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ARTICLE

SCIENTIFICATION OF POLITICS OR POLITICIZATION OF SCIENCE: REASSESSING THE LIMITS OF INTERNATIONAL FOOD SAFETY LAWMAKING[†]

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The proliferating food safety regulatory initiatives at domestic, international, and transnational levels by various actors with different perspectives have raised concerns regarding their important public health, international trade, and other implications. Standing as the hub of international food safety lawmaking, the Codex faces serious criticisms regarding its scientific soundness, legitimacy, transparency, and accountability. This Article explores the limits of the Codex lawmaking structure and processes by examining whether its institutional design is adequate for producing good governance.

Food safety is an area of international law where political and cultural fragmentation collides with deep market integration and trade liberalization. Through a thorough analysis of the recent dispute over the safety of ractopamine, a growth-promoting drug administered to livestock, in the context of multilateral cooperation failure and the debates between technocratic and democratic models of legitimacy, this Article emphasizes the forgotten role of procedural legitimacy

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in the current discourse, particularly mechanisms for avoiding conflicts of interest and fostering transparency.

I. INTRODUCTION

The past decades have witnessed an exponential increase in food scares from various sources, ranging from "mad cow disease" (bovine spongiform encephalopathy (BSE)) in British beef, dioxin in Irish pork, melamine-contaminated dairy products from China, and *E. coli* on cucumbers in Germany, to radioactive residues on a

variety of foods from Japan. Moreover, the globalization of economic activities, advancements in food science, development of transportation technology, and multinationalization of food industries, together with the advent of the World Trade Organization (WTO), have significantly transformed the production, transportation, and consumption of food.[1] They have also further intensified the scale, severity, frequency, and impact of food safety outbreaks. A World Health Organization (WHO) report indicates that food safety problems contribute to 1.5 billion cases of diarrhea in children and over three million premature deaths annually, both in developed and developing countries.[2] Every year, approximately 2.2 million children die in developing countries of diarrheal diseases caused by contaminated food and water.[3] The United States Centers for Disease Control and Prevention (CDC) estimates that foodborne diseases cause 48 million illnesses, 128,000 hospitalizations, and 3,000 deaths each year within the United States alone.[4]

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1. *See* WORLD ECONOMIC FORUM, GLOBAL RISK 2008: A GLOBAL RISK NETWORK REPORT, http://www.weforum.org/pdf/globalrisk/report2008.pdf; Fritz K. Käferstein et al., *Foodborne Disease Control: A Transnational Challenge*, 3 EMERGING INFECTIOUS DISEASES 503, 503-10 (1997); Fritz K. Käferstein & Mohammed Abdussalam, *Food Safety in the 21st Century*, 77 BULL. WORLD HEALTH ORG. 347, 347-351 (1999); Yasmine Motarjemi et al., *Future Challenges in Global Harmonization of Food Safety Legislation*, 12 FOOD CONTROL 339, 340-41 (2001).

2. Food Safety Programme, World Health Organization [WHO], *Food Safety: An Essential Public Health Issue for the New Millennium*, 9, WHO/SDE/PHE/FOS/99.4 (1999).

3. Department of Food Safety and Zoonoses, WHO *Estimating the Global Burden of Foodborne Diseases*, Baseline Information for Food Safety Policy and Measures 1 http://www.who.int/foodsafety/about/flyer_foodborne_disease.pdf (last visited Nov. 16, 2013).

4. NAT'L CTR. FOR EMERGING & ZOONOTIC INFECTIOUS DISEASES & DIV. OF FOODBORNE, WATERBORNE, AND ENVTL. DISEASES, CTRS. FOR DISEASE CONTROL AND PREVENTION [CDC], CDC ESTIMATES OF FOODBORNE ILLNESS IN THE UNITED STATES 1 (2011), http://www.cdc.gov/foodborneburden/PDFs/FACTSHEET_A_FINDINGS_updated4-13.pdf.

These food safety incidents have driven mushrooming domestic, international, and transnational regulatory responses that aim to address existing and emerging risks in many fields closely linked to public health and world trade. A variety of actors—governments, international organizations, industry, nongovernmental organizations (NGOs), scientific expert groups, and transnational business associations—have also engaged in regulation of food safety. National governments, through a multifaceted process with scientific, social, and political features, have been adopting internal and border measures to mitigate foodborne hazards. International organizations have more recently been establishing multilateral health and trade rules as well as sanitary and phytosanitary (SPS) standards that transcend national boundaries and enter the terrain of authority traditionally exercised by sovereign states. Other actors, such as multinational corporations dominating global food supply chains, consumer NGOs, and private standard-setting associations (e.g., GlobalGAP), have been actively engaging in global food safety governance through innovative approaches.[5]

However, there is arguably no meta-framework that coordinates the making of such diverse regulatory schemes. These active spheres of global food safety norm-making constitute an evolving governance complex being formed and transformed, configured and reconfigured by diverse actors at various levels with different experimental approaches. Where two or more spheres interact, for example between national governments' regulatory autonomy and international organizations' authority, many difficult questions emerge. For example, there may be

5. *See, e.g.*, Fabrizio Cafaggi, *Private Regulation, Supply Chain and Contractual Networks* (EUI Working Papers, RSCAS 2010/10, 2010), *available at* http://www.iadb.org/intal/intalcdi/PE/2012/11123a09.pdf; Tetty Havinga, *Private Regulation of Food Safety by Supermarkets*, 26 LAW & POL'Y 515 (2006).

questions regarding issues of horizontal and vertical allocation of authority, accountability of national and international regulatory bodies, transparency of lawmaking processes, and legitimacy of regulatory outcomes. Although there is no overarching framework that yields solutions to these pressing issues, it is important to note that many of the issues can be viewed through the common lens of concern regarding the role of science in the international food safety lawmaking process.[6]

The Codex Alimentarius Commission (Codex) is an international governmental body established by the United Nations Food and Agriculture Organization (FAO) and the WHO pursuant to the two resolutions adopted by the Eleventh Session of the FAO Conference in 1961 and the Sixteenth World Health Assembly (WHA) in 1963.[7] The two international institutions also adopted the Statutes and Rules of Procedure for the Commission.[8] To date, 186 members (185 member countries and one member organization) are represented in the Codex.[9] Led by the ten-member Executive Committee of the Codex Alimentarius Commission, the Codex

6. Indeed, the structures and processes that determine when to look to science, what science to look to, how to obtain scientific advice, how to use scientific advice, how to deal with scientific uncertainty, and so on, are heatedly debated topics these days in the food safety field.

7. *See* JOINT FAO/WHO FOOD STANDARDS PROGRAMME, FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS [FAO] & WHO, UNDERSTANDING THE CODEX ALIMENTARIUS 7, 9, 13, 25 (3d ed. 2006) *available at* ftp://ftp.fao.org/docrep/fao/010/a0850e/a0850e00.pdf.

8. *See generally* JOINT FAO/WHO FOOD STANDARDS PROGRAMME, FAO & WHO, CODEX ALIMENTARIUS COMM'N, PROCEDURAL MANUAL (21st ed. 2013) [hereinafter PROCEDURAL MANUAL] *available at* ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_21e.pdf (the statutes of the Codex Alimentarius Commission (Statutes) provide the legal basis for the Commission's work and formally reflect the concepts behind and reasons for its establishment, while the Rules of Procedure of the Codex Alimentarius Commission (Rules of Procedure) describe and formalize working procedures appropriate to an intergovernmental body).

9. Codex Members and Observers, *Codex Alimentarius* (Oct. 25, 2013) http://www.codexalimentarius.org/members-observers/en/.

also consists of twenty-four active committees and task forces.[10] The Codex's mandate is to develop international food standards, guidelines, and recommendations to "protect[] the health of consumers" as well as "ensur[e] fair practices in the food trade."[11] As the Codex's work stands at the center of international food safety lawmaking, the Codex faces problems involving the soundness of its science, legitimacy of rules, accountability of rulemakers, and transparency of decision-making processes. The elaboration of international food standards inevitably intertwines with science, risks, and politics, and has important economic, social, and cultural implications. This is especially true in light of the inherent tension between international harmonization and national autonomy. Therefore, states, international organizations, scientists, industry, and NGOs engage in the Codex food safety lawmaking activities via different channels and in different manners in order to advance their respective interests.[12] Their participation may either promote or undermine the legitimacy, transparency, and accountability of the Codex. Indeed, many scholars and practitioners have criticized the Codex's inability to produce good-governance regulatory results.[13] The limits of

10. In addition to the Committee on General Principles and six regional coordinating committees (Africa, Asia, Europe, Latin America and the Caribbean, the Near East, and North America and the Southwest Pacific), subsidiary bodies directly related to food safety include, *inter alia*, the Codex Committees on Contaminants in Foods, Food Additives, Food Hygiene, Pesticide Residues, Residues of Veterinary Drugs in Foods, Food Import and Export Inspection, and Certification Systems. PROCEDURAL MANUAL, *supra* note 8, at 11-24 (Rules of Procedure of the Codex Alimentarius Commission, Rule V.).

11. *Id.* at 4.

12. *See generally* Elizabeth Smythe, *In Whose Interests? Transparency and Accountability in the Global Governance of Food: Agribusiness, the Codex Alimentarius, and the World Trade Organization, in* CORPORATE POWER IN GLOBAL AGRIFOOD GOVERNANCE 93 (Jennifer Clapp & Doris Fuchs eds., 2009) (explaining and describing in particular how industry actors use state delegations as a channel to participate and influence the Codex decision-making process).

13. *Id.*; Michael Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, 81 N.Y.U. L. REV. 766 (2006). Along the same vein, we might

international food safety lawmaking led by the Codex, therefore, must be reassessed.

Bearing in mind the Codex's role as an international reference for food standards, the multilevel nature of its regulatory sphere and the complexity of food science, Part I of this Article discusses whether the Codex structure and the execution of its processes are adequate in terms of accountability, legitimacy, and transparency. Part II offers a brief overview of the important actors in international food safety lawmaking. The Codex is the most active and influential institution in this fragmented field, and Part II notes that the development of international food law orients the Codex's activities. Part III, however, shows how the Codex is being challenged in different settings of international food safety lawmaking. I use the recent ractopamine hydrochloride (ractopamine) dispute as an example to discuss the problems of legitimacy, accountability, transparency, and scientific soundness facing the Codex processes. Part IV reassesses the Codex's lawmaking activities in the context of the legitimacy and accountability deficit, technocracy-democracy debates, and the multilateral cooperation failure in food safety governance. Part V emphasizes the forgotten role of procedural legitimacy in the current discourse, particularly mechanisms for avoiding conflicts of interest and fostering transparency. Part VI concludes by going beyond the Codex as an institution. I argue that the governance complex of global food safety should evolve to facilitate active, mutually-reinforcing regulatory spheres.

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ask: What principles should apply to such relatively high-tech regulatory activities? Can the pursuits of democracy and legitimacy be in competition or even in conflict with each other in a science-based global lawmaking process? How should interested parties improve the transparency and accountability mechanisms of Codex in the interplay among governments, industry actors, and NGOs at the same time?

II. "SCIENTIFICATION OF POLITICS" IN INTERNATIONAL FOOD SAFETY LAWMAKING

Food safety lawmaking at the international level takes place primarily under the auspices of three international organizations: the WHO, the WTO, and the Codex.[14] While a meta-framework that coordinates international institutions with a collective regulatory and cooperative strategy at the global level is desirable, this part of the Article will establish that there exists no such overarching structure targeting food safety issues in a comprehensive and holistic manner. A review of the normative activities of the WTO and WHO shows that the Codex is the most active and influential institution, insofar as the Codex's activities are oriented around making international food law.

A. The WTO's Technocratic Turn and Its Influence on International Food Safety Lawmaking

Food safety standards set by national governments have extraterritorial effects on producers in other jurisdictions and decisive impacts on market access of their agricultural products, but these standards usually rest on political interests and serve strategically as non-tariff barriers to trade. Before the advent of the WTO in 1994, as considerable trade interests were at stake and no binding international rules existed except the inadequate General

14. It should be noted that other sorts of standard-setting or rulemaking by national governments or non-state actors exist. In particular, some scholars observe that private actors, especially multinational corporations (MNCs), are increasingly engaging in food safety standard setter activities by means of private regulation. *See, e.g.*, CORPORATE POWER IN GLOBAL AGRIFOOD GOVERNANCE (Jennifer Clapp & Doris Fuchs eds., 2009); Denise Prévost, *Private Sector Food-Safety Standards and the SPS Agreement: Challenges and Possibilities*, 33 S. AFR. Y.B. INT'L L. 1 (2008); Michael P. Vandenbergh, *The New Wal-Mart Effect: The Role of Private Contracting in Global Governance*, 54 UCLA L. REV. 913 (2007); Havinga, *supra* note 5; Linda Fulponi, *Private Voluntary Standards in the Food System: The Perspective of Major Food Retailers in OECD Countries*, 31 FOOD POL'Y 1 (2006); Spencer Henson, *The Role of Public and Private Standards in Regulating International Food Markets*, 4 J. INT'L AGRIC. TRADE DEV. 63 (2008). However, it is beyond the scope of the present study to examine these topics in any kind of depth.

Agreement on Tariffs and Trade (GATT) for disciplining such food safety measures,[15] states had strong incentives to use food safety standards as a disguise for advancing protectionist goals. The use of domestic regulation as a substitute for more traditional forms of agricultural protectionism was heavily criticized as unjustifiable and an illegitimate barrier to trade that frustrated the liberalization of agricultural trade under the GATT framework.[16] This partly explains why governments have treated the majority of food safety incidents as *trade* issues.

Fearing a resurgence of agricultural protectionism under the guise of domestic health regulation, governments involved in WTO negotiations have looked for objective benchmarks that can discipline arbitrary and unjustifiable measures. In 1994, the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)[17] was adopted. The primary basis for the SPS Agreement's rules was the use of scientific principles and evidence. The SPS Agreement covers measures applied to protect against various health risks, including those arising from additives, contaminants, toxins or disease-causing organisms in food. The SPS Agreement may be regarded as an attempt to mitigate the gap between genuine health-protection measures and protectionist technical regulations "through the regulation of regulation and by defining the limits to legitimate diversity."[18]

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15. *See* General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (2000), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT 1994].

16. JOANNE SCOTT, THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY 1-4 (2007).

17. *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 59 (2000), 1867 U.N.T.S. 493 (1994) [hereinafter SPS Agreement].

18. JOANNE SCOTT, THE WTO AGREEMENT ON SANITARY AND PHYTOSANITARY MEASURES: A COMMENTARY 44 (2007).

The typical responses of most countries to food safety problems, such as with the SPS standards or import bans, fall within the scope of WTO rules because they are members of the WTO.[19] Measures taken by WTO members are regulated under the provisions in Articles XI and XX of the GATT and those in the SPS Agreement.[20] When a government wants to restrict the free flow of food products based on food safety concerns, the WTO rules, especially those in the SPS Agreement, come into play. According to the SPS Agreement, WTO member countries are entitled to adopt food safety measures subject to relevant WTO rules. Such measures are deemed "necessary to protect human, animal, or plant health" and WTO-consistent when they conform to "relevant international standards."[21] When a member deviates from Codex standards, the SPS Agreement requires it to provide satisfactory scientific evidence and appropriate risk assessments to justify its measures, if challenged in the WTO dispute settlement process.[22]

Most importantly, in terms of international food safety lawmaking, the WTO refrains from taking part in the process but explicitly refers to the Codex as the international standard-setter.[23] The WTO regime can exercise considerable power through its mandatory dispute-settlement system, binding adjudicatory decisions, and retaliation mechanism.[24] Therefore, when backed up

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19. Ching-Fu Lin, *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy*, 51(3) VA. J. INT'L L. 637, 665 (2011).

20. GATT 1994, *supra* note 15, at Articles XI, XX.

21. SPS Agreement, *supra* note 17, at Articles 3.2-3.4.

22. SPS Agreement, *supra* note 17, at Articles 3.3, 5.

23. SPS Agreement, *supra* note 17, at Article 3.1, Annex A.3. The SPS Agreement specifically refers to three international standard-setting bodies, now as the oft-called "Three Sisters:" the Codex dealing with food safety, the International Plant Protection Convention (IPPC) dealing with plant health, the World Organization for Animal Health (OIE) dealing with animal health.

24. *See, e.g.*, Mitsuo Matsushita et al., THE WORLD TRADE ORGANIZATION: LAW, PRACTICE, AND POLICY 103-40 (2d ed. 2006) (describing the WTO dispute settlement mechanism as the backbone of the multilateral

by the WTO regime, the Codex becomes an influential anchor in most, if not all, food safety disputes.[25] The Codex is now commonly regarded as the quasi-legislator,[26] and its standards are *de facto* mandatory especially in WTO food safety disputes.[27]

The SPS Agreement represents governments' turn to the "scientification of politics" as well as to the Codex, because it posits scientific principles, scientific evidence, risk assessment, and international standards as benchmarks for examining members' regulatory intervention in the food safety arena. The technocratic thresholds for lawfulness and upholding international standards have profoundly changed the relationships between south and north, trade and health, and international harmonization and national autonomy in global food safety governance.

B. The WHO's Indirect and Technical Role in International Food Safety Lawmaking

The WHO is usually regarded as the first appropriate international body to play a crucial role in international food safety lawmaking, since such normative activity is within the ordinary understanding of the WHO's public health authority and mandates.[28] The broad mandates and normative tools assigned to

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trading regime, ensuring its exclusive and mandatory jurisdiction over WTO disputes between its Members, producing binding decisions, and authorizing retaliation tools.); WTO, UNDERSTANDING THE WTO 103-40 (5th ed. 2008).

25. ALBERTO ALEMANNO, TRADE IN FOOD: REGULATORY AND JUDICIAL APPROACHES IN THE EC AND THE WTO 262-67 (Cameron May, ed., 2007); Bruce Silverglade, *The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?* 55 FOOD & DRUG L.J. 517, 518–24 (2000).

26. Joel P. Trachtman, *The World Trading System, the International Legal System and Multilevel Choice,* 12 EUR. L.J. 469, 480 (2006).

27. Steve Charnovitz, *Triangulating the World Trade Organization*, 96 AM. J. INT'L L. 28, 51 (2002).

28. Constitution of the World Health Organization, Articles 2, and 19-23, July 22, 1946, 62 Stat. 2679, 14 U.N.T.S. 185.

the WHO by its Constitution empower the WHO to actively engage in and lead global food safety governance.[29]

However, as many scholars have noted, the WHO has not fully employed the normative authority given by its Constitution.[30] The WHO has abstained from adopting any international agreement regarding food safety issues for over sixty years.[31] In 2010, the WHO Executive Board suggested adopting a resolution recognizing the need for an international agreement governing global food safety management.[32] Yet the sixty-third WHA in 2010 neglected to make such recommendations and refrained from taking a leading role in global food safety governance.[33]

The WHO participates in food safety lawmaking merely in a scientific and technical manner.[34] In 1963, the sixteenth WHA adopted a resolution to establish the Codex jointly with the FAO.[35] The WHO and FAO also adopted the Codex Statutes and Rules of Procedure, which continue to serve as the legal basis and procedural guidance for the Codex's food safety lawmaking. Moreover, the two organizations provide scientific and technical support to the Codex. For example, the Joint Expert Committee for

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29. Lin, *supra* note 19, at 673-84.

30. Allyn L. Taylor & Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People: Toward a Framework Convention on Global Health*, 96(2) GEO. L.J. 331, 375 (2007); Allyn L. Taylor, *Making the World Health Organization Work: A Legal Framework for Universal Access to the Conditions for Health*, 18 AM. J.L. & MED. 301, 345-46 (1992); *see also* David P. Fidler *et al*., *Emerging and Reemerging Infectious Diseases: Challenges for International, National, and State Law*, 31(3) INT'L L. 773, 786-87 (1997) (recognizing that the WHO has a predilection for non-binding and supplementary recommendations and programs instead of binding international health treaties, as conferred in the WHO Constitution).

31. *See* David P. Fidler, *The Future of the World Health Organization: What Role for International Law?*, 31 VAND. J. TRANSNAT'L L. 1079, 1109-11 (1998).

32. WHO, *Advancing Food Safety Initiatives*, at 2, EB126.R7 (Jan. 21, 2010), http://apps.who.int/gb/ebwha/pdf_files/EB126/B126_R7-en.pdf.

33. WHA Res. 63, WHA63/2010/REC/1, para. 1.3 (May 21, 2010); Lin, *supra* note 19, at 683-84.

34. Lin, *supra* note 19, at 682.

35. UNDERSTANDING THE CODEX ALIMENTARIUS, *supra* note 7, at 7.

Food Additives (JECFA) is an expert body administered by the WHO and FAO. The JECFA is responsible for reviewing scientific evidence to conduct risk assessment that forms the basis of recommendations for the Codex food safety standards. The WHO calls for, selects, and enlists qualified experts to consider scientific evidence and perform toxicology risk assessments in the JECFA, and the FAO enlists scientists to evaluate residues.[36] The JECFA evaluation reports, regarded as authoritative reviews of all available evidence and information concerning a given food safety risk, form the basis of the Codex's recommended standards.[37]

All in all, the WHO's role in making international food safety law is of an indirect, technical nature. The WHO has a relatively weak influence on international food safety lawmaking because it is reluctant to take initiative and simply orients around the Codex's activities.

C. The Codex as the Central Platform for International Food Safety Lawmaking

The WHO and WTO are the two major international organizations in international food safety lawmaking. Although they approach lawmaking differently, they operate via the same channel—the Codex. The WHO participates at the *ex ante* stage of the Codex's lawmaking; that is, preparation of scientific evaluation and risk assessment, but not during lawmaking *per se*. The WTO, by contrast, participates not in the Codex's process, but mainly in the *ex post* reinforcement of the Codex's normative outcomes through its own effective enforcement mechanisms. Yet according

36. *See* FAO & WHO, *General Information on FAO/WHO Calls for Experts* (2011), http://www.who.int/foodsafety/chem/jecfa/experts/en/index.html.

37. The JECFA produces three major types of reports concerning veterinary drugs: toxicology monographs, residue monographs, and meeting reports. *See* AM. INST. IN TAIWAN, *Index to JECFA Evaluations of Ractopamine* 1, http://www.ait.org.tw/zh/20120326-index-to-safety-evaluations.pdf (last visited Nov. 15, 2013).

to the Appellate Body of the WTO Dispute Settlement Body (DSB), the WTO has no responsibility either to look into the Codex rulemaking process and its history or to determine whether the Codex suffers from procedural or legitimacy deficits.[38] Therefore, the two international organizations participate in an indirect way that secures the position of the Codex as the core international rulemaker[39] in the field of food safety regulation rather than a mere scientific reference point.

III. "POLITICIZATION OF SCIENCE" IN INTERNATIONAL FOOD SAFETY LAWMAKING

As the core of the international food safety lawmaking arena where significant trade interests are at stake,[40] the Codex has encountered controversial problems and severe criticisms. In this section, this Article examines in detail the recent ractopamine dispute as an example of the key challenge faced by the Codex: the politicization of science in the decision-making process.

A. Structure and Processes of the Codex

Prior to the establishment of the WTO and its explicit reference to the Codex as the international food safety standard setter, the Codex was regarded as a technical body working in a largely epistemic manner, unaffected by international power struggles or commercial interests.[41] Led by the ten-member Executive Committee of the Codex Alimentarius Commission, the Codex

38. European Communities, Trade Description of Sardines, WT/DS231/AB/R at 5 (Oct. 23, 2002).

39. *See, e.g.*, Trachtman, *supra* note 26, at 480 (arguing that the Codex has become a quasi-legislative standard setter in the area of food safety standards because of the explicit reference of the WTO SPS Agreement).

40. Lin, *supra* note 19, at 671-72.

41. Frode Veggeland & Svein O. Borgen, *Changing the Codex: The Role of International Institutions* 9-10 (Norwegian Agricultural Economics Research Institute, Working Paper No. 12, 2002) http://www.ecolomics-international.org/caa_veggeland_borgen_changing_codex_nilf_oslo_02.pdf.

consists of twenty-four active committees and task forces.[42] Mainly because of the voluntary soft-law nature of the Codex standards, the Codex members were not in conflict when faced with controversial standards. Rather than block the standard-setting process, members in disagreement over the substance of a food safety standard would simply declare that they had no intention of adhering to the standard and deviate from it.[43] Again, this practice reflects that the pre-WTO Codex standards were legally and practically non-binding—that is, entirely voluntary. As the vertical allocation of authority favors members' regulatory autonomy, they retain full discretion over whether to base their national food safety regulations on Codex standards. Therefore, while the Codex Procedural Rules specify that a "simple majority vote" is permissive and sufficient for the adoption of a standard, the customary practice has been consensual decision-making.[44]

The Codex standard-setting process, framed by the "Procedures for the Elaboration of Codex Standards and Related Texts,"[45] resembles a structured domestic rulemaking process that can be found in a democratic regulatory state. The same procedures apply to the elaboration of Codex guidelines, codes of practices, and other texts. In accordance with its standard-setting procedures, the Codex has formulated international standards for a wide range of food products and specific requirements covering pesticide residues, food additives, veterinary-drug residues,

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42. In addition to the Committee on General Principles and six regional coordinating committees (Africa, Asia, Europe, Latin America and the Caribbean, the Near East, and North America and the Southwest Pacific), subsidiary bodies directly related to food safety include, *inter alia*, the Codex Committees on Contaminants in Foods, Food Additives, Food Hygiene, Pesticide Residues, Residues of Veterinary Drugs in Foods, Food Import and Export Inspection, and Certification Systems. *Id.*

43. *See id.* at 15.

44. JACQUELINE PEEL, SCIENCE AND RISK REGULATION IN INTERNATIONAL LAW 287-89 (Cambridge University Press, 2010).

45. PROCEDURAL MANUAL, *supra* note 8, at 27-37.

hygiene, food contaminants, and labeling and certification systems.[46] The eight-step process detailed below shows important elements of a global administrative process. From initial proposals by members and scientific risk assessments by expert bodies to critical reviews by the Executive Committee and consultation with members and interested parties, the Codex standard-setting procedure can be understood as requiring rigorous scientific justification and democratic deliberation, at least in theory.

Step 1: Proposal

A Codex committee or member can propose new work or revision of an international standard.[47] The Executive Committee[48] evaluates the proposal, together with a project document[49] prepared by the committee or member, through a critical review process. The process takes into account relevant expert scientific advice available from the FAO or WHO, special needs of developing countries, and criteria and priorities established by the Codex Commission.[50] After the critical review, the Codex Commission decides whether to elaborate a new standard and designate a responsible subsidiary body for the preparatory work.

Step 2: Risk Assessment

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46. Its stated goal is "to guide and promote the elaboration and establishment of definitions and requirements for foods, to assist in the harmonization and, in doing so, to facilitate international trade." FAO & WHO, ASSURING FOOD SAFETY AND QUALITY: GUIDELINES FOR STRENGTHENING NATIONAL FOOD CONTROL SYSTEMS 4 (2003) *available at* ftp://ftp.fao.org/docrep/fao/006/y8705e/y8705e00.pdf.

47. PROCEDURAL MANUAL, *supra* note 8, at 21.

48. The Executive Committee is the executive organ of the Commission and the body responsible for managing the standards development process. *Id.* at 5 (Article 6).

49. A project document shall detail, *inter alia*, the purposes, scope, relevance, timeliness, and major aspects of the standard, together with the identification of technical or scientific advice needed, and the availability of such expert scientific data. *Id.* at 28-29.

50. *Id.*

After the Codex Commission evaluates the official standard proposal, it undergoes a drafting process, in which members, FAO and WHO expert bodies, and Codex committees participate to create the draft text. On the basis of available scientific evidence, responsible scientific committees[51] conduct risk assessments and make recommendations for the use of food additives, maximum limits for residues of pesticides or animal drugs, and so on.[52] For example, in the case of veterinary drugs, such as ractopamine, the JECFA conducts risk assessments to set recommended maximum residue limits (MRLs).[53] Arguably, step 2 is the most crucial part of the Codex standard-setting process, as it lays down the fundamental scientific basis for future deliberation and elaboration of standards.

Step 3: First Communication with Members

The Secretariat circulates the draft text (prepared in step 2) to members and other interested parties (international organizations, NGOs, and industry representatives) for comment regarding all aspects of the proposed draft standard—from scientific evidence to economic interests.[54] Unlike members' direct and formal communication with the Secretariat, non-member parties indirectly and informally exercise their influence on member delegates by publishing evaluation reports, lobbying domestic policymaker, joining national delegations, and representing as observers.[55]

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51. Joint FAO/WHO Food Standards Programme, Codex Alimentarius Comm'n, 35th Sess., Jul. 2-7, 2011, CX/CAC Doc. 12/35/14 (2011).

52. PROCEDURAL MANUAL, *supra* note 8, at 31.

53. *Id.* at 129-134.

54. *Id.* at 31.

55. Nevertheless, non-state actors have sought to play a greater role in the process. However, "the extent of corporate power in food governance and the creation of international standards and trade rules cannot be fully understood

Step 4: Committee Risk Management Review

In step 4, the Secretariat returns both the draft and comments to the relevant subsidiary body (committee), which considers and, if necessary, amends the draft text. The draft and the comments are reviewed at the committee level.[56] In the case of ractopamine, the Codex Committee on Residues of Veterinary Drugs in Foods (CCRVDF), a commodity committee hosted currently by the United States and comprising experts and member delegates,[57] considers feedback and revises the draft if needed.

Steps 5 to 7: Second Critical Review, Draft Standard Adoption, and Final Communication with Members

With the endorsement of the relevant Codex committee in step 4, the Executive Committee again conducts a critical review.[58] The Secretariat then submits the proposed draft, the Executive Committee's critical review, and members' comments to the Commission for its adoption of the draft as an official "draft standard."[59] Based on a two-thirds majority of votes and the Executive Committee's critical review, the Commission may decide that the draft standards are ready for both an accelerated procedure and the final adoption, which takes place in step 8.[60] The Secretariat again sends the official draft standard to members and

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without examining the channels of influence at the national level, given that it is still state actors that make the decisions regarding those standard and trade rules." Smythe, *supra* note 12, at 107.

56. If the proposed draft standard concerns general subject matter, the General Subject Committees undertakes the work. PROCEDURAL MANUAL, *supra* note 8, at 31, 44-49.

57. These bodies comprise experts and state members' delegates, and are chaired by the host country, which also funds them. It is here that the first agreements are reached, where the standards are formed. *Id.* at 155-191.

58. *Id.* at 31-32.

59. *Id.* at 32

60. *Id.* at 33-34 (Part 4. Uniform Accelerated Procedure for the Elaboration of Codex Standards and Related Texts).

other interested parties for a final round of review and comments. The Secretariat returns the comments to the relevant committee for consideration and, if necessary, amendment.[61]

Step 8: Adoption (and Third Critical Review)

In step 8, the Executive Committee, for the third and last time, conducts a critical review of the draft standard in its finalized form, together with the comments submitted by members or interested parties. The Commission then decides to adopt, discard, or suspend the draft standard. If adopted, the draft standard becomes a formal Codex standard and is published by the Secretariat.[62]

B. Paradigm Shift in the Post-WTO Codex: A Politicized Forum

The Codex has experienced a paradigm shift and has arguably become politicized[63] under WTO influence because significant trade interests are usually at stake in the Codex standard-setting processes. As demonstrated by the following discussion on the recent ractopamine dispute, the post-WTO Codex has also become a source of controversy in global food safety governance. The Codex standards have a decisive impact on the market access of agricultural, animal, and other food products. Given the Codex standards' normative implications in the WTO, Codex members have tended to evaluate proposed standards for their potential impact on trade interests and act strategically when

61. *Id.* at 32.
62. *Id.*
63. ALEMANNO, *supra* note 25, at 262-63. As put by Alemanno, the express reliance on the Codex standards, guidelines, and recommendations has "an impact not only on their functioning but also on their nature." *Id.* at 262. As the Codex standards directly or indirectly play a role in the results of WTO dispute-settlement cases, "WTO members have incentives to make sure that the new standards of the Codex, IPPC and OIE find inspiration in their current or future national SPS measures." *Id.* at 262-63.

deciding to adopt or discard the given standard.[64] In some cases, trade considerations may outweigh public health concerns, and countries may have material incentives to vote in Codex standard-setting processes to "advance their trade interests rather than promote food safety."[65]

The relationship between the SPS Agreement and the Codex certainly tempts countries to push for the Codex standards through the use of majority voting rather than consensus, or even to distort the decision-making process. The Codex standard-setting process may appear fairly accountable to the Codex members, given that the Procedures for the Elaboration of Codex Standards and Related Texts in theory permits members to elaborate on their comments and to be considered in the Committees. However, as there are no clear rules for determining whether there is "consensus" among the members to move onto the next step, the chairmen of the Codex Committees are effectively able to wield considerable power over the standard-setting process during steps 3 to 7. Such potential problem can be exacerbated in cases involving controversial substances when the science or non-science concerns are contentious. In effect, whether or not the Codex members raise concerns during steps 3 to 7 may matter little, and the 8-step structured process becomes ossified.

The problem of procedural ossification has far-reaching consequences. It may paralyze the accountability checks built into the Codex standard-setting process, which further allows politicization to run rampant during controversial issues, especially when there is not an external (third-party) review. Specifically, the WTO Dispute Settlement Body (DSB) has expressed that the WTO has no responsibility to look into the Codex rulemaking process

64. Veggeland & Borgen, *supra* note 41, at 18-19.
65. Lin, *supra* note 19, at 672.

and determine whether it suffers from procedural or legitimacy deficits.[66] Indeed, the Codex, despite being an international organization jointly established by the WHO and FAO, often becomes an extended WTO battlefield of public health versus international trade. Therefore, the Codex has gone far beyond its original purpose as a mere scientific reference point, and become the most controversial "lawmaker" in the international food safety regulation arena. Moreover, as the controversies over beef growth hormones, genetically modified organisms (GMOs), and ractopamine (elaborated below), demonstrate the Codex has become politicized. The problem of "politicization of science" is particularly evident in the recent ractopamine dispute, which this Article now turns to.

C. A Multi-year Deadlock in a Divided Codex: "Politicization of Science" and the Ractopamine Dispute

At its 35th Session in July 2012, the Codex adopted maximum residue levels (MRLs) for ractopamine, with a slight majority voting in favor: 69 votes in favor of adoption, 67 against. This outcome, a deviation from the Codex's customary principle of adopting food safety standards by consensus, reflects the level of controversy over ractopamine over the past years.[67] At its 34th Session in July 2011, the Codex had discussed adopting MRLs for ractopamine for the fourth consecutive year. Following that discussion, the Commission voted to hold the international

66. Appellate Body Report, European Communities—Trade Description of Sardines, WT/DS231/AB/R, adopted Oct. 23, 2002, DSR 2002: VIII, 3359. para. 222; Panel Report, European Communities—Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R/USA (adopted Aug. 18, 1997), para. 8.69; and LUKASZ GRUSZCZYNSKI, REGULATING HEALTH AND ENVIRONMENTAL RISKS UNDER WTO LAW: A CRITICAL ANALYSIS OF THE SPS AGREEMENT 88 (2010).

67. *See* U.S. DEP'T OF AGRIC., DELEGATE'S REPORT, 35TH SESSION OF THE CODEX ALIMENTARIUS COMMISSION, (2013) *available at* http://www.iica.int/Eng/Programs/AgriculturalHealth/Acceso/02-2012/nota 3.pdf.

standard on the MRLs for ractopamine at Step 8 for a year. This decision mirrored the outcomes of the 31st, 32nd, and 33rd Sessions in 2008, 2009, and 2010, respectively.[68]

Ractopamine is a synthetic compound produced by Elanco, a subsidiary of Eli Lilly and Company. It is used as a veterinary drug by the meat industry to boost feed efficiency[69] in the form of increased usable meat on animals such as cattle.[70] Ractopamine is absorbed into animals' bodies and distributed to muscle tissues, moving nutrients away from fat production and increasing protein synthesis and therefore muscle fibers.[71] In this way, ractopamine creates leaner and heavier meat, which is more valuable on the market. Unlike most veterinary drugs, ractopamine is intended for use the final stages of these animals' lives (i.e., prior to slaughter),[72] so there is no clearance period that would reduce or eliminate residues upon human consumption. According to the JECFA, administering ractopamine to humans for any medical purpose is impermissible.[73]

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68. *See* The Codex and JECFA Secretariats, FAO, *Information Sheet: Discussion on Ractopamine in Codex and in the Joint FAO/WHO Expert Committee on Food Additives (JECFA)* 1-2 (2012) [hereinafter *JECFA Info Sheet*] http://www.fao.org/fileadmin/user_upload/agns/pdf/Ractopamine_info_sheet_Codex-JECFA_rev_26April2012__2_.pdf; *see also* Alberto Alemanno & Giuseppe Capodieci, *Testing the Limits of Global Food Governance: The Case of Ractopamine*, 3 EUR. J. RISK REG. 400, 405 (2012) (discussing the political economy of the ractopamine dispute).

69. *See* Adam Anson, *The Codex Perspective on Ractopamine*, THE BEEF SITE (Aug. 11, 2009), http://www.thebeefsite.com/articles/2082/the-codex-perspective-on-ractopamine. When fed 200 mg of ractopamine per day prior to slaughter, cattle are said to undergo an average weight increase of about 14.2 lbs. In addition, the overall efficiency of animal feed is said to increase by up to 15.9%, resulting in a net monetary increase of US$8.00 per head for the meat industry. *Id*.

70. *JECFA Info Sheet*, *supra* note 68, at 1.

71. *Id.*

72. *Id.*

73. *Id.*

The JECFA, an expert body undertaking risk assessments for the Codex, reviewed the available data on ractopamine and performed toxicology risk assessments regarding its residue in meat in 1993, 2004, 2006, and 2010.[74] The 40th JECFA meeting (in 1993) was the organization's first meeting to consider ractopamine, and the participating members concluded that the scientific evidence was inadequate for establishing an Acceptable Daily Intake (ADI) level.[75] Drawing upon an Eli Lilly-sponsored study on humans' acute cardiac responses to ractopamine, the 62nd JECFA meeting in 2004 identified a broad safety margin, an ADI level, and MRLs for the drug[76] for further consideration by the CCRVDF. These conclusions were confirmed during the 66th JECFA meeting in 2006,[77] and a JECFA reevaluation in 2010 of newer related data submitted by China.[78]

The science, law, and politics of ractopamine are complicated. Ractopamine is currently allowed for use as a growth promoter only in twenty-five countries, [79] and is restricted or banned in 160 countries worldwide.[80] Although the JECFA, the internationally accepted expert body responsible for risk assessment, has determined an ADI and proposed MRLs for

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74. *Id.*

75. Joint FAO/WHO Expert Comm. on Food Additives [JECFA], WHO, *WHO Technical Report Series 832,: Evaluation of Certain Veterinary Drug Residues in Food* 49 (1993), http://apps.who.int/iris/bitstream/10665/38637/1/WHO_TRS_832.pdf.

76. JECFA, FAO, *WHO Technical Report Series 925, Evaluation of Certain Veterinary Drug Residues in Food* 48-49 (2004), http://whqlibdoc.who.int/trs/WHO_TRS_925.pdf.

77. JECFA, FAO, *WHO Technical Report Series 939, Evaluation of Certain Veterinary Drug Residues in Food* 50 (2006), http://whqlibdoc.who.int/publications/2006/9241209399_eng.pdf.

78. JECFA, FAO, *Residue Evaluation of Certain Veterinary Drugs* 38 (2010), http://www.fao.org/docrep/012/i1618e/i1618e00.pdf.

79. *JECFA Info Sheet*, *supra* note 68, at 1.

80. Carey Gillam, *U.S. Food, Animal Groups Seek Lower Ractopamine Limits*, REUTERS (December 20, 2012) http://www.reuters.com/article/2012/12/20/us-usa-meat-hormones-idUSBRE8BJ15N20121220.

ractopamine, food safety concerns have not ceased in the Codex. Such concerns, given their significant public health and economic repercussions, have divided the Commission.

Members of the Codex such as Argentina, Australia, Brazil, Chile, Canada, Mexico, South Africa, and the United States supported the JECFA's risk-assessment findings and the Codex's proposed adoption of the MRLs. Those members stressed that the JECFA had followed the *Risk Analysis Principles Applied by the Codex Committee on Residues of Veterinary Drugs in Foods*[81] by reviewing "all available data" three times to determine the ADI and the MRLs, and that such MRLs could be reevaluated upon new scientific evidence at some point.[82] After reaffirming their confidence in the JECFA, supporting members argued that the persisting deadlock over the Codex adoption of science-based MRLs could "undermin[e] the work of JECFA and risk assessment."[83] Some members also worried that the Codex's "failure to adopt the MRLs for ractopamine could negatively impact food security as the establishment of MRLs for ractopamine would allow the safe use of new technologies to meet the increasing demand for food production foreseen by FAO."[84]

In contrast, member countries such as China, the European Commission, Egypt, India, Japan, Russia, and Turkey[85] opposed adopting such MRLs and continuously expressed concerns regarding the scientific data related to the safety of ractopamine. These members pointed out unanswered food safety questions that

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81. PROCEDURAL MANUAL, *supra* note 8, at 85 (Section III).

82. Rep. of the Joint FAO/WHO Food Standards Programme, Codex Alimentarius Comm'n, 34th Sess., July 4-9, 2011, REP11/CAC (2011) para. 95, [hereinafter CAC Report] *available at* http://www.who.int/foodsafety/codex/34thCAC.pdf.

83. *Id.* paras. 95-96.

84. *Id.* para. 96.

85. Scott C. Tips, *Codex Avoids Implosion - By Five Votes*, NAT'L HEALTH FED'N (July 14, 2011), http://www.thenhf.com/article.php?id=2945.

merited further study. They also noted that the Codex should "base its decision on a broad consensus [so as] not to undermine its credibility."[86] In particular, China noted that it, together with the European Union, accounted for 70% of the pork production and more than 70% of the pork consumption in the world; thus, it could be argued that "adopting a standard without the support of these two major actors would undermine the credibility of [the] Codex."[87] China declared that the Codex should consider adopting MRLs for ractopamine only after the relevant risk assessment is finished and food safety questions are completely addressed.[88]

During its 34th Session, the Codex struggled to not vote on the ractopamine standard because the customary practice is consensual decision-making.[89] Faced with extensive debate and a divided assembly, the chairperson emphasized that "every effort had been made to reach consensus before proceeding with [voting]," as required by Rule XII.2 of the Rules of the Procedure of the Codex Alimentarius Commission.[90] While members such as China, the European Commission, India, and Russia warned that a vote carried the risk of an irreversible breakup among the members of the Codex, the United States demanded a roll-call ballot; Australia, Brazil, and Canada suggested a secret ballot; and Japan proposed a ballot for whether a vote should even proceed.[91] The

86. CAC Report, *supra* note 82, para. 98.
87. *Id.* para. 99.
88. *Id.* para. 100.
89. Peel, *supra* note 44, at 287-89.
90. CAC Report, *supra* note 82, paras. 105-10. In the same vein, the FAO Legal Counsel clarified that the chairperson is empowered to determine whether the requirements of Rule XII.2 of the Codex Rules of the Procedure are being satisfied, but such determination is subject to an overruling by the CAC. *Id*. para. 109.
91. As a verbatim or detailed meeting history is not provided by the official Codex Report, here I resort to a report prepared by the National Health Federation as a supplementary source. *See* Tips, *supra* note 85, para. 17. Martin Shapiro brilliantly described the problem as, "[p]erhaps the chat can be put online and thus subject to some degree of public scrutiny and even democratic control. But the languages in which regulatory chats are conducted tend to be

dispute lasted for almost an hour, and the chairperson ruled that because most members supported the consensus approach to decision-making, there should not be a vote. The chairperson also stated that the draft MRLs for ractopamine should be held in abeyance at Step 8 owing to the nearly equally divided Commission.[92] However, the United States pressed the chairperson to a vote on whether to adopt the ractopamine MRLs.[93] The chairperson ultimately agreed to a roll-call ballot to decide whether members wanted the subsequent vote in a roll-call or secret-vote manner.[94] The majority voted for secret ballots.[95] Finally, after a secret simple-majority vote, the Commission decided not to vote whether to adopt the MRLs for ractopamine at the 34th session, with 59 delegates in favor of voting, 68 against, and 9 abstentions; the draft MRLs for ractopamine were retained at Step 8.[96]

One year later, the Commission's 35th Session failed to reach consensus again and eventually adopted the ractopamine MRLs suggested by JECFA with a one-vote majority and 7 abstentions. The core institution of international food safety lawmaking once again became the core of the controversy—a *déjà vu* situation like the 1995 Hormones dispute.[97]

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highly complex—technical ones that privilege those with the greatest resources and highest incentives to attain fluency." Martin Shapiro, *"Deliberative," "Independent" Technocracy v. Democratic Politics: Will the Globe Echo the E.U.?*, 68 LAW & CONTEMP. PROBS. 341, 351-52 (2005). In this regard, Shapiro notes the contribution of transnational NGOs in providing "a window into transnational regulatory corporatism." *Id.* at 352.

92. *See* Tips, *supra* note 85, para. 18.

93. *Id*. para. 19.

94. *Id*. para. 19-20; CAC Report, *supra* note 82, paras. 110-11.

95. CAC Report, *supra* note 82, para. 112.

96. *Id.* paras. 112-15.

97. *See generally* Doaa Abdel Motaal, *The "Multilateral Scientific Consensus" and the World Trade Organization*, 38 J. WORLD TRADE 855, 865-75 (2004) (discussing the multi-year dispute between the US and the EU over the "particularly controversial" Codex standard-setting process for the use of growth-promoting hormones, the failure to reach any consensus in the Codex Alimentairus Commission, and the final adoption of the standard by a 33 to 29 (7 abstentions) votes in 1995).

IV. BETWEEN TECHNOCRACY AND DEMOCRACY: MULTILATERAL COOPERATION FAILURE

The serious problem of politicization of science has discouraged states from further engaging in multilateral cooperation to any meaningful extent. More and more states have become members of the Codex and participated in the standard-setting process, yet have failed to cooperate further. The Codex standards have a decisive impact on the market access of agricultural, animal, and other food products. This influence is clearly reflected in the ractopamine dispute, where the positions held by member countries such as the United States and Australia echo the business rationale of those same countries' meat-exporting industries.[98] In fact, countries in food-exporting[99] and food-importing industries have a crucial stake in the Codex standards. This is evident in the Codex meetings, where industry actors have been increasingly participating as the majority of observers and even government delegates.[100]

The trade implications of the Codex standards also explain why the ractopamine dispute over scientific issues has found its way into SPS Committee meetings, a trade forum under the WTO umbrella.[101] At numerous SPS Committee meetings, China has raised concerns about the scientific basis for the proposed Codex standard for ractopamine. China has argued that the ongoing deadlock over MRLs for ractopamine translates into "no scientific consensus" regarding the safety of the veterinary drug.[102]

98. *See infra* Part II.3.

99. *See* Smythe, *supra* note 12, at 99-102.

100. *Id.* at 95.

101. WTO, *Committee Debates Pros and Cons of Standard for Lean Meat Additive*, WTO NEWS (July 1, 2011) http://www.wto.org/english/news_e/news11_e/sps_30jun11_e.htm.

102. Shih Hsiu-chuan, *"No Obligation" on Ractopamine Levels: WTO*, TAIPEI TIMES (Mar. 26, 2012) http://www.taipeitimes.com/News/taiwan/print/2012/03/26/2003528737.

Contrastingly, the United States has pressured Taiwan at SPS Committee meetings and on other various occasions regarding its ban on the use of ractopamine in beef and pork.[103] The enforceability and the effectiveness of the WTO dispute-settlement system reinforce the anchoring power of the Codex standards to expand or limit food-exporting countries' ability to push for market access; therefore, it is common to see the WTO Secretariat participate in different the Codex meetings and play a consulting role with regard to the relationship between the Codex and the WTO.[104]

Increasingly, as a result, credible scientific foundations are no longer the core consideration in terms of the source of the legitimacy of the Codex standards. Consequently, discourse about the Codex's legitimacy has shifted from the technocracy model to the democracy model. While the WTO hardens the Codex standards and at the same time turns its back on problems of procedural regularity within the Codex, the vertical allocation of authority between international harmonization and national autonomy no longer favors the latter. Scientific foundations have therefore become a source of disagreement throughout the Codex standard-setting processes, and members of the Codex have begun to vote on standards rather than adopt them based on consensus.[105] Due to the gradual paradigm shift in the discourse on the Codex's legitimacy from one extreme to the other along the technocracy-democracy continuum, states have strenuously criticized developing countries' insufficient participation in the process[106]

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103. Helena Bottemiller, *U.S. Presses Taiwan on Ractopamine Ban*, FOOD SAFETY NEWS, (Feb. 7, 2012) http://www.foodsafetynews.com/2012/02/us-presses-taiwan-on-ractopamine-ban/#.UmqOMJTF1L8; *see also* Shih, *supra* note 102.

104. Veggeland & Borgen, *supra* note 41, at 14-15.

105. Peel, *supra* note 44, at 287-88.

106. *See generally* Michael Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex*

and the legality of the Codex's non-consensus method for adopting standards.

Debates over the technocracy-democracy continuum also lead to further normative inquiries, which merit future research and reference. To what extent is developing countries' participation critical to the validation and legitimacy of the Codex standards? Is it that the Codex is no longer regarded as an international organ able to facilitate multilateral scientific consensus? Is a Codex standard adopted by consensus but based on sloppy science more legitimate than a Codex standard based on sound science but adopted by a slim majority vote? Can the focus on participation and democratic deliberation, to a certain extent, undermine the core value of scientific standard-setting processes? What are the limits of more political, less scientific risk management? How accountable should supposedly purely scientific risk assessment be? And to whom should the assessment be accountable? Given the dramatic changes in the Codex lawmaking environment, are the Codex's previous "gentlemen's club" procedural rules still valid for the organization's now "international regulator" status? How do we explore the optimal institutional design for good global governance in this case?

V. THE FORGOTTEN ROLE OF PROCEDURAL LEGITIMACY: FOSTERING ACCOUNTABILITY THROUGH TRANSPARENCY AND AVOIDANCE OF CONFLICTS OF INTEREST

Food safety is an area of international law where political and cultural fragmentation collides with deep market integration and trade liberalization. In the multi-level structure of governance

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Alimentarius, 81 N.Y.U. L. REV. 766, 781-89 (2006) (discussing in details the considerable gap between the presentation between developing and developed countries, where the former are less able to participate in Codex process because of a lack of resources and abilities).

like the one in which the Codex operates, problems with delegation, accountability, and legitimacy may arise. These problems become even more contentious when the space of where rulemaking occurs is highly technical and specialized, and when the issue goes to the core of national sovereignty, as the food safety case demonstrates.

For some, the mere fact of the Codex's technocratic direction is enough to condemn the international food safety lawmaking process, for such an approach ignores cultural particularity in the production of knowledge, different perceptions of risk, and alternative values other than science. Under this view, the current lawmaking arena fails to appreciate cultural diversity (even culinary traditions) and national autonomy in the politically-sensitive area of food safety and public health. Proponents of this view tend to argue for full participation and consensus at the final stage of standard adoption while being indifferent to the soundness of the "science" used in the process.[107]

For others, anchoring to objective epistemic premises legitimizes the outcomes of standard setting, particularly in fields that require knowledge, expertise and quantitative data. From that perspective, science serves as a rigid approach toward technical rulemaking and is able to deliver objective recommendations for food safety standards. Even more, proponents of this view believe that new and complex technologies call for more involvement of and appreciation for science.[108]

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107. *Id.*

108. *See, e.g.*, Christian Joerges, *Law, Science and the Management of Risks to Health at the National, European and International Level: Stories on Baby Dummies, Mad Cows and Hormones in Beef*, 7 COLUM. J. EUR. L. 1, 2-3 (2001); CASS SUNSTEIN, LAWS OF FEAR: BEYOND THE PRECAUTIONARY PRINCIPLE (2005).

What is missing in this discourse is focus on the process in which food safety standards are engineered. The problem is not with the use of science *per se*, or with participation or consensus, but with the process by which science is called upon, utilized, interpreted, applied, and abused. Clinging to the technocratic approach insufficiently accommodates the reality of scientific uncertainty and the limitations of science, while blind embrace of the democratic approach fails to appreciate the legitimating effect of using sound science and the boundaries of popular judgment.[109]

It is therefore crucial to emphasize the procedural legitimacy of international food safety lawmaking. In light of the characteristics and problems of the Codex's normative activities, it is constructive to foster accountability and legitimacy by securing transparency and avoiding conflicts of interest in the scientific decision-making processes.

The Codex operates in a multi-level structure of governance, and constitutes a space of lawmaking in a broad sense, producing international standards that are implemented through domestic law and regulation by national governments. The Codex uses its expert bodies (such as the JECFA) to conduct risk assessment, which the Codex committees use to suggest risk-management recommendations that are adopted by Codex members as international standards. Codex members, WTO members, and other international entities further internalize such international standards. The relationship between the Codex, JECFA and WTO members are multi-level and, thus, involve possible problems of delegation, accountability, and legitimacy.

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109. For a masterful analysis on science and democracy, see generally SHEILA JASANOFF, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES (2007).

Moreover, the Codex is a highly technical, specialized, and scientific institution in charge of generating professional knowledge and data, all of which is respected by members of their respective groups by default. Lacking adequate financial and technical capacities to assess various health risks on its own, the Codex relies heavily on external technical and scientific expertise in different highly specialized fields (such as toxicology and microbiology) accessed on either a regular roster or an *ad hoc* basis. As the Codex's activities have significant effects on not only public health but also international trade, the trade interests of various actors—such as multinational food corporations and countries with strong agricultural sectors—may factor into the rulemaking processes. As such interests can translate into political influence, the Codex can experience problems with the politicization of science. To avoid the politicization of science, the Codex follows a structured decision-making process and a separation of risk assessment and risk management by means of institutional design. That is, scientific advisory bodies responsible for risk assessments are organizationally or functionally separated from the decision-making (often political) body in charge of risk management. For instance, the Joint FAO/WHO expert committees that provide scientific risk assessments for the Codex standard-setting process are not formally part of the Codex.

In order for the Codex to increase its legitimacy as the international food safety lawmaker, soundness of scientific evidence, transparency of decision-making process, and avoiding conflicts of interest are of great importance. However, as aforementioned, the Codex has been seriously criticized for its inadequate institutional design for fostering independent scientific opinions as well as the lack of transparency in its decision-making process. In the following sections, this Article identifies two key

institutional designs that are critical for future Codex reforms to take into account. These two institutional design models are mechanisms for avoiding conflicts of interest when formulating scientific advice and requirements to foster transparency and openness.

A. Mechanisms for Avoiding Conflicts of Interest

As mentioned above, international food safety lawmaking, especially the work of the Codex, relies greatly on technical and scientific expertise from different highly specialized fields. The Codex does not have adequate financial and technical capacities to assess various health risks on their own thus has to use scientific bodies comprised of external experts for its risk-assessment mandates. External scientists from various backgrounds come to investigate scientific data, deliberate on risk issues, and finally develop scientific opinions to inform regulatory decision-making, so the platform on which they convene must be designed to ensure excellent scientific advice and avoid conflicts of interest.

The JECFA and other Joint FAO/WHO expert committees, while not organizationally part of the Codex, provide scientific advice as requested by the Codex. Following a call-for-experts announcement, scientist candidates are considered by a selection board and appointed as members of the joint expert committees.[110] If appointed, member experts are placed on a roster for a five-year

110. "FAO and WHO have complementary functions in selecting experts to serve on the Committee. FAO is responsible for selecting members with chemical expertise for the development of specifications for the identity and purity of food additives, for the assessment of residue levels of veterinary drugs in food, and to assess the quality of the monitoring data. WHO is responsible for selecting members for the toxicological evaluations of the substances under consideration, in order to establish acceptable daily intakes (ADIs), or other relevant guidance values, or to give a quantitative estimate of the health risk. Both FAO and WHO invite members who are responsible for assessing exposure." WHO, *About the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*, para. 1, http://www.who.int/foodsafety/chem/jecfa/about/en/index3.html.

term and are called upon to address specific subject matters related to their expertise.[111] The selection board considers candidates based on their scientific and technical excellence, diversity, objectivity, and independent judgment.[112] To avoid conflicts of interest, experts are appointed according to their individual scientific capacity and not as agents of a government or an institution.[113] Experts of the joint expert committees must submit an initial declaration of any real or potential conflicts of interest that may unjustifiably influence their position.[114]

The Codex should design a set of much stricter and more nuanced rules for conflict-of-interest declarations. First, instead of the Codex/JECFA system's current loose mechanism for avoiding conflicts of interest, there should be some general principles and detailed rules for defining and identifying declarable interests, such as assessing declared interests, screening experts, reviewing decisions, and handling breaches of rules. In particular, the definition of "conflicts of interests" should be reasonably broad so as to include situations where a scientific expert or an individual is in a position to exploit his or her professional or authorized capacity in some way for undue corporate or personal benefits when cooperating with the Codex. In addition, the timing for declaring potential conflicts should not be limited to the selection process. Rather, it should also occur at different temporal points.

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111. *Id.*

112. *See, e.g.*, FAO & WHO, *Joint FAO/WHO Expert Meeting on Risk Assessment Tools for* Vibrio Parahaemolyticus *and* Vibio Vulnificus *Associated With Seafoods, Call for Data and Experts,* World Health Organization 1, 3 (Sept. 13, 2010), http://www.who.int/foodsafety/micro/jemra/meetings/Call_Sept2010.pdf (As expressed in the FAO/WHO call-for-experts announcements, "[i]n selecting experts FAO and WHO will consider, in addition to scientific and technical excellence, diversity and complementarities of scientific backgrounds, and balanced representation from geographic regions including developing and developed countries as well as gender.").

113. *Id.* at 4.

114. *Id.*

For example the Codex should require annual or regular written, specific declarations of interest when any change occurs that may alter previous determinations, and oral declarations of interest prior to every scientific meeting. The conflict of interest rules should cover a wider range of positions within and even outside the Codex, such as internal staff and outside consultants, instead of limited to scientific experts. Finally, rather than rely on voluntary declarations, the Codex should systematically and regularly examine individuals' compliance with declarations of interest and seek additional information if any is missing.

It should be acknowledged that, given the complex food science and biotechnology involved in modern industrialization of food industry, an overly strict mechanism for conflicts of interest might undermine the quality of risk assessments. In some very specialized fields of food-related science and technology (such as toxicity and carcinogenicity studies on newly invented substances), the list of experienced scientific experts may be very short. Thus, for those fields, it may be especially difficult to locate enough qualified scientific experts who do not have prior experience with the relevant industry that would preclude them from participating in the risk assessment process. Therefore, in designing a robust set of rules to avoid conflicts of interest, the Codex should be cautious to strike an appropriate balance between using best available scientific expertise and ensuring the independence of the scientific work.

In a technical lawmaking body like the Codex, declaration-of-interest rules play a critical role in the process for nominating experts as well as decision-making. With properly designed rules that ensure apparent conflicts of interest are avoided, the Codex may be better able to foster technocratic legitimacy and facilitate subsequent cooperation.

2. Requirements to Foster Transparency and Openness

The transparency of decision-making processes is a crucial element in promoting decision-makers' accountability, securing sound scientific deliberation, and informing interested parties about important facts.[115] In this regard, although stakeholders are not allowed to participate in developing scientific advice, the Codex ensures that they have access to meeting minutes (not word-for-word records), scientific reports, risk assessments, safety evaluations, and other information.[116] For expert groups' meetings, such as the JECFA, the WHO and FAO, websites publish electronic summaries of both key data used and conclusions reached. Dissenting scientific opinions are summarized in the published reports.[117]

The Codex should establish a mechanism for facilitating transparency that goes beyond its current practice. This recommendation comes with a caveat: Transparency is constructive, but too much or meaningless transparency can undermine the desired effect. An overflow of formalistic information that obscures much of what actually happened overwhelms interested civil society groups and discourages public

115. *See generally* Benedict Kingsbury, Nico Krisch & Richard B. Stewart, *The Emergence of Global Administrative Law*, 68 LAW AND CONTEMP. PROBS. 15, 37-42 (2005) (arguing that transparency is a crucial element of NGO involvement and accountability in decisionmaking process, especially in the Codex); David E. Winickoff and Douglas M. Bushey, *Science and Power in Global Food Regulation: The Rise of the Codex Alimentarius*, 35 SCI. TECH. & HUM. VALUES 356, 375 (2010) (emphasizing that transparency, together with representation and accountability, are "new procedures" that can move hybrid bodies like the Codex toward democratic expert process).

116. *See* Codex Alimentarius Comm'n, *Meetings & Reports*, http://www.codexalimentarius.org/meetings-reports/en/ (last visited Nov. 12, 2013) (listing meeting minutes and reports).

117. *See, e.g.*, WHO, *Joint FAO/WHO Expert Committees on Food Additives (JECFA) Publications*, http://www.who.int/foodsafety/chem/jecfa/publications/en/ (last visited Nov. 12, 2013) (listing JECFA publications, including summaries and conclusions from JECFA meetings).

participation.[118] Mandatory publication of everything without delay or attention to relevance and importance may incur unnecessary financial and administrative costs. Member states' discretion over adoption of plenary meeting reports poses another practical concern regarding international organizations' operation. It might be practically difficult to have verbatim reports that address real and crucial public concerns, since such reports have to be adopted by Codex members, which often ask for addition or deletion of words during the adoption process. In controversial cases, such reports might be not only costly, but also politically challenging to adopt without compromise.

Therefore, design and implementation of an effective and efficient transparency mechanism needs to balance qualitative and quantitative concerns so as to foster the nexus between transparency, public participation, and accountability. In line with its core principle of transparency and openness, the Codex should, in consultation with the WHO and FAO, publish details of relevant expert-selection processes and experts' declarations of interest. With regard to the scientific committees and working groups, the Codex should endeavor to publish—without delay—accountability-oriented documents, such as agendas and minutes of committees and working groups, detailed majority and minority opinions, declarations of interest made by covered personnel, and exchanges between the Codex and its member states. Furthermore, the Codex's meetings should be held in public as a general principle. The Codex Secretariat should play a key role in institutional support, ensuring comprehensive access to its

118. *See generally* Jennifer Shkabatur, *Transparency with(out) Accountability: Open Government in the United States*, 31 YALE L. & POL'Y REV. 79, 121-35 (2012) (arguing that the transparency system should be "goal-oriented and more narrowly tailored to target accountability-related information" and further supported by implementation tools that orient towards civil society monitoring and enforcement).

documents and information. The Codex should further consider developing and *proactively* circulating scientific reports, risk-assessment data, and other information tailored to satisfy the needs of different stakeholders, including those from consumer NGOs and industry. In short, because the Codex has been criticized for insufficient transparency and weak accountability, establishing a set of more comprehensive rules that foster a higher level of transparency and openness in the scientific decision-making process seems necessary.

VI. CONCLUSION

The proliferating food safety regulatory initiatives at domestic, international, and transnational levels by various actors with different perspectives have raised concerns for their important public health, international trade, and various other implications. As the hub of international food safety lawmaking, the Codex faces serious criticisms regarding its scientific soundness, legitimacy, transparency, and accountability. Such problems perpetuate rather than alleviate the current multilateral cooperation failure.

Although members of the Codex have initiated several reform projects (such as amending the Codex Rules of Procedure and setting guidelines and principles for risk analysis) so that the Codex now has more structured procedural rules governing scientific and political decision-making, the Codex has yet to actively look for models of good governance. Likewise, with respect to technical cooperation and normative dialogue with other scientific networks, the Codex's current practice seems rather one-way, passive, and narrow. For example, in the ractopamine dispute, when the European Union's European Food Safety Authority (EFSA) submitted its opinion to the JECFA, the JECFA Secretariat

made an unusual move at the Codex 34th Session Assembly that the JECFA, by rejecting the EFSA opinion because EFSA had not conducted a risk assessment by considering the original raw data.[119]

As noted above, there seems to be no meta-framework—either in place or under development—that would dictate crafting of diverse food safety norms in a coordinated manner. Active spheres in the evolving global food safety governance complex are separately searching for optimal approaches to better governance. International food safety lawmaking is an ongoing process of experimentation—both in a scientific and regulatory fashion. The limits of science and the limits of international food safety regulation should be seriously appreciated. The Codex should play its "hub" role by actively building scientific networks that address specific issues by coordinating activities, the exchange of information, development and implementation of joint projects, and the exchange of expertise and best practices. When a scientific and regulatory network of cooperation comes into play, the Codex can undergo reconfiguration into a constructive forum with mutually reinforcing participants. This forum would facilitate cross-sector collaboration, technical exchange, and data sharing that would strengthen global food safety governance.

Most importantly, as the international food safety lawmaking platform, the Codex must be designed to foster civil society engagement and public scrutiny, enable a better nexus between international harmonization and national regulatory diversity, and, more generally, increase horizontal accountability of policymakers. Institutional designs for safeguarding

119. FAO & WHO, *Joint FAO/WHO Expert Meeting on Dietary Exposure Assessment Methodologies for Residues of Veterinary Drugs, Draft Report including Report of Stakeholder Meeting*, *available at* http://www.who.int/foodsafety/chem/jecfa/FAO-WHO_exposure_report_for_public_review_3_feb_2012.pdf.

transparency and avoiding conflicts of interest in the highly technical decision-making process, while not synonyms for good governance, can increase accountability, legitimacy, and a better balance of science and politics.