretic perspective. *IEEE Transactions on Engineering Management*, *65*(1), 46-58.

Zuzul, T. W. (2019). "Matter battles": Cognitive representations, boundary objects, and the failure of collaboration in two smart cities. *Academy of Management Journal*, *62*(3), 739-764.

Appendix 3.1

GHANA HEALTH SERVICE ETHICS REVIEW COMMITTEE

In case of reply the number and date of this Letter should be quoted.

Research & Development Division
Ghana Health Service
P. O. Box MB 190
Accra
Digital Address: GA-050-3303
Mob: +233-50-3539896
Tel: +233-302-681109
Fax + 233-302-685424
Email: ethics.research@ghsmail.org

My Ref. GHS/RDD/ERC/Admin/App 121/248
Your Ref. No.

7th July, 2021

Derrick Boakye
Brunel University
London

The Ghana Health Service Ethics Review Committee has reviewed and given approval for the implementation of your Study Protocol.

GHS-ERC Number	**GHS-ERC: 004/06/21**
Study Title	(Non)Cognitive Routines in Regulatory Review of New Product Innovation: A Discursive Practice Approach
Approval Date	7th July, 2021
Expiry Date	6th July, 2022
GHS-ERC Decision	**Approved**

This approval requires the following from the Principal Investigator

- Submission of a yearly progress report of the study to the Ethics Review Committee (ERC)
- Renewal of ethical approval if the study lasts for more than 12 months,
- Reporting of all serious adverse events related to this study to the ERC within three days verbally and seven days in writing.
- Submission of a final report after completion of the study
- Informing ERC if study cannot be implemented or is discontinued and reasons why
- Informing the ERC and your sponsor (where applicable) before any publication of the research findings.

You are kindly advised to adhere to the national guidelines or protocols on the prevention of COVID -19

Please note that any modification of the study without ERC approval of the amendment is invalid.

The ERC may observe or cause to be observed procedures and records of the study during and after implementation.

Kindly quote the protocol identification number in all future correspondence in relation to this approved protocol

SIGNED.....Bannerman.....
Dr. Cynthia Bannerman
(GHS-ERC Chairperson)

Cc: The Director, Research & Development Division, Ghana Health Service, Accra

Appendix 3.2

University Research Ethics Committee
Brunel University London
Kingston Lane
Uxbridge
UB8 3PH
United Kingdom

www.brunel.ac.uk

3 September 2021

LETTER OF CONDITIONAL APPROVAL

APPROVAL HAS BEEN GRANTED FOR THIS STUDY TO BE CARRIED OUT BETWEEN 03/09/2021 AND 01/10/2021

Applicant (s): Mr Derrick Boakye

Project Title: (Non)Cognitive routines in regulatory review of new product innovation: A discursive practice approach

Reference: 30688-LR-Jul/2021- 33399-3

Dear Mr Derrick Boakye,

The Research Ethics Committee has considered the above application recently submitted by you.

The Chair, acting under delegated authority has agreed that there is no objection on ethical grounds to the proposed study. Approval is given on the understanding that the conditions of approval set out below are followed:

- **The agreed protocol must be followed. Any changes to the protocol will require prior approval from the Committee by way of an application for an amendment.**
- **In addition to the above, please ensure that you monitor and adhere to all up-to-date local and national Government and organisational health advice for the duration of your project.**
- **Please provide copies to the REC of all updated documents (PIS, Risk Assessment) and a copy of the FDA Covid-19 safety protocol. You have previously provided a web link that makes reference to this protocol, but the REC require a copy of the protocol itself (specific to the area you will be working in). Please provide copies of these documents via email to res-ethics@brunel.ac.uk prior to commencement of the study.**

Please note that:

- Research Participant Information Sheets and (where relevant) flyers, posters, and consent forms should include a clear statement that research ethics approval has been obtained from the relevant Research Ethics Committee.
- The Research Participant Information Sheets should include a clear statement that queries should be directed, in the first instance, to the Supervisor (where relevant), or the researcher. Complaints, on the other hand, should be directed, in the first instance, to the Chair of the relevant Research Ethics Committee.
- Approval to proceed with the study is granted subject to receipt by the Committee of satisfactory responses to any conditions that may appear above, in addition to any subsequent changes to the protocol.
- The Research Ethics Committee reserves the right to sample and review documentation, including raw data, relevant to the study.
- You may not undertake any research activity if you are not a registered student of Brunel University or if you cease to become registered, including abeyance or temporary withdrawal. As a deregistered student you would not be insured to undertake research activity. Research activity includes the recruitment of participants, undertaking consent procedures and collection of data. Breach of this requirement constitutes research misconduct and is a disciplinary offence.

Kind regards,

Dr Derek Healy

Chair of the University Research Ethics Committee

Brunel University London

Appendix 3.3

PARTICIPANT INFORMATION SHEET

Study title

(Non)Cognitive routines in regulatory review of new product innovation: A discursive practices approach

Invitation Paragraph

You are being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

What is the purpose of the study?

The study seeks to explore how Regulators' experience and knowledge about the products they review influence the formally codified regulatory review processes. In recent times, there have been rising concerns about how the regulatory review processes and requirements could adjust and respond to markets, new production processes and the changing social contexts within which the technologies underpinning new products are induced. The discussions so far have directed attention to the everyday adaptive practices of product reviewers as a potential source of knowledge that is required to enable the adaptivity of regulatory review frameworks. However, we know little about the mechanism through which this adaption process unfolds. This study is being carried out with the aim to provide a much-needed clarity to discussions by defining, in cognitive terms, the interaction between explicit and tacit knowledge in regulatory review processes, and how their mutual influence facilitates the adaption process of the regulatory review framework.

Why have I been invited to participate?

You have been chosen to join 39 other participants in this study because you have met the following criteria to participate. First, you are a full-time employee of the FDA Ghana. Second, you have held a position as a product reviewer or product review supervisor for a minimum of 6 months.

Do I have to take part?

As participation is entirely voluntary, it is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and you may be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time up until 31/03/2024 and without having to give a reason. Your right to decline or withdraw from this research will in no way influence or adversely affect your employment at the FDA. You can rest assured that no commercially sensitive questions will be asked and the information you provide in this interview will not be revealed to your employer.

What will happen to me if I take part?

You will be invited to a 1.5 hour face-to-face semi-structured interview at a set date, time and place that would be convenient to you and the researcher. At the start of the interview, you will be informed that your voice will be digitally recorded, and you will be asked not to discuss what would be said in the interview publicly. In the interview, please feel free to provide response to the best of your knowledge and abilities. You will also be made aware of your right to withdraw from the study at any stage of the interview.

The information is provided in confidence – no information will be disclosed about you or any individual and all original interviews will be destroyed on completion of transcription. The data analysis will be anonymous – no names will be used in the data analysis, and all data will be aggregated.

Please note that the interview will be conducted under strict Covid-19 safety protocols. You will be required to wear a face covering and remain behind a plain shield mounted between you and the interviewer. Also, you will be required to sanitize your hands with alcohol-based sanitisers that will be made available at the interview. Should you, and/or the researcher, show symptoms or test positive for Covid-19 less than 10 days after the interview, all other participants, including the researcher, will be required to take Covid-19 tests and adhere to self-isolation rules and guidelines if necessary. Kindly adhere to all, and any further Covid-19 safety instructions BEFORE, DURING, and AFTER the interview.

Are there any lifestyle restrictions?

There are no lifestyle restrictions associated with this study, as you have met the criteria to participate in the study.

What are the possible disadvantages and risks of taking part?

Risks associated with Covid-19 are anticipated. However, the interview will be conducted under strict Covid-19 safety protocols. You will be required to wear a face covering and remain behind a plain shield mounted between you and the interviewer. Also, you will be required to sanitize your hands with alcohol-based sanitisers that will be made available at the interview. Should you, and/or the researcher, show symptoms or test positive for Covid-19 in less than 10 days after the interview, all other participants, including the researcher, will be required to take Covid-19 tests and adhere to self-isolation rules and guidelines if necessary. Kindly adhere to all, and any further Covid-19 safety instructions BEFORE, DURING, and AFTER the interview.

Again, you are reminded of your right to refuse to provide responses to questions you are not comfortable to discuss, and to withdraw from the study at any point.

What are the possible benefits of taking part?

As a participant, you will receive a copy of the research findings along with the discussion on how the findings can help improve your understanding of what Reviewers do in their situated practice and how they influence the dynamism of the regulatory review processes.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action, but you may have to pay for it. Should you have any questions please feel free to get in touch with me using my contact details (please see contact details at the end of this document for further information and complaints).

Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential and will be used for research purposes in this study at Brunel Business School. With your permission, anonymised data will be stored and may be used in future research. Any information about you which leaves the University will have all your identifying information removed. The digitally recorded interviews will be stored on a computer that is password protected. The recordings will be destroyed at a later date upon completion of the research. The data analysis will be anonymous – no names will be used in the data analysis, and all data will be aggregated.

If during the course of the study evidence of harm or misconduct comes to light, then it may be necessary to break confidentiality. You will be informed at the time if we think we need to do this, and let you know what will happen next.

Will I be recorded, and how will the recording be used?

Your voice will be digitally recorded, using a mobile phone, from the start to the end of the interview. The digital recordings will be transcribed anonymously and will be destroyed at a later date upon completion of the study.

What will happen to the results of the research study?

Interviewees who select to receive a copy of the research findings will have their names and contact details retained in a separate file for those purposes only.

Who is organising and funding the research?

The research is funded and organised by me, Derrick Boakye.

What are the indemnity arrangements?

Participation in the study will not affect your health-related insurance.

Who has reviewed the study?

The College of Business, Arts and Social Sciences Research Ethics Committee reviewed and granted permission for this research to be conducted.

Research Integrity

Brunel University London is committed to compliance with the Universities UK Research Integrity Concordat. You are entitled to expect the highest level of integrity from the researchers during the course of this research.

Contact for further information and complaints

Researcher name and details:

Derrick Boakye (Derrick.Boakye@brunel.ac.uk)

Supervisor name and details:
Dr David Sarpong (David.Sarpong@brunel.ac.uk)

For complaints, Chair of the Research Ethics Committee:
College of Business, Arts and Social Sciences Research Ethics Committee Chair – Professor David Gallear (David.Gallear@brunel.ac.uk)

Please note that you will be given a copy of this information sheet and a consent form to sign and keep. Thank you for taking the time to read this through - please do not hesitate to contact me if you have any further queries. Please let me know whether or not you would like to participate via email.

Appendix 3.4

CONSENT FORM

(Non)Cognitive routines in regulatory review of new product innovation: A discursive practice approach

Derrick Boakye

APPROVAL HAS BEEN GRANTED FOR THIS STUDY TO BE CARRIED OUT BETWEEN 15/07/2021 AND 01/10/2021

The participant (or their legal representative) should complete the whole of this sheet.		
	YES	NO
Have you read the Participant Information Sheet?	☐	☐
Have you had an opportunity to ask questions and discuss this study?	☐	☐
Have you received satisfactory answers to all your questions?	☐	☐
Who have you spoken to about the study?		
Do you understand that you will not be referred to by name in any report concerning this study?	☐	☐
Do you understand that:		
• You are free to withdraw from this study at any time	☐	☐
• You don't have to give any reason for withdrawing	☐	☐
• Choosing not to participate or withdrawing will not affect your rights	☐	☐
• You can withdraw your data any time up to 31/03/2024	☐	☐
I agree to adhere to all Covid-19 safety protocols, as outlined in the participant information sheet, during the course of the interview.	☐	☐
I agree to my interview being audio recorded	☐	☐
I agree to the use of non-attributable quotes when the study is written up or published.	☐	☐
The procedures regarding confidentiality have been explained to me.	☐	☐

I agree that my anonymised data can be stored and shared with other researchers for use in future projects.	☐	☐
I agree to take part in this study.	☐	☐

Signature of research participant:	
Print name:	Date: