Regulatory 'reliance' in global trade governance

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Abstract: One of the most significant recent trends in global trade governance has been the increasing use of regulatory 'reliance' arrangements as a significant element of trade alliances. Against this backdrop, an important set of questions are raised about how existing institutions of global trade governance – especially the World Trade Organization, and international regulatory standards organisations – should respond. To what extent, and how, should such institutions facilitate reliance arrangements, and what role can they usefully play in overseeing and guiding their use? This paper begins to answer that question through a focussed case study of regulatory reliance in the agrifood sector. Four challenges are identified regarding the implementation of such arrangements: the high costs of establishment and maintenance; the lack of agreed and reliable assessment methodologies; the potential for arbitrary discrimination between trade partners; and the difficulties of dealing with regulatory change over time. In light of these challenges, the paper surveys assesses the work of existing international organisations in governing reliance arrangements in the agrifood sector. The paper concludes with a number of preliminary suggestions as to how this architecture of global governance might be supplemented or harnessed to address some of the challenges posed by reliance arrangements.

Introduction

One of the most significant trends in global trade governance over the last decade or so has been the increasing prioritisation of regulatory interoperability as a central element of trade alliances. This trend can be seen in at least three related developments. First, over the last ten years or so, a range of new generation trade agreements have been negotiated – such as the CPTPP, the EU-Japan EPA and the USMCA, but also many others – which establish a cross-border institutional framework for ongoing regulatory cooperation between the parties.[1]

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[1] For a selection of the literature on regulatory cooperation in FTAs, see See, eg, Steger, 'Institutions for Regulatory Cooperation in 'New Generation' Economic and Trade Agreements' (2012) 38(4) Legal Issues of Economic Integration 109-26; Bollyky, 'Regulatory Coherence in the TPP Talks' in Lim et al., The Trans-Pacific Partnership: A Quest for a Twenty-First Century Trade Agreement (CUP, 2012), chapter 11; Mumford, 'Regulatory Coherence: blending trade and regulatory policy' (2014) 10(4) Policy Quarterly 3-9; Alemanno, 'The Regulatory Cooperation Chapter of Transatlantic Trade and Investment Partnership: Institutional Structures and Democratic Consequences' (2015) 18 Journal of International Economic Law 625-40; Marks, 'The Right to Regulate (Cooperatively)' (2016) 38 University of Pennsylvania Journal of International Law 1-69; Wiener and Alemanno, 'The Future of International Regulatory Cooperation: TTIP as a Learning Process Toward a Global Policy Laboratory' 78 Law and Contemporary Problems 103-36; Bull, Mahboubi, Stewart, Wiener, 'New Approaches to Regulatory Cooperation: The Challenge of TTIP, TPP, and Megaregional Trade Agreements' 78 Law and Contemporary Problems 1-29; Polanco Lazo and Sauve, 'The Treatment of Regulatory Convergence in Preferential Trade Agreements' (2018) 17(4) World Trade Review 575-607; Mertenskotter and Stewart, 'Remote Control: Treaty Requirements for Regulatory Procedures' 104 Cornell Law Review 165-231; Liu and Lin, 'The Emergence of Global Regulatory Coherence: A Thorny Embrace for China?' (2018) 40(1) University of Pennsylvania Journal of International Law 133-89; Kauffmann, 'Adapting Regulation to Globalization: A Typology of Approaches to the Internationalization of Regulation' in Brousseau, Glachant and Sgard (eds), Institutions of International Economic Governance and Market Regulation (Oxford, 2018); Hale, 'Regulatory Cooperation in North America: Diplomacy Navigating Asymmetries' (2019) 49(1) American Review of Canadian Studies 123-49; Hoekman and Sabel, 'In a World of Value Chains: What Space for Regulatory Coherence and Cooperation in Trade Agreements' in Kingsbury et al (eds) Megaregulation Contested: Global Economic Ordering After TPP (OUP, 2019), Chapter 10; Mavroidis, (2016) Regulatory Cooperation: Lessons from the WTO and the World Trade Regime, E15 Task Force on Regulatory Systems

'Regulatory cooperation' under these new generation trade agreements can take many different forms, but they typically include: establishing spaces for routinised dialogue between regulators; providing for prospective notice and comment regarding regulatory changes; supporting the negotiation of equivalence and recognition arrangements; sharing information about emergent cross-border risks; facilitating verification audits of each others' regulatory systems; and so on. Second, it is increasingly common to see a range of trade-facilitating regulatory determinations being made in connection with the conclusion of trade agreements – even where they do not form part of the trade treaty itself. The EU data adequacy decisions in respect of Japan and the UK are paradigmatic examples, but there are many others.[2] Third, most recently and perhaps most significantly, is the emergence of a number of high profile initiatives which seek to create new kinds of standards-based trade alliances built around aligned regulatory systems. One example is the emerging transatlantic Global Arrangement on Sustainable Steel and Aluminium, which seeks (in part) to promote decarbonisation of the steel sector by facilitating trade in steel products which conform to agreed standards for sustainable steel production. The G7-proposed Climate Club takes a similar form, that is to say, it is a club of like-minded countries seeking to pursue market liberalisation in 'green' products, based on aligned sustainability standards. Another key example is the US-led Indo-Pacific Economic Framework, as well as the Americas Partnership for Economic Prosperity, both of which foreshadow the construction of dynamic economic alliances predicated in part on high ambition and compatible regulatory frameworks.

While these developments are not wholly new, nevertheless they are clearly distinguishable from what has come before. While earlier generations of trade agreements did, of course, address regulatory issues, by and large they did so by establishing general disciplines requiring regulatory decision-making to be transparent, even-handed, objective and rigorous. They sometimes also contained exhortations to use international standards, and to cooperate around international standard-setting, and they loosely encouraged the use of equivalence and recognition arrangements, but these provisions were only patchily operationalised. New-style agreements are designed to go beyond this[3]: first, by generating the kinds of routinised cross-border interactions which help to build trust and confidence in each others' regulatory systems; and second, by seeking to establish much more specific frameworks and mechanisms for improving the interoperability of parties' regulatory frameworks. In that sense, these new-style arrangements can look a little like deep integration arrangements, such as most famously the EU single market, which have developed over many decades a variety of different mechanisms of regulatory interoperability. But here, too, the comparison is inapt: while deep integration arrangements do prioritise mechanisms of regulatory interoperability, they tend to combine these mechanisms with a complex and powerful supranational governance structure, as well as aspirations to broad regulatory harmonisation in many sectors. What is distinctive about the kinds of trade alliances I described above is precisely that they seek to establish forms of interoperability without such a supranational framework, nor even an aspiration to substantive regulatory harmonisation over time.

Coherence – Policy Options Paper, E15 Initiative, International Centre for Trade and Sustainable Development (ICTSD) and World Economic Forum.

[2] See generally, European Commission, 'Adequacy Decision', https://commission.europa.eu/law/law-topic/data-protection/international-dimension-data-protection/adequacy-decisions_en, accessed 16 Sep 2023, and for examples in the context of food safety, see further nn56-59 below.

[3] On this point, see also Lim and Holzer, 'Trading in the era of carbon standards: how can trade, standard setting, and climate regimes cooperate?' (2023) 39(1) Oxford Review of Economic Policy 110–122.

Regulatory 'interoperability' is an imprecise term, and for the purposes of this paper I will use the related concept of regulatory 'reliance' to focus my object of enquiry. This is an existing term of art in the regulatory literature. The World Health Organization (WHO), for example, defines 'reliance' as: an 'act whereby the regulatory authority in one jurisdiction takes into account or gives significant weight to assessments performed by another regulator, or other trusted institution, or to any other authoritative information, in reaching in its own decision'.[4] Accordingly, in this paper I use the generic term 'regulatory reliance' to describe those cross-border arrangements which facilitate 'reliance' by regulators in one jurisdiction on decisions, assessments or information produced by actors in a foreign regulatory system, based on their confidence in the quality and adequacy of that foreign system. As the WHO makes clear, such arrangements do not involve any transfer of regulatory authority: 'the relying authority remains independent, responsible and accountable for the decisions taken, even when it relies on the decisions, assessments of information of others'.[5] Examples of regulatory reliance include equivalence arrangements, mutual recognition agreements, streamlined authorisation or inspection procedures for favoured jurisdictions, arrangements for the joint conduct of market supervision, among others.

As a result of these developments, a new set of questions has emerged for trade negotiators and trade policy professionals. How useful are regulatory reliance arrangements as techniques of trade liberalisation, and what are their limitations? To the extent that they are useful, what obstacles exist to their implementation? What specific role can trade agreements play in facilitating and supporting such mechanisms? And most generally: how should the existing institutions of global trade governance – especially the World Trade Organization, and existing international standards bodies – both accommodate and respond to the emergence of trade alliances built around reliance arrangements of this type?

The starting point of this paper is that in order to answer these questions, it is helpful first to take a step back, and to review both the existing landscape of practices of regulatory reliance, and the governance architectures which have already evolved around them. Although these are (mostly) new questions for trade policy professionals, regulators across a wide variety of sectors have for some decades experimented with different mechanisms of regulatory reliance outside of the context of trade alliances and agreements. Similarly, a number of international institutions have already developed streams of work on regulatory reliance, and have created at least the beginnings of a normative, procedural and methodological framework for it at the global level. The first step, then is to assess the strengths and weaknesses of this existing architecture. On that basis, we can begin to offer some ideas of what improvements might be needed, and what an adequate governance structure for regulatory reliance might look like.

I focus on a single sectoral case study, that of food safety regulation. It is a field in which practices of regulatory reliance are historically amongst the most extensive. At the same time, it is also an area in which there has been considerable innovation over the last decade, including at the interface between food safety regulation and free trade agreements, as well as with the conclusion of new modalities of cross-border arrangements. In addition, international institutions in this field have been amongst the most active in facilitating and promoting regulatory reliance, and their experience is an excellent resource for analysis and

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[4] WHO, 'Good reliance practices in the regulation of medical products: high level principles and considerations', 55th Report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations', WHO Technical Report Series 1033 (2021), p243 and Annex 10, available at https://apps.who.int/iris/bitstream/handle/10665/340323/9789240020900-eng.pdf, accessed 16 September 2023.

[5] *Ibid*.

reflection on the potential role of such institutions. That said, a single case study naturally only provides a limited window from which to draw conclusions, and this represents only the first fruits of a larger project which examines practices of regulatory reliance across a range of diverse fields of regulation.

Equivalence and systems recognition in food safety regulation

a. Illustrative practice

The legislative framework for reliance-based arrangements in the food safety sector have formally existed in many countries for over a century. In the US, for example, it has long been a core regulatory principle that imports of certain products are only permitted from countries and production establishments which have been determined in advance to have food safety control systems which achieve the same level of safety as domestic regulation systems.[6] This applies to imports of meat, poultry and egg products, shellfish and some dairy products,[7] and is administered by the Food Safety Inspection Service (FSIS) and Food and Drug Administration (FDA) within their respective areas of competence. Notably, pre-approval is only an initial regulatory hurdle for products seeking to enter these markets: such products are still subject to certification and documentary requirements, various forms of reinspection and testing at their ports of entry, as well as other approvals. The level of regulatory trust and confidence implied by equivalence-based pre-approval in the food safety context, then, is significant, but somewhat lower than it might initially seem.

The specific procedures and institutional structures for determining equivalence have changed considerably over the decades. In the US, the earliest formulations of the principle merely permitted the relevant regulatory authorities to refuse entry to meat products from countries with regulatory systems found *not* to be equivalent, and prior to 1948 formal equivalence determinations were not published at all.[8] The process was gradually institutionalised, however, over subsequent decades.[9] In 1977, the Food Safety and Quality Service – renamed the Food Safety and Inspection Service (FSIS) in 1981 – was created and took over responsibility for inspecting foreign establishments to determine whether or not they were 'at least equal to' domestic US establishments as regards production safety standards. During this period, food safety systems principally relied on regular inspection and testing of production facilities by public authorities, and as a consequence equivalence determinations also relied heavily on the conduct of on-site inspections and testing abroad. This significantly limited the practice: over the 1980s, the FSIS had inspection officials stationed in only eight overseas jurisdictions, though in 1988 the process was revised considerably to rely more heavily on port of entry inspections and past audit results.

Important changes to the system occurred from the 1990s onward, and it is here that the modern story really begins. This was a decade in which the US' regulatory approach to food

[6] Such requirements were first enshrined under the Federal Meat Inspection Act [Public Law 90-201] (enacted 1906), the Poultry Products Inspection Act [Public Law 85-172] (enacted 1957), and the Egg Products Inspection Act [PL 91-597] (enacted 1970), as well as the Humane Methods of Slaughtering Act [Public Law 85-765] (enacted 1958).
[7] See, eg, 9 CFR § 327.2; 9 CFR § 381.196; 9 CFR § 590.910; 21 USC 620; 21 USC 466; 21 USC 1046.
[8] McMurtrey and Burr, 'The US Food Safety System and Equivalence: Perspectives from Two US Agencies', paper presented to WTO SPS Committee, 18 March 2019, footnote 1 (copy on file with author).
[9] Some brief historical background on FSIS equivalence practices can be found in FSIS, 'Ongoing Equivalence Verifications of Foreign Food Regulatory Systems', 78 FR 5409, 25 January 2013.

safety management began a long and incremental transformation in the direction of risk-based regulation. This occurred in part as a response of a number of high profile cases of foodborne illness, but also was part of a much broader turn toward risk-based approaches which began to be adopted across many regulatory domains around the same time. The turn to risk-based regulation meant, first, that the focus of regulatory attention was expanded, so as to include not just final products and production facilities, but the entire production cycle from farm to market. Second, and as a consequence, it also entailed a turn to risk management – that is to say, approaches which relied less on discrete inspection points and procedures, and rather more on the development of comprehensive systems and protocols for managing risk at all points throughout the production chain, using the principles of risk analysis and process control. The governance protocol developed for these purposes was the Hazard Analysis and Critical Control Point (HACCP) model, which, famously, has since been adopted as standardised practice across most developed country agrifood markets and production networks. Third, and again as a consequence, this meant that regulators increasingly relied on internal control systems designed and implemented by producers themselves. In line with broader regulatory trends occurring at the same time, the new regulatory approach reconfigured the relative roles of producers and regulators, with the former responsible for establishing and implementing a plan for managing risk at all points throughout the production chain, and the latter taking on the role of overseeing and ensuring its adequacy.

The shift towards risk-based approaches had important implications for practices of equivalence, not only changing the nature of equivalence assessments, but also helping to provide the enabling conditions for equivalence relationships with a greater range of foreign jurisdictions. Where, in earlier decades, equivalence had been based largely on the results of on-site inspections and testing in foreign establishments, the new regulatory paradigm necessitated a much more comprehensive assessment of the entire food control system in place in a foreign country. The scope of the FSIS' equivalence assessment process was accordingly broadened significantly over the 1990s, to include, for example: 'country laws and documents related to program implementation; records of establishment operations, inspection results, and enforcement activities; chemical residue controls from farm to slaughter; microbiological and chemical testing programs; laboratory support, sampling programs, and sampling and testing methodologies; and other U.S. import requirements such as pathogen reduction and HACCP program'.[10]

The new approach helped to enable and prompt greater reliance on foreign regulatory systems in a number of ways. For one thing, the rapid spread of HACCP-based governance technologies in transnational agrifood production networks, alongside concerted efforts to harmonise and disseminate best practice risk-based approaches amongst regulators in the most significant agrifood markets, helped to provide a degree of familiarity and commonality between food safety systems in different jurisdictions.[11] Just as importantly, the new regulatory approaches reconfigured the role of regulatory authorities - now acting primarily as guarantors and overseers of safety control systems designed and implemented by private

[10] *id.*, 5410.

[11] In fact this worked both ways. As Murano et al report, the rapid adoption of the HACCP framework in many countries not only facilitated equivalence but in fact was also driven in part by the requirement inserted into US law requiring HACCP programmes domestically, coupled with the requirement that foreign countries' regulatory systems achieved an equivalent level of protection. The best solution for many exporters of meat and poultry was to similarly require HACCP domestically: Murano, Russell Cross and Riggs, 'The outbreak that changed meat and poultry systems worldwide', (2018) 8(4) *Animal Frontiers* 4-8, at 5.

firms - and in doing so prompted regulators to develop technologies for assessing governance quality, and to build confidence in their reliability. It is a relatively short step from there to the assessment of foreign regulatory systems: in both of these cases, food safety regulators take on a role of establishing and verifying compliance with best risk management practices, as well as assuring the quality and reliability of governance carried out by others. Indeed, their ability to work at a distance is one of the great advantages of risk-based regulatory approaches, and key to their position as a key governance technology enabling the transnationalisation of the agrifood sector.

Accordingly, the number of foreign jurisdictions subject to, for example, an FSIS equivalence determination with respect to meat, poultry or eggs, has gradually increased since the 1990s, with 17 having at least one approved establishment in 2002, rising to around 40 at present, and more than 50 determinations currently listed as pending.[12] Of those, almost all are in the Americas or Europe, with one from the African continent, one from the Middle East, four from East and Southeast Asia, as well as Australia and New Zealand. For its part, the FDA did not determine food safety system equivalence prior the enactment of the Food Safety Modernization Act 2011. However, it has recently concluded its very first equivalence determination, in the context of an agreement with European counterparts relating to the mutual equivalence of inspection and control systems for shellfish.[13]

The procedure for determining equivalence can be lengthy and involved, often taking many years, and involving a number of steps.[14] An initial documentary stage, in which the exporting country reports in detail on the structure and operation of its food control systems, is typically followed by an on-site verification audit of implementation capacity, involving visits to foreign government offices, exporting establishments and laboratories. The assessment is focussed at least as much on the governance capacity of foreign regulatory systems – including especially the capacities to prevent, detect, identify and rapidly respond to food safety incidents – and its interoperability with US systems, as it is on its substantive similarity with US law and practice. Evidently, the process is relatively one-sided in the sense that the onus is on the petitioning exporting country to demonstrate the reliability of its

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[12] The current list of eligible foreign establishments, and their homes countries, can be found at USDA, 'Eligible Foreign Establishments', https://www.fsis.usda.gov/inspection/import-export/import-export-library/eligible-foreign-establishments, accessed 16 Sep 2023, along with the relevant listing date. Most of these relate to meat and poultry: only two countries currently are listed as equivalent with respect to egg products, Canada and the Netherlands. A list of pending determinations, current as at August 2023, can be found at FSIS, 'Status Chart for Active Equivalence Requests', https://www.fsis.usda.gov/sites/default/files/media_file/2022-04/equivalence-status-chart.pdf, accessed 16 Sep 2023.

[13] This agreement, which facilitates exports from Spain and the Netherland to the US on one hand, and from Washington and Maine to the EU on the other, is structured as two more or less coincident unilateral equivalence determinations, and provides for simplified certification procedures and documentation for bilateral trade in specified shellfish. . FDA,' Food and Drug Administration Equivalence Determination Regarding Implementation by Spain and the Netherlands of the European Union System of Food Safety Control Measures for Raw Bivalve Molluscan Shellfish With Additional Controls' 85 *Federal Register* 60172, 24 Sep 2020; FDA, 'Equivalence Determination Regarding the European Union Food Safety Control System for Raw Bivalve Molluscan Shellfish' 83 *Federal Register* 10487, 9 March 2018; Commission Implementing Regulation (EU) of 4 Feb 2022, amending Implementing Regulation (EU) 2020/1641 regarding imports of live, chilled, frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods for human consumption from the United States of America, C(2022) 562 final.

[14] An overview of the FSIS process, for example, can be found at FSIS, 'Equivalence', https://www.fsis.usda.gov/inspection/import-export/equivalence, accessed 16 Sep 2023.

inspection and control systems. This can involve a degree of adjustment of the exporting country's regulatory systems and practices to the satisfaction of US authorities.[15]

Food safety equivalence practice in a number of other jurisdictions shares similar features to the US practice just described.[16] In the EU, pre-authorisation of countries and establishments is required for live animals, most products of animal origin, seafood, and some plant products.[17] As in the US, approval is a necessary but not sufficient condition for importation: imports from eligible countries and establishments are still subject to a range of documentary checks, physical inspections and veterinary inspections. The application process is initiated by a third country by request to the European Commission, and is followed by a process of detailed documentary review based on written responses to a questionnaire, as well as (in most cases) an on-the-spot inspection by relevant European authorities. The factors taken into account are broadly similar to those mentioned above: the governance capacity of the foreign regulatory system, including its level of resources, the training of staff, the nature of routinised procedures; actual hygiene conditions throughout the supply chain; prior experience with imports of products from that country; the assurances which are given by the third country regarding compliance with EU requirements; the mandatory implementation of HACCP-based control systems in all facilities, and so on. Furthermore, approval itself is not necessarily an all or nothing matter: approval may be made subject to specific additional commitments, or qualifications, relating for example to certification requirements, particular territorial restrictions, additional treatment or vaccination programmes, exclusions, and so on. These bilaterally tailored requirements are memorialised in the relevant EU regulations, and updated as appropriate.

It is important to note that equivalence is not the only modality of regulatory reliance which has been adopted in the food safety context. Another, more recent, modality is that of 'systems recognition'. Unlike the equivalence arrangements just described, systems recognition arrangements are not prerequisites for importation, but rather mechanisms by which regulatory authorities in two jurisdictions can mutually agree to subject bilateral trade to more streamlined procedures, less stringent testing and inspection, and reduced auditing requirements, based on an assessment of the reliability of their respective regulatory infrastructures. They are a relatively recent innovation, and have been analysed by some as illustrative of a paradigmatically new modality of regulatory cooperation.[18]

In the US, systems recognition was introduced as part of a broader reorganisation of the US food safety system initiated by the Food Safety Modernization Act 2011 (FSMA). In part to

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[15] A process of adjustment in the case of the shellfish determination, for example, is described in FDA (2018) and FDA (2022), above n13.

[16] See, for example, the summaries of the various jurisdictions' practice covered by the WTO SPS Committee's thematic days on equivalence, available at WTO, 'SPS Thematic Session on Equivalence (Part 2), https://www.wto.org/english/tratop_e/sps_e/workshop18032019_e.htm, accessed 16 Sep 2023.

[17] See, eg, Regulation (EU) 2016/429 of the European Parliament and of the Council of 9 March 2016 on transmissible animal diseases and amending and repealing certain acts in the area of animal health, Article 229. It is supplemented by Commission Delegated Regulation (EU) 2020/692, and Commission Implementing Regulation (EU) 2021/404, the latter laying down the lists of third countries, territories or zones thereof from which the entry into the European Union of animals, germinal products and products of animal origin is permitted.

[18] See, eg, Hoekman and Sabel, 'In a World of Value Chains: What Space for Regulatory Coherence and Cooperation in Trade Agreements' in Kingsbury et al (eds) *Megaregulation Contested: Global Economic Ordering After TPP* (OUP, 2019), Chapter 10; Hoekman and Sabel, 'Open Plurilateral Agreements, International Regulatory Cooperation and the WTO' (February 2019). Robert Schuman Centre for Advanced Studies Research Paper No. RSCAS 2019/10.

encourage a more efficient and flexible use of limited regulatory resources, and in part to remove unnecessarily duplicative regulatory processes and facilitate bilateral trade, the FSMA formally authorised the FDA to rely on foreign regulatory systems as appropriate in fulfilling its mandate. This was followed in 2012 by Executive Order 13609 explicitly promoting international regulatory cooperation across government, including in the food safety context.[19] Pursuant to this mandate, the FDA has concluded what it calls Systems Recognition Arrangements (SRA) with regulatory counterparts in New Zealand (2012), Canada (2016) and Australia (2017).[20] These arrangements are non-binding understandings concluded directly between regulators, and the FDA is careful to distinguish them from 'equivalence' properly so-called.[21] Unlike equivalence decisions, they are reciprocal agreements, not unilateral determinations. But like equivalence assessments, they are preceded by extensive evaluation by each partner of the other's regulatory system, including both desk review and on-site inspections. This assessment includes, according to the FDA, an assessment of the capacity of each other's regulatory systems to learn and adapt over time: '[s]ystems recognition assessments focus not only on the ability of food safety systems to help ensure food safety, but also on the ability of food safety authorities to identify, address and contain food safety issues and outbreaks that may arise, learn from past events and strengthen the system over time'.[22]

Just as in the equivalence context, the conclusion of an SRA is not a one-off process, but instead establishes conditions for regular interactions. SRAs envisage the establishment of mechanisms for the exchange of confidential information necessary for ongoing regulatory cooperation, as well as mechanisms for notification and case-by-case resolution of specific food safety issues as they arise. They provide for mutual monitoring, periodic reassessment and mutual audits, as well as the possibility of additional follow up assessments wherever there is a significant change to the level of food safety control in either jurisdiction. They record the intention of the parties to consult in advance on any changes which may affect the relationship. They envisage also ongoing collaboration also on audit and inspection activity, including the sharing of results.[23]

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[19] 'Promoting International Regulatory Cooperation, Executive Order 13609 of May 1, 2012, 77 *Federal Register* 26413.

[20] Information on the FDA's process for systems recognition, as well as the texts of each of these agreements, can be found at FDA, 'Systems Recognition (Food)', https://www.fda.gov/food/international-cooperation-food-safety/systems-recognition-food.

[21] *Id.*, especially section entitled 'Systems Recognition v Equivalence'.

[22] The quoted language is attributed to Frank Yiannas, Deputy Commissioner for Food Policy and Response, 9 July 2021, see FDA, 'FDA in Brief: FDA Issues Systems Recognition Draft Guidance' https://www.fda.gov/news-events/press-announcements/fda-brief-fda-issues-systems-recognition-draft-guidance, accessed 16 Sep 2023. A similar point is made by Hoekman and Sabel in the papers cited in n18 above.

[23] See, eg, Food Safety Systems Recognition Arrangement Between The Australian Department Of Agriculture and Water Resources and The FDA of The United States of America ('Australia SRA'), https://www.fda.gov/international-programs/cooperative-arrangements/food-safety-systems-recognition-arrangement-between-australian-department-agriculture-and-water, accessed 16 Sep2023, Sections IV, V, VI; Food Safety Systems Recognition Arrangement Between The Canadian Food inspection Agency and the Department of Health Canada and the Food and Drug Administration of the United States ('Canada SRA'), https://www.fda.gov/international-programs/cooperative-arrangements/fda-cfia-and-health-canada-food-safety-systems-recognition-arrangement, accessed 16 Sep 23, Sections IV, V, VI; Food Safety Systems Recognition Arrangement between The Ministry for Primary Industries of New Zealand and The Food and Drug Administration of the United States ('New Zealand SRA'), 10 Dec 2012, https://www.fda.gov/international-programs/cooperative-arrangements/fda-new-zealand-mpi-food-safety-systems-recognition-arrangement, accessed 16 Sep 2023, Paragraphs IV, V, VI.

Little is said in the SRA itself about the consequences which flow from the determination of mutual comparability, aside from simply noting that systems recognition 'allows for' greater mutual reliance, and 'may result' in reductions in the type and frequency of verification activities. More detail is found in a policy guidance document issued by the FDA in June 2022.[24] This document makes clear that the FDA will not 'prioritise' foreign establishment inspections in countries with which it has an SRA, except in response to a specific cause or request, or for matters outside the scope of the arrangement. In addition, it will adjust its screening and targeting criteria for imports to reflect the reduced risk associated with imports from such jurisdictions, and will not prioritise import samples and field examinations of food products covered by an SRA.

Although the EU, for its part, does not conclude systems recognition agreements as such, it does have a longstanding practice of concluding Veterinary Agreements with selected trade partners, which have a somewhat similar function. It currently has fifteen such agreements, with the first concluded with New Zealand as early as 1996.[25] Some of these agreements – such as those with Switzerland, Andorra, San Marino, Liechtenstein – eliminate virtually all certification requirements and border inspections in respect of the regulations covered, but are predicated on the trade partner largely agreeing to align its plant and animal health and food safety rules with those of the EU. They are typically concluded with closely associated countries in the European space. Others, however – such as those with New Zealand, the United States, Canada, and others – are predicated on a lesser degree of alignment, and are more relevant to this study.

These latter agreements set out an agreed framework for the initiation and conduct of equivalence and adequacy determinations. This includes setting out the main procedural steps to be followed, as well as the elements of foreign food safety systems which are relevant to an equivalence assessment. They also memorialise equivalence determinations: that is to say, those measures which have been recognised as equivalent, or otherwise conditionally adequate, are listed in an annex to the agreement, and updated as needed. For products covered by such equivalence determinations, bilateral trade is streamlined: the frequency of physical border checks is significantly reduced, though not eliminated, and simplified veterinary certification procedures are applied, involving the recognition by the importing country of certificates issued by the exporting country. Importantly, also, these agreements provide for ongoing monitoring of each other's regulatory systems in order to maintain mutual confidence in the arrangement. This includes provision for periodic audit and verification of each others' control programs, as well as risk-based frontier checks. Finally, they establish mechanisms for routine dialogue and information exchange, requiring notification of significant changes to health status, opportunities to consult on proposed regulatory changes, and scientific exchanges.[26]

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[24] FDA, *FDA Oversight of Food Covered by Systems Recognition Arrangements: Guidance for Food and Drug Administration Staff*, June 2022, available at https://www.fda.gov/media/150676/download, accessed 16 Sep 2023.

[25] The text of these agreements can be found at European Commission, 'Food Safety: Agreements with Non-EU Countries' https://ec.europa.eu/food/horizontal-topics/international-affairs/agreements-non-eu-countries_en, accessed 16 Sep 2023.

[26] See, eg, Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products, OJ L 57, 26.2.1997, p. 5–59, as amended, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A01997A0226%2802%29-20150401 accessed 16 Sep 2023.

What we see in SRAs and VAs, then, in a similar but more developed manner to pre-approval equivalence practice, is the adoption of highly tailored reliance arrangements, in which regulatory resources and burdens are carefully calibrated to qualitative assessments of the governance capacities and risk profile of specific foreign jurisdictions. The deference arrangements which are established under them are flexible and indeed in principle readily reversible, and they are operationalised largely at the level of regulatory practice rather than rigid rule.

b. Key challenges in the implementation of reliance arrangements

Reliance arrangements of one type or another, then, underpin a substantial amount of global agrifood trade, and are an established and important part of the regulatory architecture of global food trade. Although historically grounded in quite rigid equivalence requirements, which are probably best understood as impediment to trade, the last decades have seen experimentation with more flexible instruments of regulatory reliance as techniques, and frameworks, for market liberalisation. Indeed, a number of major agricultural exporting nations have begun to see reliance arrangements as central tools for facilitating access to markets with key trade partners.[27] In that context, it is worth setting out some of the attractions of flexible reliance arrangements as techniques of liberalisation, from the perspective of regulators themselves.

When compared to most other mechanisms typically used to address regulatory barriers in projects of economic integration – such as harmonisation, or binding treaty-based regulatory disciplines, for example – reliance arrangements involve relatively little loss of regulatory freedom. That is to say, they represent a mechanism of liberalisation which entails relatively few upfront and irreversible legal commitments, which maintains a high degree of regulatory discretion, and which is consistent with political demands for regulatory 'autonomy'. Furthermore, given their relatively easy reversibility in principle, reliance arrangements can present less of a risk for regulators than more permanent or rigid instruments, providing regulators the possibility of dynamically changing the arrangement in response to evolving risks. In addition, as noted above, they offer regulators a highly differentiated instrument of liberalisation: they can be as narrow or as broad as regulators are comfortable with, and can broaden over time as levels of comfort and trust increase. Taken together, these factors suggest that such arrangements are a means for regulators to respond to demands for the reduction of regulatory burdens and the liberalisation of markets, with fewer risks and constraints than at least some other available mechanisms.

That said, they are far from perfect, and most stakeholders would agree there is considerable room for improvement in their operationalisation.[28] Four specific difficulties are worth highlighting here.

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[27] See, for one example, 'Developing Guidance on Consideration of Systems Approaches as Equivalent to Existing Measures: Communication from Australia', G/SPS/W/299, 6 June 2018, noting that the 'application of systems approaches may be the only option available to exporting Members to maintain existing trade' (para 5).

[28] The work of the WTO's SPS Committee is an important source of information on experiences with equivalence and recognition in the agrifood sector. 'Equivalence' is a standing item on its agenda, and part of the regular reviews of the agreement conducted by the Committee. Evidence of the views of a number of WTO Members can be found in both in meeting minutes and in documentation submitted to the Committee. The SPS Committee has also conducted two thematic days on equivalence in 2018, in the context of the fifth review of the SPS Agreement, at the initiative of Canada. See WTO, 'SPS Thematic Session on Equivalence (Part 1)', https://www.wto.org/english/tratop_e/sps_e/workshop301018_e.htm, accessed 16 Sep 2023; WTO, 'Summary of the Meeting of 1-2 November 2018: Note by the Secretariat', WTO Document G/SPS/R/93, 11 Feb 2019;

Establishment costs. Establishing and maintaining reliance arrangements can be costly. For the importing jurisdiction, assessments of the adequacy and reliability of foreign regulatory systems require considerable work and time to conduct. Furthermore, beyond these initial assessment costs, successful arrangements can require the establishment of structures for routine interaction and relationship-building across borders. As a consequence, even for large and well-resourced regulators in major importing jurisdictions, there is a limit to how many such relationships can be adequately maintained at any one time. At the same time, for exporting jurisdictions, the process of demonstrating equivalence is also resource-intensive and time-consuming: different importing jurisdictions typically have different comparability assessment protocols, with their own informational demands, timelines, and evaluative metrics; the transparency of the process is often lacking; and there may be considerable costs involved in making changes to domestic regulatory processes to satisfy risk-averse foreign regulators. For many, these costs often outweigh the (uncertain) commercial benefits to be gained from the arrangements themselves.

Lack of reliable and agreed assessment methodologies. Methods for determining equivalence vary considerably from jurisdiction to jurisdiction, and, notwithstanding the practice described above, it is still the case that regulators in a number of jurisdictions have little familiarity or experience with the process at all. While it is common ground that equivalence determinations should be 'outcome-based', this leaves many questions open. What outcomes are the most salient? How are they to be measured? How in particular can one reliably measure the operational effectiveness of regulatory systems? And what degree of similarity is required for a determination of equivalence, comparability or reliability? In the absence of well-developed and agreed answers for such questions, the reliability of processes of governance assessment will always remain in question. Moreover, it is a common complaint that major importing countries can in practice place too much weight on minor textual differences between their own and foreign regulatory frameworks, or rigidly apply the same process for approvals for domestic and foreign establishments.[29] In such cases, the process can function more as an inflexible means of projecting regulatory preferences abroad rather than as a mechanism of genuine deference and flexibility.

Potential for discrimination, and politicisation. The process is by and large not as transparent it should be, and the reasons for which some partners are chosen over others is not always clear. Sometimes, such reasons are straightforwardly protectionist: the process is, after all, not always immune from pressure from interested commercial stakeholders, including import-competing producers. More generally, however, the assessment process can also can

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WTO, 'SPS Thematic Session on Equivalence (Part 2), https://www.wto.org/english/tratop_e/sps_e/workshop18032019_e.htm, accessed 16 Sep 2023; WTO, 'Summary of the Meeting of 1-2 November 2018: Note by the Secretariat', WTO Document G/SPS/R/94, 27 Jun 2019. Similar work has been carried out in respect of the recognition of pest-free areas, including both a thematic session and a more formal survey of Members soliciting their experience and views regarding recognition arrangements in this area. See WTO Document, 'Article 6 of the SPS Agreement, Questions for Discussion, Compilation of Comments Submitted by Members: Note by the Secretariat', G/SPS/W/311/Add.1/Rev.2, 20 Sep 2019. The following paragraphs draw on this work of the SPS Committee, with attention focussed on issues also identified in reviews of reliance arrangements conducted in other sectors, suggesting generic challenges posed by such agreements, see eg, European Commission, 'EU Equivalence Decisions in Financial Services Policy: An Assessment' SWD (2017) 102, 27 February 2017; Correia de Brito, Kauffmann, and Pelkmans, 'The Contribution of Mutual Recognition to International Regulatory Co-operation', OECD Regulatory Policy Working Paper No. 2, 2016.

[29] These points were consistently made, for example, in the presentations to the WTO SPS Committee's thematic sessions on equivalence, *id*.

depend to a significant extent on extraneous matters, including the larger relationship between two jurisdictions at issue. A particularly extreme example of this was the May 2006 decision of the US Congress to ensure that none of the funds made available to the USDA in the normal budgeting process could be used to implement an equivalence determination in favour of poultry imports from China, a measure which gave rise to a WTO dispute.[30] Expectations of reciprocity can also operate to impair the objectivity of the assessment procedure. But there are other, more mundane, reasons for a lack of evenhandedness in practice. The resources and priority accorded to any individual negotiation can have a huge impact on the speed and efficiency of the assessment process. Furthermore, there is a natural tendency for regulators to feel more comfortable entering into arrangements with jurisdictions which are well-known to them, and where strong historical commercial ties exist – even where the evidentiary case for arrangements with less familiar jurisdictions may be just as strong. Given the discretionary, uncertain and often opaque nature of the process, this is a real concern, especially for developing countries who may lack the resources and technical know-how adequately to engage in the process.

The problem of regulatory change over time. Further challenges, for both importing and exporting countries, arise from the fact that food safety systems are dynamic. Equivalence arrangements, consequently, must also be dynamic – that is to say, kept under regular review, and accompanied by ongoing bilateral communication including prior notification of changes. This is a difficult process to get right.[31] Adequate monitoring is difficult and resource intensive. Even for a comparatively well-resourced bodies the monitoring costs are very significant, and as a result processes have been developed to tailor the nature and intensity of monitoring according to the degree of risk posed by different jurisdictions and different products. The FSIS, for example, conducts periodic country performance assessments as a form of triage, to determine the frequency and scope of on-site audits.[32] Even aside from these monitoring costs, it is also the case that there can be powerful incentives on both sides (export and import) not to disrupt existing commercial relationships and supply chains without very good reason.

c. International governance

I turn now to examine the international governance architecture which has incrementally emerged alongside practices of regulatory reliance of this kind in the food safety sector since the 1990s. What does this architecture do, and how adequately does it do it? In particular,

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[30] See Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, adopted 25 October 2010; see also, for another example, WTO Dispute Settlement Body, *Minutes of Meeting held on 31 August 2015*, WT/DSB/M/367, 30 October 2015, para 11.5.

[31] See, eg, the comments from the representative of the Canadian Food Inspection Agency during the WTO SPS Committee's thematic day of discussion on equivalence, above n28, noting that 'ongoing bilateral communication is critical to maintain the recognition status, including proactive notification of any changes to its inspection system or legislation governing its inspection system'. The difficulties associated with ongoing monitoring and review and not specific to food safety, and have been explicitly noted in other regulatory domains. See, on this point, the specific challenges noted in the EU review of equivalence arrangements in the financial services context: European Commission, 'EU Equivalence Decisions in Financial Services Policy: An Assessment' SWD (2017) 102, 27 February 2017; also European Commission, 'Communication From The Commission To The European Parliament, The Council, The European Central Bank, The European Economic And Social Committee And The Committee Of The Regions: Equivalence in the Area of Financial Services', COM(2019) 249, 29 July 2019.

[32] See FSIS, 'Ongoing Equivalence Verifications of Foreign Food Regulatory Systems', 78 FR 5409, 25 January 2013, 5411ff.

how well placed is it to address the four key difficulties and challenges enumerated in the previous section?

At the multilateral level, one of the key institutions is the World Trade Organization, which has worked to facilitate equivalence arrangements in the food safety context in particular through its Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).[33] This agreement provides an agreed framework of normative principles – albeit somewhat rudimentary one – governing the conduct of equivalence assessments, and the making of equivalence determinations. Article 4 of the agreement provides, for example, strong and specific encouragement to Members to enter into equivalence arrangements: 'Members shall accept the sanitary or phytosanitary measures of other Members as equivalent … if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection'. It further provides that that Members 'shall, upon request, enter into consultations with the aim of achieving bilateral and multilateral agreements on recognition of the equivalence of specified sanitary or phytosanitary measures'. Furthermore, and just as importantly, all of the core regulatory disciplines of the SPS Agreement apply to equivalence determinations and associated practices.[34] As a result, such practices must for example be non-discriminatory and even-handed, scientifically justified, based on international standards where they exist and are appropriate (including those noted below), no more trade restrictive than required, timely and transparent.[35]

It is fair to say that, on their face, these rules provide the foundations of an adequate normative framework for reliance arrangements. The non-discrimination provisions, as well as those relating to the requisite objective evidentiary basis of reliance practices, in principle are especially suitable for addressing some of the challenges noted above – namely, those related to the *politicisation* of deference arrangements, and *discrimination* in the choice of jurisdictional partners. The provisions relating to timeliness of decision-making can also address the sometimes significant problems of delay and deferral which can affect the costs associated with equivalence and related processes.

Nevertheless, it is generally acknowledged that this legal framework has been hard to operationalise. With relatively minor exceptions,[36] Members' SPS equivalence practices have not been the subject of WTO dispute settlement, and these provisions have not been extensively judicially interpreted. (Disputes are even less likely now, given the current state of disrepair in which WTO dispute settlement currently finds itself.) WTO Members have complained about the low levels of implementation of the agreement as it relates to

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[33] Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 493 ('SPS Agreement').
[34] See, eg, Panel Report, *United States – Certain Measures Affecting Imports of Poultry from China*, WT/DS392/R, adopted 25 October 2010, paras 7.131-155.
[35] See, eg, SPS Agreement, Articles 2, 3, 5, 7, 10.
[36] Aspects of the US equivalence regime were at issue in *US-Poultry*, above n34. In a more general sense, a number of cases brought under Articles 2 and 5 have involved an assessment of claims that alternative individual measures are equivalent to those imposed by an importing country, though they did not involve the application of Article 4, see, eg, Panel Report, *Australia – Measures Affecting Importation of Salmon*, WT/DS18/R and Corr.1, adopted 6 November 1998, as modified by Appellate Body Report WT/DS18/AB/R; Panel Report, *Japan – Measures Affecting Agricultural Products*, WT/DS76/R, adopted 19 March 1999, as modified by Appellate Body Report WT/DS76/AB/R; Panel Report, *Japan – Measures Affecting the Importation of Apples*, WT/DS245/R, adopted 10 December 2003, upheld by Appellate Body Report WT/DS245/AB/R.

equivalence.[37] Developing countries in particular have expressed concern about their inability to benefit from equivalence arrangements in major export markets, and have actively sought to operationalise the WTO's legal framework in this area through the work of the WTO's SPS Committee. A number of proposals for strengthening this framework have been made in the context of the fifth review of the SPS Agreement.[38]

The WTO's SPS Committee – part of the extensive administrative (non-legislative) infrastructure of the WTO system tasked with the operationalisation and oversight of the SPS Agreement – has equivalence as a standing item on its agenda, and has conducted a number of different activities under that item, with varying levels of success. For example, it receives and collates notifications from Members on equivalence determinations, though there are few tangible costs for Members of failing to notify, and it is generally understood that these notifications capture only a small proportion of actual practice in the area.[39] The Committee has heard from Members wishing to share their experience of negotiating equivalence arrangements, and has organised a thematic session on equivalence for the purposes of information sharing and knowledge building.[40] Probably the Committee's most significant work, however, has been its Decision on the Implementation of Article 4, adopted originally in 2001 and updated a number of times since.[41] While the normative content of this document is relatively rudimentary, it nevertheless does succeed in elaborating some additional principles for the conduct of equivalence assessments. It notes, for example, the respective responsibilities of the importing and exporting member as regards the provision of information, the clear establishment of the level of protection, and duties of scientific evaluation and explanation. It notes that ongoing equivalence processes should not in themselves interfere with existing trade flows, and provides further, that equivalence determinations can and should take into account historical bilateral trade flows. It notes, albeit in hortatory terms, the importance of technical assistance in this area, and, importantly, specifically urges the three standard-setting bodies in the areas of food safety (Codex), animal health (WOAH), and plant health (IPPC), to elaborate guidelines on equivalence agreements, and to keep the SPS Committee informed regarding the progress of this work.

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[37] See, eg, WTO Document, 'Review of the Operation and Implementation of the SPS Agreement: Draft Report of the Committee: Note by the Secretariat', G/SPS/W/313/Rev.3, 12 June 2020; WTO Document, 'Review of the Operation and Implementation of the SPS Agreement: Report Adopted by the Committee on 26 June 2020 – Part A', G/SPS/64, 3 August 2020.

[38] These proposals can be found, for example, in WTO Document, 'Review of the Operation and Implementation of the SPS Agreement: Report Adopted by the Committee on 26 June 2020 – Part A', G/SPS/64, 3 August 2020; WTO Document, 'Developing Guidance on Consideration of Systems Approaches as Equivalent to Existing Measures: Communication from Australia', G/SPS/W/299, 6 June 2018; WTO Document, 'SPS Measures: Discussion Paper from Brazil, Fifth Review', G/SPS/W/301, 6 June 2018; among others.

[39] See WTO, 'Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, Revision', G/SPS/19, 26 October 2001, para 11; WTO, 'Recommended Procedures for Implementing the Transparency Obligations of the SPS Agreement (Article 7)', G/SPS/7/Rev.2, 2 April 2002, para 38; WTO, 'Proposed Format for the Notification of Agreements Of Equivalence', G/SPS/W/114, 19 February 2002; and on implementation, WTO Document, 'SPS Measures: Discussion Paper from Brazil, Fifth Review', G/SPS/W/301, 6 June 2018, eg para 3.1.

[40] See, eg, WTO Document, 'Memorandum Of Understanding Between Senegal And China On Phytosanitary Requirements For Ground-Nut Exports, Communication Concerning Article 4 Of The WTO Agreement On Sanitary and Phytosanitary Measures: Principle of Equivalence', G/SPS/GEN/1461 (and Corr.1), 20 Oct 2015.

[41] WTO, 'Decision on the Implementation of Article 4 of the Agreement on the Application of Sanitary and Phytosanitary Measures, Revision', G/SPS/19, 26 October 2001, which has been revised a number of times since. For one account of the SPS Committee's work, see Veggeland and Elvestad, 'Equivalence and Mutual Recognition in Trade Arrangements Relevance for the WTO and the Codex Alimentarius Commission', NILF-report 2004–9, November 2004, pp.17-21.

The standard-setting organisations have responded to this call.[42] The International Plant Protection Convention, for example, developed 'Guidelines for the determination and recognition of equivalence of phytosanitary measures', adopted as ISPM 24 in 2005 after a relatively short period of deliberation.[43] This document specifically addresses equivalence of individual measures (rather than systems equivalence, or combinations of measures). The World Organisation for Animal Health developed a new chapter of its Terrestrial Code, adopted in 2003, providing for a framework for equivalence determinations of a variety of different kinds (measure, programme, and system/infrastructure) in the context of animal health regulation.[44] In a separate but related initiative, it has also established a framework for the cross-border recognition of 'disease free zones' to facilitate continued trade even in the context of an outbreak of infectious disease.[45] The Codex Alimentarius Commission (CAC) has been particularly active, producing three texts which explicitly reference equivalence in 1997,[46] 1999[47] and 2003,[48] with more under development.[49] These documents have themselves been cross-referenced with approval in revisions to the SPS Committee's Decision on equivalence, such that the normative influence of work in each body flows both ways.[50]

These documents aim incrementally to set out an agreed framework for equivalence (and similar) determinations at the bilateral level, drawing on WTO law but also recursively influencing it, to facilitate their greater use. They do this in at least four ways. First, they establish a set of general normative principles which govern the conduct of equivalence determinations. These general principles overlap considerably with those derived from WTO law, though they also draw from other texts such as the IPPC itself. These documents establish, for example, that equivalence processes must be non-discriminatory, based on risk analysis, technically justified, have minimal impact on trade, be timely, consistent, transparent, objective, accompanied by adequate information exchange, and promptly modified as new evidence emerges. They can and should be based on all relevant information, including prior experience of bilateral trade, prior knowledge of foreign countries' systems, and the specificities of foreign conditions. Equivalence processes therefore not only can be, but ought to be, tailored to the specific conditions of different

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[42] See also the contribution by Wearne and co-authors in this issue.
[43] FAO, 'ISPM24: Guidelines for the determination and recognition of equivalence of phytosanitary measures' (FAO, 2017), available at https://www.fao.org/3/j5046e/j5046e.pdf, accessed 16 Sep 2023
[44] See OIE Terrestrial Code, Chapter 5.3, 'OIE Procedures Relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization', available at https://www.woah.org/en/what-we-do/standards/codes-and-manuals/terrestrial-code-online-access/?id=169&L=1&htmfile=chapitre_procedures_SPS_agreement.htm, accessed 16 Sep 2023, (originally introduced as Chapter 1.3.7 in 2003.)
[45] Recognition of disease-free zones in foreign countries is a different modality of regulatory reliance than equivalence. The IPPC, it is worth noting, has a similar system for the recognition of 'pest free areas' and 'areas of low pest prevalence'.
[46] Codex Alimentarius Commission, 'Guidelines For The Design, Operation, Assessment And Accreditation Of Food Import And Export Inspection And Certification Systems', CAC/GL 26-1997, adopted 1997, revised 2010.
[47] Codex Alimentarius Commission, 'Guidelines for the Development of Equivalence Agreements Regarding Food Imports and Export Inspection and Certification Systems', CAC/GL 34–1999.
[48] Codex Alimentarius Commission, 'Guidelines on the judgement of equivalence of sanitary measures associated with food inspection and certification systems', CAC/GL 47–2003.
[49] See, Codex Alimentarius Commission, 'Proposed Draft Consolidated Codex Guidelines Related to Equivalence', CX/FICS 20/25/7, February 2020.
[50] See WTO Documents, G/SPS/19, including Rev.1 and Rev.2, above n39, which cross-refers some of the work of the CAC and others on equivalence.

foreign territories.[51] They re-assert the core principle that an importing country has the right to determine its own appropriate level of protection.

Second, these documents establish certain procedural principles and an indicative sequence of steps for the conduct of equivalence negotiations. For example, they allocate the respective responsibilities of importing countries (as regards the initiation of an application, the provision of sufficient information, and access to facilities) and exporting countries (as regards the provision of reasons, ensuring clarity of standards and requirements, and so on). They note the utility of pilot studies, as well as the need for continual post-determination verification and review, as well as exchange of information. Third, they compile checklists of factors which authorities may wish to consider before entering into equivalence negotiations, and while conducting an equivalence assessment, as well as issues which ought to be addressed in equivalence agreements themselves.

Fourth, they seek to establish their own international standards as an important indicator of governance quality, noting that equivalence determinations ought to be facilitated where regulatory systems conform to international standards. For example, the CAC cross-refers to its Guidelines for National Food Control Systems as well as its Principles for Food Import and Export Inspection and Certification.[52] This is important: alignment with international standards of good regulatory practice clearly is clearly imagined to provide a basis for confidence in the governance capabilities and capacities of foreign food safety authorities and systems, and therefore to facilitate mutual reliance between regulators across borders. In this sense, these international standards-setting bodies can be understood to be taking on a supporting role in assuring the quality and credibility of domestic governance systems. In one (unusual) case, the WOAH has gone a step further, by establishing a procedure for the *international* recognition of disease freedom for six specific diseases.[53] This procedure has been well-used, and a number of export-oriented developing countries have argued for its greater use in domestic recognition processes.[54] In their view, where a safe area is established in conformity with international standards, importing states should have limited flexibility to refuse recognition. But the point has been controversial amongst the major importing markets.

Taken together, then, the 'three sisters' standards-setting bodies are playing an active role in pragmatically supporting, encouraging and facilitating equivalence arrangements in the food safety sector. That said, while this work is important, most would agree that it remains under-developed. The normative framework for equivalence set out in international guidance is couched in very general terms, and still leaves considerable room for discretion and differential treatment in the conduct of equivalence assessments. The incentives for states to

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[51] See, for one illustrative example, ISPM 24, above n43, section 2.4 (regarding the specific way in which the non-discrimination norm applies) and section 3.5 (regarding the relevance of historical trade between the parties).

[52] Codex Alimentarius Commission, 'Guidelines for National Food Control Systems', CXG 82-2013; Codex Alimentarius Commission, 'Principles for Food Import and Export Inspection and Certification', CAC/GL 20 – 1995; as well as generally Codex Alimentarius Commission, 'Principles and Guidelines for the Exchange of Information between Importing and Exporting Countries to Support the Trade in Food', CXG 89-2016.

[53] See WOAH (OIE), 'Standard Operating Procedure for official recognition of animal health status and for the endorsement of official control programmes of Members', May 2021, available at https://www.oie.int/app/uploads/2021/06/en-sop-application.pdf., accessed 16 Sep 2023.

[54] See the responses to a survey conducted by the WTO in WTO Document, 'Article 6 of the SPS Agreement: Questions For Discussion, Compilation Of Comments Submitted By Members, Note by the Secretariat, Revision', G/SPS/W/311/Add.1/Rev.2, 20 September 2019.

conform strictly to the requirements of international standards, furthermore, can often be weak in practice.

Finally, and especially in the context of this paper, it is important to note the way that FTAs are increasingly being used to help establish and consolidate reliance arrangements of the sort just described. Sometimes, for example, equivalence determinations themselves have become matters of interest in FTA negotiations. A number of the US's free trade agreements contain side agreements according to which the foreign trade partner agrees to recognise US food safety systems as equivalent to theirs.[55] For example, in a 2006 side agreement to the US-Panama FTA, Panama recognizes, among other things, that the US food safety inspection system for 'meat … poultry, and products thereof is equivalent to Panama's inspection system for those products', and therefore agrees not to require certification of individual US establishments by Panamanian authorities, and to accept certain Export Certificates issued by US authorities as sufficient to authorise importation and sale in Panama.[56] Similar side agreements accompanied US agreements with Colombia[57] and Peru.[58] These constitute binding agreements between the parties, and thus give some degree of rigidity to the arrangements, though it is worth noting that these agreements can and have been updated and modified on a number of occasions through a further Exchange of Letters, and in no case are the relevant obligations subject to FTA dispute settlement. Additionally, during the negotiation of the Trans-Pacific Partnership – which ultimately was concluded as the CPTPP without US participation – the US negotiated four side agreements with Chile, Canada and Vietnam regarding similar issues, though with less substantial content.[59] Similarly, while the EU's earliest Veterinary Agreements were concluded outside the context of a larger trade agreement, and some continue to be, most are negotiated with partners where such a deal exists, and some are directly incorporated into larger trade deals. The 2002 agreement with Chile, for example, is an annex to its agreement with the EU.[60] The Canadian agreement started life independently, but subsequently has been incorporated into the larger trade relationship defined by CETA.[61]

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[55] Marks, 'The Right to Regulate (Cooperatively)' (2016) 38 University of Pennsylvania Journal of International Law 1-69, 55.

[56] United States-Panama Agreement Regarding Certain Sanitary and Phytosanitary Measures and Technical Standards Affecting Trade in Agriculture Products, 20 December 2006, available at https://ustr.gov/sites/default/files/2006%20US-Panama%20SPS%20letter%20exchange%20Text.pdf, accessed 16 Sep 2023.

[57] US-Colombia Trade Promotion Agreement, available at https://ustr.gov/trade-agreements/free-trade-agreements/colombia-tpa/final-text, accessed 16 Sep 2023, (see Annexures to SPS Chapter, '2006 SPS Letter Exchange' and August 2006 SPS Letter Exchange' as well as 2012 additional exchanges in April 2012).

[58] US-Peru Free Trade Agreement, available at https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text, accessed 16 Sep 2023, (see Annexures to SPS Chapter, Exchange of Letters in January 2006, April 2006, October 2006 and March 2016).

[59] Trans-Pacific Partnership, text available at https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text, accessed 16 Sep 2023, see 'US-CL SPS Letter Exchange regarding Salmonid Eggs', 'US-CA Letter Exchange on Milk Equivalence', 'US-VN Letter Exchange on Catfish', and 'US-VN Letter Exchange on Offals'.

[60] Agreement establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part, available at https://eur-lex.europa.eu/resource.html?uri=cellar:f83a503c-fa20-4b3a-9535-f1074175eaf0.0004.02/DOC_2&format=PDF , accessed 16 Sep 2023, at p1048.

[61] For a simple explanation of the sequence of events, see European Commission, 'Food Safety: Agreements with non-EU Countries', https://food.ec.europa.eu/horizontal-topics/international-affairs/agreements-non-eu-countries_en: 'Since 1999, a veterinary agreement on sanitary measures to protect public and animal health in respect of trade in live animals and animal products between the EU and Canada had been in place. This agreement has been suspended on September 21, 2017, whilst the provisions and achievements of the agreement

Perhaps more importantly in the present context, FTAs increasingly include provisions establishing the institutional structure necessary for building and supporting bilateral regulatory reliance arrangements. It was already noted in the introductory section above that the inclusion of horizontal 'regulatory cooperation' chapters is an important and much-discussed feature of the latest generation of FTAs. The SPS chapters of new FTAs are also part of this trend. These chapters vary in form and detail, but increasingly they include provisions performing many of the same functions as described above: setting out an agreed framework of procedures and principles governing future equivalence determinations; providing for mutual audit and inspection of facilities to maintain confidence in each others' systems; establishing a specialised committee for ongoing dialogue and information exchange; provide for notification of, and an opportunity to comment on, proposed regulatory changes by the other party; and so on. Good examples of the state of the art can be found, for example, in the UK-Australia FTA, CETA, the USMCA, and EU FTAs with Vietnam and Singapore.[62] In most cases, these new bilateral and plurilateral treaty arrangements are in their infancy, and it is an open question how effective they will ultimately prove to be in facilitating cooperation around deference arrangements. But their contribution could be important, given the consistent message from exporters that having clear existing structures for communication, and established inter-regulatory relationships, can make a big difference in the resolution of interpretive and other issues which arise around equivalence and other deference arrangements.

Reflections

Although cross-jurisdictional regulatory reliance arrangements have a long history, and can be found in some form across many regulatory fields, they have a mixed record of success, and they have historically played a secondary role in most trade alliances. I have suggested, however, that this is in the process of changing. There are already signs that cooperative regulatory arrangements of this kind are likely to be central to the next generation of free trade agreements, and to other novel trade initiatives. In that context, it is important to reflect on the role that institutions of global economic governance can play in facilitating the

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were transposed into the Comprehensive Economic Trade Agreement (CETA) that became provisionally applicable at that date'.

[62] Free Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and Australia, 17 December 2021, https://www.gov.uk/government/collections/free-trade-agreement-between-the-united-kingdom-of-great-britain-and-northern-ireland-and-australia, accessed 16 Sep 2023, Chapter 6; Free Trade Agreement between the United Kingdom of Great Britain and Northern Ireland and New Zealand, 28 Feb 2022, https://www.gov.uk/government/collections/free-trade-agreement-between-the-united-kingdom-of-great-britain-and-northern-ireland-and-new-zealand, accessed 16 Sep 2023, Chapter 5; Comprehensive and Progressive Agreement for Trans-Pacific Partnership, 8 March 2018, https://www.dfat.gov.au/trade/agreements/in-force/cptpp/official-documents, accessed 16 Sep 2023, Chapter 7; Agreement between the United States of America, the United Mexican States, and Canada, 1 Jul 2020, https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement/agreement-between, accessed 16 Sep 2023, Chapter 9; EU-Canada Comprehensive Economic and Trade Agreement, 30 Oct 2016, https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/text-texte/toc-tdm.aspx?lang=eng, accessed 16 Sep 2023, Chapter 5; Free Trade Agreement between the European Union and the Socialist Republic of Viet Nam, 1 Aug 2020 https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:22020A0612(01), accessed 16 Sep 2023, Chapter 6; EU-Singapore Free Trade Agreement and Investment Protection Agreement, 21 Nov 2019, https://policy.trade.ec.europa.eu/eu-trade-relationships-country-and-region/countries-and-regions/singapore/eu-singapore-agreement/texts-agreements_en, accessed 16 Sep 2023, Chapter 5.

effective functioning of reliance arrangements, overcoming some of common obstacles to their use, as well as addressing the challenges they pose for the trading system more generally. The single case study above provides only a narrow window onto this question, and any conclusions drawn from it can only be provisional and preliminary. Nevertheless, a number of observations can be made.

First, there is a clear need for an adequate normative and procedural framework at the international level, governing the negotiation of reliance arrangements. This is especially important, given the real risk of arbitrariness and *de facto* discrimination in the application of these arrangements, and the significant challenges such arbitrariness may pose for developing countries in particular. In fact, the WTO SPS Agreement, combined with the reasonably extensive work of the Codex, WOAH and the IPPC, , already provides the fundamentals of a reasonably comprehensive framework of this kind. Certainly, the array of rules, principles and associated institutions created by these bodies is more advanced than in many other regulatory fields. Even so, there is room to develop it further. For example, more work is needed to define consistent and uniform standards setting out the documentation and evidence which applicants for equivalence must submit, as well as on-site inspection protocols which can be used across multiple jurisdictions. This could help to alleviate some of the burden associated with multiple applications and application processes. Consideration could also be given to defining indicative deadlines for different stages of the process. The normative framework is also relatively silent regarding the special position of developing countries and the ways in which development needs may be addressed. More generally, it is notable that bodies working in other regulatory fields have developed different sets principles for reliance arrangements – the WHO's 'principles of good reliance practices' are one important example. Systematic comparison across sectors could yield important insights to help guide normative developments in the field of food safety.

Furthermore, this framework remains quite weak at the level of operationalisation and enforcement. This is partly because the formal dispute settlement procedures provided under WTO law, and indeed FTAs, are not well suited to the enforcement of these obligations. By and large, third party judicial dispute settlement of the sort provided by the WTO is often too cumbersome to adequately respond to modalities of regulatory reliance which are operationalised through soft and flexible legal forms, and largely at the level of the exercise of administrative discretion.[63] Given the apparent reluctance of WTO Members to bring formal disputes in this area, alternative non-judicial means for resolving difficulties – including alternative dispute resolution mechanisms such as mediation – may provide a better avenue for promoting better adherence to core WTO standards of non-arbitrariness and non-discrimination.

Second, an important issue is the lack of robust and consistent methodologies for the assessment of the comparability/adequacy of foreign regulatory systems. International standards-setting bodies could do more to develop such methodologies, including more detailed specification of factors to be considered in comparability assessment, indicative weightings of such factors, and evaluative techniques. An important aspect of this would also be to identify the weaknesses and limits of existing methodologies, for example by noting common uncertainties and information gaps and suggesting means for responding to them; as well as the providing information regarding common potential biases or errors, as a way of

[63] This point is also made in Hoekman and Sabel, 'Plurilateral cooperation as an alternative to trade agreements: innovating one domain at a time' Working Paper, EUI RSCAS, 2021/01, Global Governance Programme-429, available at https://cadmus.eui.eu/handle/1814/69578., accessed 16 Sep 2023.

encouraging reflexivity on the part of assessors. Separately, there is a case for international bodies, including the WTO's SPS Committee, to provide further space for cross-jurisdictional and cross-sectoral sharing of experience around assessment practices and methods, to a greater extent than they currently do. There is a strong case for complementing these activities with the facilitation/provision of technical assistance by the appropriate international bodies for developing countries in the preparation of applications for equivalence and recognition to major export markets.[64]

Third, the oversight and transparency functions of international bodies could also be further developed. For example, more work needs to be done to operationalise the transparency provisions of the SPS Agreement as they relate to reliance arrangements, given that a number of the key challenges in this area result from their opacity and complexity. Furthermore, processes of monitoring and supervision already undertaken by international bodies could be adapted to include a greater focus on reliance arrangements, including the conformity of these processes with international guidance.

Fourth, there is an important and very difficult set of questions regarding the direct involvement of international bodies in the assessment of the reliability of national regulatory systems. On one hand, a favourable assessment of a state's regulatory system by a credible international body can in principle play an important role in building the cross-jurisdictional trust and confidence necessary to make reliance arrangements works. This is particularly the case between jurisdictions which do not have long historical experience of cooperation, where the significance of the opinion of a trusted third party may be more critical. Importantly, also, using the resources and expertise of international organisations in this way can defray the significant resource costs of engaging in multiple such reviews at the domestic level. WOAH's system of international recognition of disease-free zones is an interesting exemplar in this respect, and there is scope to experiment with similar processes in other areas. On the other hand, it is important to recognise that there are limits to the role that international standards-setting organisations can realistically play in this regard. One reason has to do with international institutions themselves: international bodies simply do not have the broad-based legitimacy and structures of accountability to act as final (as opposed to persuasive or reflexive) arbiters of regulatory credibility and adequacy. Another reason has to do with the nature of the process of governance assurance itself: put simply, governance assurance is never a purely technical exercise, but rather inevitably depends in part on the values, risk tolerances and political judgements of regulatory communities. Normative yardsticks of 'quality' and 'credibility' are inevitably to some degree contextually specific, variable over time, and relative to the priorities and values of the observer. It follows that the primary role of international bodies in systems of governance assurance should arguably not be to act as ultimate arbiters and gatekeepers of regulatory reliability, but rather to use their own assessments to instil a greater degree of reflexivity and rigour into the national systems of governance assurance which underpin reliance arrangements.

Fifth, although there is a clear trend to seek to use FTAs to facilitate reliance arrangements, we are still at the early stages of understanding the contribution that FTA structures can make in this regard. Clearly, reliance arrangements can be, and are routinely, organised outside of the ambit of FTAs, and it is important to avoid the duplication of governance functions. Nevertheless, the case study above suggests a number of possible roles for the institutional

[64] Nicolaidis and Shaffer, 'Transnational Mutual Recognition Regimes: Governance without Global Government' (2005) 68 (3/4) Law and Contemporary Problems 263-318, at 295-6.

structures of regulatory cooperation established in recent FTAs. For example, at the most general level, routinised practices of information sharing established by FTA institutional structures can help to build the background levels of mutual familiarity, knowledge and trust necessary for the establishment of reliance arrangements. More specifically, they can also play an important role in maintaining reliance arrangements over time, especially by providing a space for the prospective identification and resolution of issues caused by regulatory change. The advance notice and comment procedures set in place under many new generation FTAs, for example, can help to identify issues at an early stage and provide a technical space for their discussion. FTA institutions can also be used as a venue for building shared positions on certain technical matters – such as assessment methodologies, procedural frameworks, and so on – which can then inform and drive action in international standard-setting bodies, discussed above. Furthermore, the cross-sectoral nature of FTAs is also a distinct advantage: there is certainly scope for using FTA institutional structures to share experiences with successful (and unsuccessful) reliance arrangements across different sectors. Finally, and importantly, established mechanisms for domestic stakeholder engagement around FTAs can be leveraged to provide greater oversight, transparency and momentum to regulatory reliance initiatives.