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The Codex Alimentarius Commission, Corporate Influence, and International Trade: A Perspective on FDA's Global Role

Sam F. Halabi[†]

I. INTRODUCTION

The FDA Food Safety Modernization Act (FSMA)¹ is by all accounts the most sweeping and comprehensive update to U.S. food laws in seventy years, aiming to confront the reality that the nation's food supply has undergone fundamental shifts in its sources, distribution channels, and intermediate handlers. The law's intent is to prevent problems that can cause foodborne illness and enable the Food and Drug Administration (FDA) to keep a record of facilities processing food for sale in the United States, a mandate that expands FDA's already global regulatory activities.² FSMA gives FDA broad new powers to prevent food safety problems, detect and respond to food safety issues, and improve the safety of imported foods.³ Because the law specifically aims to update FDA authority in light of the reality of global food and food additive markets, Section 305 FSMA calls for FDA to develop a comprehensive plan to expand the "technical, scientific, and regulatory capacity of foreign governments and their respective food industries in countries that export foods to the United States."⁴ Part of its plan for fulfilling its Section 305 obligation is actual presence: FDA has established overseas offices in China, India, Costa Rica, Chile, Mexico, Belgium, the UK, Italy, South Africa, and Jordan (closed).⁵ A separate aim is to incorporate the work and insights from international organizations ranging from the Food and Agriculture Organization to the World Health Organization to the World

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¹ FDA Food Safety Modernization Act, Pub. L. No. 111-353, 124 Stat. 3885 (2011) (codified as amended at 7 U.S.C. § 7625 and in scattered sections of 21 U.S.C.).

² See FDA, FDA'S INTERNATIONAL FOOD SAFETY CAPACITY BUILDING PLAN 5 (2013), <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM341440.pdf>; *Food Safety Modernization Act*, VT. AGENCY OF AGRIC. FOOD & MKTS., http://agriculture.vermont.gov/food_safety_consumer_protection/fsma.

³ See Vt. Agency of Agric. Food & Markets, *supra* note 2.

⁴ FDA, *supra* note 2, at v.

⁵ *Report to Congress on the FDA Foreign Offices*, FDA (Feb. 2012), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm291803.htm#summary>.

Bank to the OECD.⁶ The FSMA statute specifies one particular international organization for FDA attention with respect to its global activities: the Codex Alimentarius Commission (“Codex”).

FSMA requires that FDA develop “[r]ecommendations on whether and how to harmonize requirements under” Codex, an international organization charged with developing food standards, guidelines, codes of practice and other recommendations “to protect the health of consumers and to ensure fair practices in food trade.”⁷ Codex sets standards on food quality and safety, including food commodity standards and codes of hygienic or technological practice.⁸ In addition, Codex evaluates pesticides, food additives and veterinary drugs, establishes limits for pesticide residues, and creates guidelines for contaminants.⁹ Although the statutory language takes an agnostic approach to Codex standards, FDA’s International Food Safety Capacity-Building Plan is supportive and deferential to Codex, arguing that “the use of Codex standards helps assure a safe global food supply.”¹⁰ To be sure, Codex’s stated mission and policies should create and facilitate adoption of universal standards and best practices to ensure a safe global food supply, supported as it is by the World Health Organization and the Food and Agricultural Organization, specialized U.N. agencies with well-regarded research capacity and public health-oriented mandates.¹¹ Yet Codex has been the subject of substantial criticism for failing to uphold its consumer protection mandate.

Using the principal common criticisms of Codex—that it favors trade liberalization over health, industry concerns over consumers’, and rich countries over poor ones—this article encourages FDA to leverage its new role as a global regulatory body to inform its Codex work. This article contributes to the existing literature by clarifying the scope and gravity of these common criticisms and showing how FDA may use them to anticipate the changes global trade liberalization portends for keeping the food supply safe. First, Codex’s lean toward trade liberalization over consumer health did not commence after it became the international standard-setting organization under the WTO’s Sanitary and Phytosanitary Measures Agreement (SPS). From its structure to its purpose, Codex processes have always favored trade liberalization over high levels of health protection. Emphasizing Codex’s emergence from relative obscurity after 1994 distracts from the political and economic forces that have shaped the organization from its founding and the infrastructure WHO, FAO and Codex have put in place to ensure those forces are harnessed to the greatest extent possible to further the organization’s mission.

Second, studies and analyses of Codex decision-making frequently accuse it of subordinating its agenda to industry interests. For the most part, these criticisms are proven indirectly by, for example, counting industry representatives at Codex meetings or as part of national delegations. But the real threats to the integrity of Codex’s processes have emerged not through routine industry participation on national delegations or as observers, but through hidden efforts to influence scientists supplying Codex’s committees and subcommittees with purportedly objective information. The

⁶ FDA, *supra* note 2, at 3.

⁷ FDA Food Safety Modernization Act, Pub. L. No 111-353, § 305(c)(5), 124 Stat. 3885, 3958 (2011); FDA, *supra* note 2, at 21.

⁸ For a list of the standards Codex covers, see *Codex Standards*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/standards/en/> (last updated Mar. 3, 2015).

⁹ *Id.*

¹⁰ FDA, *supra* note 2, at 21.

¹¹ See *About Codex*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/codex-home/en/> (last updated Apr. 8, 2015).

response to that threat is better systems for declarations of interest and transparency, an effort FDA is well positioned to lead. Third, critics accuse Codex of undertaking its work with insufficient participation by developing countries or inadequate sensitivity to their resource constraints. But, other than the argument that participation matters for its own sake, there has been little investigation as to concrete harms to developing countries by existing levels of participation. Indeed, there is evidence to suggest that the problems for developing countries are not caused by Codex, but by developed countries' insistence on imposing standards more stringent than Codex adopts or allowing private entities to effectively push standards higher through supply agreements.

It *is* reasonable to assume that, if the Doha trade round ever results in freer trade in agricultural goods, Codex will be a prime target for erecting barriers to entry for those goods not necessarily related to its consumer health protection mandate. These weaknesses in the current Codex standard development process are outlined with the objective of informing FDA's approach to determining which Codex standards have been effectively and responsibly informed and, if so, how they may be harmonized with U.S. law. This article is part of a larger story about how FDA's mandate—protection of U.S. consumers' health—will adapt as rules it adopts will be subject to challenge under international trade and investment treaties.

Part II of this Article provides a brief history of Codex and how its members are chosen as well as the general nature of its activities. Part III outlines the three common criticisms of Codex and how FDA may address each within the scope of its new FSMA authority. Part IV provides a brief conclusion and preview of how FDA's role must adapt in the face of the increasing strength of international trade and investment treaties.

II. THE HISTORY AND FUNCTION OF THE CODEX COMMISSION

A. CODEX'S HISTORY AND STRUCTURE

The history of Codex dates back to the creations of the FAO and WHO in the late 1940s.¹² In 1950, the FAO and WHO formed the First Joint Expert Committee on Nutrition ("Joint Expert Committee"), emphasizing the need to address the inconsistencies of international food standards. In 1955, the Fourth Joint Expert Committee declared the uncontrolled use of food additives a pressing matter of public concern and established a committee to draft guidelines on food additive control and use.

The Joint Expert Committee joined a number of international and regional food regulatory agencies that had evolved in the post-war period. The United Nations Economic Commission for Europe, for example, established a Geneva Protocol which proposed standards and guidelines for food commodities, mainly fruits and vegetables. The FAO/WHO Committee of Governmental Experts worked with the International Dairy Federation to implement milk quality and labeling requirements. Europe had worked out a region-wide harmonization system, the Codex Alimentarius Europaeus, based on a model developed under the Austrian-Hungarian Empire.¹³ The Codex

¹² *Codex Timeline from 1945 to the Present*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/about-codex/codex-timeline/en/> (last visited May 5, 2015).

¹³ The term "Codex Alimentarius" derives from the Codex Alimentarius Austracius, a collection of food standards developed by the former Austrian-Hungarian empire, which originated as early as 1891 and was completed in 1917. Rep. of the Joint FAO/WHO Codex Alimentarius Comm'n, 19th Sess., July 1-10,

Europeaeus was co-sponsored by the International Commission on Agricultural Industries and the International Bureau of Analytical Chemistry.¹⁴

In 1960, the Codex Alimentarius Europeaeus partnered with WHO and FAO as part of an effort to create a global set of food safety, testing, labeling and nutrition standards. During the 1961 FAO/WHO Eleventh Joint Expert Committee, the FAO passed the resolution, which led to the establishment of the Codex Alimentarius Commission as it is known today. The resolution created the FAO/WHO Food Standards Programme and designated the newly international Codex as the body responsible for implementing the Programme.

The First Session of the Codex Alimentarius Commission was held in Rome in October 1963, and was attended by an estimated 120 participants from 30 countries. Codex has seen dramatic increase in membership since; 625 delegates from 180 countries and international organizations attended the Commission's thirty-fourth session in 2011. Both independent international experts and other international organizations assist Codex in meeting its obligation to develop an extensive scientific basis for the standards it adopts.¹⁵

Codex offers three avenues of organizational participation based on a party's qualifications. First, membership is open to all countries but is contingent upon memberships in both the WHO and FAO.¹⁶ Only member countries and member organizations ("Members") approve standards and guidelines, sit on committees within the organization, and submit candidates for executive positions.¹⁷ Second, countries and organizations who either do not qualify for membership or choose not to become Members can still participate in Codex as observing parties ("Observers").¹⁸ While Observers are technically not entitled to give input at sessions, Observers customarily have been permitted to express their opinions on particular issues and policies.¹⁹ Third, intergovernmental organizations ("IGOs") and nongovernmental organizations ("NGOs") also may attain Observer status.²⁰ IGOs are required to submit an application for review by the Codex Secretariat and the legal offices of both the WHO and FAO, where additional inquiries may be required.²¹ The application process for unaffiliated NGOs is similar, though NGO applications require more detailed information.²²

1991, ALINORM 91/40 app. 2 (1991), available at <http://www.fao.org/docrep/meeting/005/t0490e/t0490E04.htm>.

¹⁴ *Codex Timeline from 1945 to the Present*, *supra* note 12.

¹⁵ See *Scientific Basis for Codex Work*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/scientific-basis/en/> (last updated Mar. 3, 2015).

¹⁶ *Codex Members and Observers*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/members-observers/en/> (last updated Mar. 3, 2015).

¹⁷ CONSUMERS INT'L, CODEX ALIMENTARIUS FOR CONSUMERS 12 (2nd ed. 2000), <http://www.consumersinternational.org/media/302887/codex%20alimentarius-%20a%20set%20of%20three%20resource%20manuals.pdf>.

¹⁸ *Codex Members and Observers*, *supra* note 16.

¹⁹ CONSUMERS INT'L, *supra* note 17.

²⁰ *Codex Members and Observers*, *supra* note 16.

²¹ *Id.* The IGO application for observer status is available online. CODEX ALIMENTARIUS COMM'N, INFORMATION REQUIRED FROM INTERNATIONAL GOVERNMENTAL ORGANIZATIONS REQUESTING "OBSERVER STATUS" (2013), available at ftp://ftp.fao.org/codex/forms/Observer_Application_Form_IGO_2013e.pdf (last visited May 5, 2015).

²² See *Principles Concerning the Participation of International Non-Governmental Organizations in the Work of the Codex Alimentarius Commission*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/members-observers/ngo-participation/en/> (last updated Mar. 3, 2015). The application for observer status for NGOs is available online. CODEX ALIMENTARIUS COMM'N, INFORMATION REQUIRED FROM INTERNATIONAL NON-GOVERNMENTAL ORGANIZATIONS REQUESTING

B. CODEX DECISION-MAKING

The top of Codex's hierarchal ladder is the Codex Alimentarius Commission ("Commission"), which represents the collective interests of the aforementioned Members and Observers. The Commission sets Codex's overall agenda and is the final decisionmaking body in all standard creation.²³ Every Member present at a particular session is entitled to one vote on all issues submitted to the Commission.²⁴ The U.S. government and its agencies play an active role throughout Codex's organizational hierarchy and frequently drive new policy.²⁵ For example, FDA participates in every Codex Subsidiary Body.²⁶ The FDA works to influence the committees to adopt standards in accordance with U.S. law, while also pressing for domestic adoption of Codex standards.²⁷

The Codex Alimentarius Commission's main authoritative organ is its Executive Committee ("Executive Committee"), which consists of seventeen members drawn from both Codex's general membership and regional representatives.²⁸ The Executive Committee manages the development of committee standards and guidelines, and develops strategic plans for implementation.²⁹ Typically, the Executive Committee combines such submissions with those of lower level subcommittees for Commission consensus or vote.³⁰ The Executive Committee may exercise the Commission's powers to appoint subcommittee officials or implement Commission approved standards.³¹ Commission votes often are conducted by secret ballot, and while Codex custom, like that of other international organizations, stresses consensus,³² it has adopted several standards through secret ballot applying majority vote (sometimes narrowly so) for such decisions.³³ The Codex Secretariat facilitates communications between members, committees, and the commission.³⁴

Beneath the Codex's executive and administrative organs sit four subsidiary bodies responsible for developing the standards to be reviewed by the Commission and Executive Committee.³⁵ These subsidiary bodies create subcommittees to develop

"OBSERVER STATUS" (2013), available at ftp://ftp.fao.org/codex/forms/Observer_Application_Form_NGO_2013e.pdf (last visited May 5, 2015).

²³ CONSUMERS INT'L, *supra* note 17.

²⁴ *Id.* at 19.

²⁵ See U.S. Codex & Codex Alimentarius, USDA, <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius> (last updated Mar. 24, 2015).

²⁶ See CVM's Participation in the Codex Committee on Residues of Veterinary Drugs in Foods and the Ad Hoc Intergovernmental Task Force on Antimicrobial Resistance, FDA, <http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cvm/whatwedo/ucm282088.htm> (last updated Aug. 25, 2014); FDA's Participation in Codex, FDA, <http://www.fda.gov/food/internationalinteragencycoordination/internationalcooperation/ucm106250.htm> (last updated Dec. 12, 2014).

²⁷ FDA's Participation in Codex, *supra* note 25.

²⁸ CODEX ALIMENTARIUS COMM'N, FAO/WHO CODEX TRAINING PACKAGE: MODULE 2.3 3, ftp://ftp.fao.org/es/esn/food/capacity_building/2_3.pdf.

²⁹ Codex Alimentarius Comm'n, Codex Alimentarius Commission: Procedural Manual 9 (12th ed. 2001), <ftp://ftp.fao.org/docrep/fao/005/Y2200E/Y2200E00.pdf>.

³⁰ *Id.* at 19-21.

³¹ *Id.* at 9.

³² The Codex has clarified that consensus does not require unanimity, but rather alludes to a standard less than unanimity but more than supermajority. See CONSUMERS INT'L, *supra* note 17, at 15.

³³ *Id.* at 11.

³⁴ See *id.* at 19-21.

³⁵ For an organization chart, see Codex Alimentarius Comm'n, Guidelines for Codex Contact Points and National Codex Committees (Asia) 8, CAC GL/57-1999 (1999), available at www.codexalimentarius.org/input/download/standards/.../cxg_057Re.pdf.

standards for specific issues.³⁶ Each subcommittee is headed by a host country, which is responsible for subcommittee maintenance and administrative functions.³⁷ Host countries are also required to shoulder a considerable amount of the costs of subcommittee operations. Cost requirements restrict hosting privileges to developed countries and the ability to host gives that country a heavy hand in setting the agenda with WHO and FAO.³⁸

The first subsidiary body contains Codex's General Subject Committees.³⁹ Currently, the General Subject Committees consist of ten subcommittees that develop generally applicable principles.⁴⁰ The General Subcommittees are commonly called "horizontal committees" because their work applies broadly to all foods.⁴¹ As the chief subsidiary body, the General Subcommittees assist the Executive Committee in reviewing and endorsing standards derived from other committees and subcommittees. Horizontal committees focus on health and safety recommendations such as food hygiene, additives or contaminants, labeling, and inspection systems. The General Subcommittees develop such standards and recommendations based on the advice of expert scientific bodies.⁴²

The Commission's second grouping of subsidiary bodies are called Commodity Committees and are responsible for the largest number of specific standards.⁴³ The Commodity Committees are also known as "vertical committees" because, unlike the General Subcommittees, the Commodity Committees are restricted in focus and responsibilities. These committees research and develop proposals for standards in non-individualized food products such as fats and oils, milk and milk products, processed fruits and vegetables, and sugars. Commodity Committees are created as needed to address particular issues in such food categories. The Commodity Committees have integrated NGOs into standard development.⁴⁴ Frequently, NGOs combine to shoulder the workload of certain Commodity Committees, which occasionally leads the NGO groupings to become subcommittees themselves.

Codex has also developed a process by which "Ad Hoc Task Forces" may be formed for specific purposes and a limited time.⁴⁵ An Ad Hoc Task Force's scope is narrower than that of a Commodity Committee; Ad Hoc Task Forces are assembled to create guidelines for one or more specific issues within a subgroup of a food category already covered by general or commodity committees.⁴⁶ Ad Hoc Task Forces originated in 1999 when the Commission realized that its rigid committee structure was incapable of the flexibility required to meet the volatile and ever-increasing demands for additional standards.⁴⁷

³⁶ See CODEX ALIMENTARIUS COMM'N, UNDERSTANDING THE CODEX ALIMENTARIUS 16-19 (3d ed. 2006), ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf.

³⁷ *Id.* at 16-17.

³⁸ See *id.* at 19.

³⁹ *Id.* at 17-18.

⁴⁰ Food & Agric. Org. of the U.N. [FAO], *Lesson 2.1 – How Codex is Organized: The General Subject Committees*, IMARK GROUP, <http://www.imarkgroup.org/projects/course/moduleX/EN/downloadresource.asp?filelocation=pdf/GeneralSubjectCommittees.pdf> (last visited May 5, 2015).

⁴¹ CODEX ALIMENTARIUS COMM'N, *supra* note 36, at 17.

⁴² See *id.* at 22-24. Expert scientific bodies include: Joint FAO/WHO Expert Committee on Food Additives (JECFA); Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA); Joint FAO/WHO Meetings on Pesticide Residues (JMPR). *Id.* at 23; see also FAO, *supra* note 50.

⁴³ CODEX ALIMENTARIUS COMM'N, *supra* note 36, at 18.

⁴⁴ *Id.* at 9.

⁴⁵ *Id.* at 18.

⁴⁶ See *id.* Previously assembled Ad Hoc Task Forces include: Task Force on Animal Feeding (1999-2004) and Task Force on Fruits and Vegetable Juices (1999-2005). *Id.* at 19.

⁴⁷ *Id.* at 18.

C. THE COMMISSION'S PROCEDURES

The Codex meetings are listed as open to the public on condition that anyone aspiring to be invited provide written notice to the Codex Secretariat at least one month prior to the particular meeting.⁴⁸ However, such public invitations are subject to spacing availability.⁴⁹ Frequently, heads of relevant industries attend and contribute to Codex sessions consultatively.

Codex standard creation and adoption follows a common pattern throughout all organizational levels. First, the Executive Committee reviews and prioritizes all proposals, which may be submitted by any Member party. The Executive Committee may even consider proposals from Observers or other parties.⁵⁰ If a proposal is prioritized for further review, the Executive Committee submits a proposal draft to all Member countries for comment.⁵¹ Next, Subsidiary Bodies and subcommittees relevant to the particular issue review the revised draft to ensure compliance with Codex standards.⁵² The Codex Commission, either by consensus or vote, determines whether the draft standards should be submitted for finalization. The draft then enters a final comment period, after which the Commission adopts the standards and the Secretariat publishes them.⁵³ Standards sometimes may be adopted and published before the second round of Member comments if a two-thirds majority was shown during the first comment round.⁵⁴

III. STRUCTURAL DEFICIENCIES IN THE CODEX DECISION-MAKING PROCESS

A. BALANCING CODEX'S TRADE AND HEALTH MISSIONS

Technically, Codex standards are neither binding nor self-executing even among its member countries.⁵⁵ Each government is free to develop its own food health and safety standards framework.⁵⁶ Practically, Codex guidelines are more influential.⁵⁷ Codex has been designated the official standard reference body for the WTO when food safety or labeling measures are challenged as burdening free trade, according to its Sanitary and Phytosanitary (SPS) Agreement.⁵⁸ It plays a similar, although not dominant, role for the Technical Barriers to Trade (TBT) Agreement. All countries who agreed to the creation of the WTO in 1994 may be bound by WTO panel decisions regarding SPS and TBT issues;⁵⁹ therefore, these countries may be

⁴⁸ *Codex Members and Observers*, *supra* note 16.

⁴⁹ *Id.* Codex's documented Members, Observers, and invitees currently account for over 600 delegates. CODEX ALIMENTARIUS COMM'N, *supra* note 36, at 15.

⁵⁰ CONSUMERS INT'L, *supra* note 17, at 16.

⁵¹ CODEX ALIMENTARIUS COMM'N, *supra* note 36, at 15.

⁵² *Id.* at 15-16.

⁵³ *Id.* at 16.

⁵⁴ See CONSUMERS INT'L, *supra* note 17, at 16.

⁵⁵ *FAQs – General Questions*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/faqs/general-questions/en/> (last visited May 5, 2015).

⁵⁶ *Id.*

⁵⁷ See *Codex Timeline from 1945 to the Present*, *supra* note 12.

⁵⁸ The WTO's SPS Agreement was established in 1995 to regulate food, plant, and animal safety and health regulations. *Id.* The adjudicatory arm ("Panels") of the WTO resolves trade disputes regarding such issues, and can impose or permit trade-based punitive measures for violations of the SPS Agreement. See *Understanding the WTO Agreement on Sanitary and Phytosanitary Measures*, WTO, http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm (last visited Mar. 16, 2015).

⁵⁹ See Michael A. Livermore, *Authority and Legitimacy in Global Governance: Deliberation, Institutional Differentiation, and the Codex Alimentarius*, 81 N.Y.U. L. REV. 766, 768 (2006).

constrained by Codex standards.⁶⁰ If a Member country wishes to impose SPS-related standards more stringent than Codex's standards, the country must provide an adequate scientific basis for taking such actions.⁶¹

Criticism aimed at Codex activities after 1994 has frequently if not uniformly referred to the special role afforded it under the World Trade Organization's free trade regime.⁶² Emily Lee, for example, argued that the "linkage between Codex standards and the WTO has diverted the focus of the Commission from health to trade considerations."⁶³ Elizabeth Smythe added that "[a]s a result of its changing role, Codex rule-making processes have become more politicized . . . reflected in . . . the increased involvement of national trade officials pursuing their interests, and the increased attention and involvement of other organizations."⁶⁴ Ching-Fu Lin echoes the sentiment, asserting that "[a]ll of [Codex's] problems have rendered Codex unbalanced between public health and fair food trade practices . . ."⁶⁵

But from Codex's origin—when a number of regional standard-setting organizations threatened to disrupt global trade in food—to the present day, the organization's mission has always been trade-oriented.⁶⁶ In 1973, L.M. Beacham, the Assistant to the Director of the FDA for International Standards wrote of Codex's mission that it was to create "a collection of internationally adopted food standards that harmonize the legal requirements of the participating countries, thereby facilitating international trade and affording consumers sound, wholesome products, informatively labeled in a uniform manner."⁶⁷ In their brief history of Codex, Franz Vojir, Erwin Schubl and Ibrahim Elmadfa wrote that "the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) of the United Nations were intent on impeding . . . regional activities [in rules for the testing of food samples] to prevent

⁶⁰ *Id.* at 768-69. The WTO's near codification of Codex Alimentarius standards regarding sanitary and phytosanitary measures likely casts Codex's SPS-related actions as the organization's most significant activity. See A.W. Randell & A.J. Whitehead, *Codex Alimentarius: Food Quality and Safety Standards for International Trade*, 16 REVUE SCIENTIFIQUE ET TECHNIQUE DE L'OFFICE INTERNATIONAL DES ÉPIZOOTIES 313, 316-17 (1997).

⁶¹ The SPS Agreement instructs its Members "to base their sanitary or phytosanitary measures on international standards" (Article 3.1.) and presumes those international standards to "be consistent with the relevant portions of this Agreement and of GATT [General Agreement on Tariffs and Trade] 1994" (Article 3.2). *The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*, WTO, https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm (last visited May 5, 2015); see also David A. Wirth, *The Transatlantic GMO Dispute Against the European Communities: Some Preliminary Thoughts*, in EU AND WTO LAW: HOW TIGHT IS THE LEGAL STRAIGHTJACKET FOR ENVIRONMENTAL PRODUCT REGULATION? 175, 183 (Marc Pallemarts ed., 2006).

⁶² See Jennifer Clapp & Doris Fuchs, *Agrifood Corporations, Global Governance, and Sustainability: A Framework for Analysis*, in CORPORATE POWER IN GLOBAL AGRIFOOD GOVERNANCE 1, 14 (Jennifer Clapp & Doris Fuchs eds., 2009).

⁶³ Emily Lee, *The World Health Organization's Global Strategy on Diet, Physical Activity, and Health: Turning Strategy into Action*, 60 FOOD & DRUG L.J. 569, 595 (2005).

⁶⁴ 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, 96 (Jennifer Clapp & Doris Fuchs eds., 2009).

⁶⁵ Ching-Fu Lin, *Public-Private Interactions in Global Food Safety Governance*, 69 FOOD & DRUG L.J. 143, 146 (2014); see also Doris Fuchs et al., *Retail Power, Private Standards, and Sustainability in the Global Food System*, in CORPORATE POWER IN GLOBAL AGRIFOOD GOVERNANCE 30, 37 (Jennifer Clapp & Doris Fuchs eds., 2009).

⁶⁶ See *The Codex Alimentarius Commission: Looking Ahead to Its Future Scope*, 3 WORLD FOOD REG. REV. 16, 16 (1993) ("[Codex's] purpose is to guide and promote the elaboration and establishment of definitions and requirements for food, to assist in their harmonisation and, in doing so, facilitate international trade."), available at <http://legacy.library.ucsf.edu/tid/moo24a99/pdf>.

⁶⁷ L.M. Beacham, *Ten Years of Codex Alimentarius—A Progress Report*, FOREIGN AGRIC. 10, 10 (1973), available at <http://legacy.library.ucsf.edu/tid/odj92a99/pdf>.

trade barriers at a global level.”⁶⁸ Some of Codex’s closest majority votes have favored trade-facilitation over health concerns, even those expressed by wealthy, influential members.⁶⁹

To be fair to critics, Codex and its participants have done little to diminish the appearance of imbalance toward trade or industry influence. Codex’s structure has always leaned in favor of not only trade, but also countries with substantial interests in a given food or subject area, which Codex gives privileged status within the standard-setting process. Norway, for example, has always hosted standard-setting for fish and fishery products; China hosts the food additives and pesticide residues committees; and Switzerland hosts the now-adjoined committees on natural mineral waters and cocoa or chocolate products.⁷⁰ In each of these cases, the host country is either a leading exporter of the regulated commodity or chemical or home to major global firms.

1. Advancing Public Health through Codex Processes

But Codex has also incorporated international health agreements and evidence generated by the strong research capacities of WHO and FAO. Codex standards on infant formula, for example, not only tightly regulate the components of formula (e.g., vitamins, minerals, and essential nutrients) but also incorporate key aspects of the 1981 World Health Organization’s International Code on the Marketing of Breastmilk Substitutes. This is to enable regulatory authorities to require manufacturers to include labels stating the superiority of breastfeeding for infants, prohibiting pictures of infants or women that idealize formula use, and advising consumers that they should use formula only on the advice of an independent health worker, without falling afoul of the SPS Agreement. These measures may be subject to challenge, however, under another WTO agreement like TBT or TRIPS.⁷¹ To be sure, that standard and standards that followed gave regulators and firms ways to circumvent the full protections of the 1981 Code. But the inclusion of these key health measures in Codex standards belies the claim that Codex cannot be used to advance the cause of global or population health or give flexibility to governments that wish to do so. Similarly, Codex standards, when read together, provide significant flexibility for governments to protect consumers’ health.⁷²

2. FDA’s Role in Endorsing Advances in Nutrition Science

FDA is therefore well positioned to influence standard-setting in light of advances in nutrition science as assessed by both FDA and WHO. One of the ways in which consumers are consistently misled about their calorie and nutrient intake is by labels that depict nutritional information *per serving* even for food packages or bottled

⁶⁸ Franz Vojir et al., *The Origins of a Global Standard for Food Quality and Safety: Codex Alimentarius Austriacus and FAO/WHO Codex Alimentarius*, 82 INT’L. J. VITAMIN & NUTRITION RES. 223, 223 (2012).

⁶⁹ See *International Harmonization of Food Safety and Labeling Standards: Threats and Opportunities for the U.S. Food and Drug Administration and the U.S. Department of Agriculture*, CTR. FOR SCI. PUB. INTEREST (June 1997), <http://www.cspinet.org/reports/codex.htm>.

⁷⁰ See LINHAI WU & DIAN ZHU, FOOD SAFETY IN CHINA: A COMPREHENSIVE REVIEW 239 (2015); *List of Active Codex Committees*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/committees-and-task-forces/en/> (last updated Mar. 3, 2015).

⁷¹ CODEX STANDARD 72-1981 § 9.6 (Codex Alimentarius Comm’n 2011).

⁷² See F. Edward Scarbrough, *Codex—What’s All the Fuss?*, 65 FOOD & DRUG L.J. 631, 631-33 (2010).

beverages that are commonly consumed in a single sitting.⁷³ Codex standards largely accommodate this labeling method, and an effective way to use the Codex process to advance global health is to eliminate the option for manufacturers to provide nutritional information in unrealistic ways.

Codex has a mixed record with respect to allowing advances in global population health analysis to inform its standard setting process. The aforementioned Codex standards on infant formula, for example, are relatively progressive but Codex has largely ignored the relationship between food labeling and agricultural policies on diet and health.⁷⁴ The WHO Global Strategy on Diet, Physical Activity, and Health calls on Codex to undertake processes that ensure better labeling to allow more effective information about the benefits and contents of foods; measures to minimize the impact of marketing on unhealthy dietary patterns; and production and processing standards regarding the nutritional quality and safety of products.⁷⁵ WHO recommendations track to a significant extent similar conclusions reached by FDA along with other federal agencies on advice about consuming fewer calories and making informed food choices to attain and maintain a healthy weight, reduce risk of chronic disease, and promote overall health.⁷⁶ These calls have been more or less ignored, so that current Codex standards may be and are effectively used to hide consumption risks.⁷⁷ As an example, Codex standards now require the listing of ingredients in descending order according to proportion, but do not effectively limit the re-characterization or overlap of ingredients so that salts and sugars may comprise a much larger portion of a labeled food than a descending order of ingredients would lead a consumer to believe.⁷⁸ Similarly, Codex standards for “natural flavouring substances” leave substantial flexibility to manufacturers to process any “natural material of animal or vegetable origin” through drying, torrefaction, fermentation, microbiological or enzymatic process and other methods even when those processes result in changes in the chemical structure of the flavouring.⁷⁹

B. INDUSTRY REPRESENTATION AS A PROXY FOR INDUSTRY INFLUENCE

FDA’s credibility when asserting the desirability of Codex standards will be jeopardized as long as Codex’s processes for adopting standards appear compromised. To be clear, Codex critics are often vague as to how industry influence (and whether it is beneficial or not) is to be measured. There is wide consensus in the literature on Codex that its processes are subject to industry capture, but the primary means of proving the claim are anecdotal or derived through reference to relative participation by firms or industrial groups. An oft-quoted 1993 study conducted by the National Food Alliance found that “over eighty percent of the nongovernmental participants on national delegations to recent Codex committees represented industry, while only one

⁷³ See *Proposed Changes to the Nutrition Facts Label*, FDA, <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm385663.htm#Summary> (last updated Aug. 1, 2014).

⁷⁴ See Lee, *supra* note 63, at 577-78.

⁷⁵ *Id.* at 578-79.

⁷⁶ *Dietary Guidelines for Americans*, USDA, <http://www.cnpp.usda.gov/DietaryGuidelines> (last visited May 5, 2015).

⁷⁷ See Lee, *supra* note 63, at 580.

⁷⁸ CODEX STANDARD 1-1985 § 4.2.1.3 (Codex Alimentarius Comm’n 2010).

⁷⁹ Codex Alimentarius Comm’n, *Guidelines for the Use of Flavourings*, CAC/GL66-2008 (2008), available at www.codexalimentarius.org/input/download/standards/.../cxg_066e.pdf.

percent represented public interest organizations.”⁸⁰ Elizabeth Smythe notes that the Codex Committee on Food labeling has shown similar industry influence with 35 of 50 international non-governmental organizations in attendance at the 2000 meeting representing industry and about 75% of observers in 2006 and 2007.⁸¹ Industry representatives similarly enjoy greater participatory roles as part of national delegations.⁸²

It is a fair inference that greater participation of both observers and national delegates translates into greater influence,⁸³ but it is not always clear that influence as part of one or more delegations or as observers will move the needle on the standards as they move through the process. New Zealand’s National Organisations for Fruit and Vegetable Growers and Grocery Marketers Association might both attend or participate in New Zealand’s Codex processes, but advocate opposing positions for their government.⁸⁴

Codex standards as adopted by FDA will not only gain legitimacy in consumers’ eyes but also better reflect the high scientific standards Codex promises if FDA adopts two principal review mechanisms for Codex standards. First, FDA should apply its own internal conflict of interest policies to its review of Codex standards with the same rigor as it applies to outside scientific advice on its current portfolio of consumer products. Because FDA is a participant in Codex standard setting, there is an implicit assumption that FDA has undertaken a full analysis of potential conflicts at the international level. FSMA’s regime of reviewing conflicts of interest for third-party verification entities for food imports⁸⁵ counsels in favor of stricter review of the scientific assessments that inform Codex work. Second, FDA should make the selection of non-governmental Codex representatives in the U.S. national delegation more transparent. While both steps would require FDA taking a larger leadership role within the U.S. Codex Office (now housed at USDA), there is no formal legal hindrance to these steps by FDA that FSMA implicitly authorizes or encouraged.

1. Breaches in Codex’s Scientific Assessment Integrity

The most alarming episodes of industry influence at Codex have not occurred through routine member or observer participation at the subcommittee level in the Codex process but at WHO/FAO joint scientific committees, ostensibly neutral and highly-qualified scientific bodies whose conclusions are given substantial weight in the standard setting process. In 1990, an international tobacco research arm, Centre de Coopération pour les Recherches Scientifiques Relatives au Tabac (CORESTA), hired a former WHO toxicologist and former technical secretary of the Joint Food and

⁸⁰ Lucinda Sikes, *FDA’s Consideration of Codex Alimentarius Standards in Light of International Trade Agreements*, 53 FOOD & DRUG L.J. 327, 330 (1998) (citing NATALIE AVERY ET. AL., CRACKING THE CODEX: AN ANALYSIS OF WHO SETS WORLD FOOD STANDARDS 1 (1993)).

⁸¹ Smythe, *supra* note 64, at 98.

⁸² *Id.*

⁸³ OTHO D. EASTERDAY & JULIA C. HOWELL, REPORT OF THE INTERNATIONAL FOOD LAWS COMMITTEE 1 (1989), available at <http://legacy.library.ucsf.edu/tid/rrh14d00/pdf> (“The activities of the ad hoc FEMA [Flavor and Extract Manufacturers Association]/FDA/USDA group that developed a system for prioritization of flavorings was of particular interest to the committee members. . . JECFA has commenced using the system by selecting high priority compounds from the list of prioritized flavorings. One substance, quinine hydrochloride, is being evaluated by JECFA in June 1989.”).

⁸⁴ See FOOD STANDARDS AUSTRALIA, N.Z., DRAFT ASSESSMENT REPORT: PROPOSAL P237: COUNTRY OF ORIGIN LABELLING [sic] OF FOOD 18-33 (2004).

⁸⁵ See, e.g., Accreditation of Third-Party Auditors/Certification Bodies to Conduct Food Safety Audits and to Issue Certifications, 78 Fed. Reg. 45,782 (proposed July 29, 2013) (to be codified at 21 C.F.R. pts. 1, 16).

Agriculture Organization/WHO Meeting on Pesticide Residues (JMPR), Gaston Vettorazzi, to influence the international standard for ethylene thiourea (ETU). ETU is a breakdown product for a tobacco pesticide known to cause cancer.⁸⁶ The JMPR is an international meeting of scientists whose decisions often formed the basis of Codex standards and the consultant effectively raised the ADI level from 0.002 to 0.004 mg/kg body weight.⁸⁷ Vettorazzi exercised his influence through the benign-sounding (Codex qualified International Non-Governmental Organization) International Toxicology Information Centre (ITIC) which was financed through “sale of its various scientific outputs” and by “Vettorazzi Associates”, the entity through which CORESTA hired Vettorazzi for \$100,000 per year.⁸⁸ In internal promotional literature, ITIC touted its “counseling on matters related to the Codex Alimentarius, particularly the Codex Committee on Food Additives and Contaminants (CCFAC), the Codex Committee on Pesticide Residues (CCPR) and the Codex Committee on Veterinary Drugs Residues.”⁸⁹ In one promotional newsletter, it stated:

The development of a new ITIC International Safety Review is a process that requires a close interaction between the ITIC and the party interested in the safety of a specific chemical. It is this mutual collaboration that makes this program a novel and unique project. The results are objective, functional, tailored-to-the-need, scientific and credible safety reviews on commercially viable products.⁹⁰

In other words, ITIC’s scientific assessments and its connection to members of key WHO bodies were up for sale. Safety evaluations from ITIC included not only ETU, but zineb (registrations canceled in U.S. following EPA special review), maneb and ziram (linked to increased risk of Parkinson’s)⁹¹ and Allura Red AC (Red #40).⁹²

2. Opaque Relationships between Codex and Industry Coalitions

The International Life Sciences Institute (ILSI) is an industry coalition organization that funds research in “pathology, toxicology, and nutrition,” but the organization’s Board of Members consists of one representative from each member company, most of which are global firms with a significant footprint in agrifood, food additive, and food chemical markets like Cargill, Monsanto, Mars, Coca-Cola, Nestlé, PepsiCo, and Unilever.⁹³ Remarking on ILSI’s mission in the face of increasing food regulation in the late 1980s, Alex Malaspina from Coca-Cola declared that “ILSI is prepared to meet [new] challenges by continuing to generate scientific data to resolve

⁸⁶ Patricia A. McDaniel et al., Commentary, *The Tobacco Industry and Pesticide Regulations: Case Studies from Tobacco Industry Archives*, 113 ENVTL. HEALTH PERSPECTIVES 1659, 1661 (2005).

⁸⁷ *Id.*

⁸⁸ Consultancy Agreement Between Vettorazzi Associates and CORESTA (Sept. 30, 1993), available at <http://legacy.library.ucsf.edu/tid/cwb24e00>.

⁸⁹ VETTORAZZI ASSOCS., PAMPHLET, <http://legacy.library.ucsf.edu/tid/zhq25c00/pdf> (pamphlet describing Vettorazzi Associates operating principles, services, and credentials of Director Gaston Vettorazzi); see also *The ITIC in [sic] now an NGO*, ITIC NEWSLETTER (Int’l Toxicology Information Ctr., San Sebastian, Spain) Dec. 1992, at 1, available at <http://legacy.library.ucsf.edu/tid/suo24a99>.

⁹⁰ *Id.* at 4.

⁹¹ Anthony Wang et al., *Parkinson’s Disease Risk from Ambient Exposure to Pesticides*, 26 EUR. J. EPIDEMIOLOGY 547, 552 (2011).

⁹² Gaston Vettorazzi et al., *International Safety Assessment of Pesticides: Dithiocarbamate Pesticides, ETU, and PTU—A Review and Update*, 15 TERATOGENESIS CARCINOGENESIS & MUTAGENESIS 313, 313 (1995).

⁹³ Board of Directors, INT’L LIFE SCI. INST., <http://www.ilsilife.org/Europe/Pages/Board-of-Directors.aspx> (last visited May 5, 2015); *Leadership and Supporting Companies*, INT’L LIFE SCI. INST., <http://www.ilsilife.org/Pages/Leadership.aspx> (last visited May 5, 2015).

pending issues, providing relevant scientific data to state agencies, and working to harmonize food regulations and facilitate international trade.”⁹⁴ ILSI enjoys a close relationship with regulatory bodies including the Joint WHO/FAO Expert Committee on Food Additives⁹⁵ and the European Food Safety Authority,⁹⁶ which rely on the substantial resources controlled by the ILSI.

The organization not only influences Codex standards through direct cooperation with national and international regulators, but also indirectly through the networks it develops. Between 1987 and 1989, for example, Dr. John Kirschman served as a member of ILSI representing RJR Nabisco; one of the “Tobacco” staffers of RJR Nabisco’s Corporate Center for Excellence in Toxicology (established to coordinate toxicology activities across at least two affiliate business lines); and as a member of the U.S. national delegation alongside representatives from the Department of Commerce, FDA, and USDA.⁹⁷ Wearing all three hats, Kirschman reported to RJR Nabisco’s corporate toxicologist about Codex priorities, computerization of WHO and FAO operations, other members of the U.S. delegation, and country-specific developments that affected RJR Nabisco business and research priorities.⁹⁸

3. FDA’s Role in Advancing Transparency Domestically and at Codex

It is not that Codex does not solicit information on potential conflicts of interest from scientists or experts, it is that it does not appear to have processes in place to ensure candor and, even when it receives relevant information, does not elaborate on its reasons for finding a conflict or not. For example, from its 69th Report on the Joint WHO/FAO Committee on Food Additives,

The Secretariat informed the Committee that all experts participating in the present sixty-ninth meeting had completed declaration-of-interest forms and that no conflicts had been identified. The following declared interests and potential conflicts were discussed by the Committee. Professor Andrew Renwick consulted for the International Sweeteners Association and hence did not participate in the discussions on steviol glycosides. The employer of Dr [sic] Ian Munro receives part of its revenues from consulting on the safety assessment of food additives. The company, but not Dr [sic] Munro himself, prepared submissions regarding the assessments of steviol glycosides. Dr [sic] Paul Kuznesof consulted for Tate & Lyle to gather publicly available information on steviol glycosides, but this activity was not regarded as a conflict of interest. Professor Ron Walker consulted for one of the producing

⁹⁴ Minutes of the Joint Meeting of the ILSI and ILSI-NF Boards of Members 1 (Jan. 21, 1989), available at <http://legacy.library.ucsf.edu/tid/pyu56a00/pdf>.

⁹⁵ Robert Verkerk, *The International Food Code of Codex Alimentarius*, ETHICAL CONSUMER, <http://www.ethicalconsumer.org/commentanalysis/factsvgreenwash/codexalimentarius.aspx> (last visited May 5, 2015).

⁹⁶ See generally EUR. FOOD SAFETY AUTH., EFSA MEETING SUMMARY REPORT: EFSA/WHO INTERNATIONAL CONFERENCE WITH SUPPORT OF ILSI EUROPE ON RISK ASSESSMENT OF COMPOUNDS THAT ARE BOTH GENOTOXIC AND CYTOTOXIC (2006), available at <http://www.efsa.europa.eu/en/home/publication/efsawho2006.pdf>.

⁹⁷ See RJR Interoffice Memorandum from John C. Kirschman to A. Wallace Hayes (July 31, 1987), available at <http://legacy.library.ucsf.edu/tid/pct75a00/pdf>.

⁹⁸ See RJR NABISCO, INC., CORPORATE CENTER OF EXCELLENCE IN TOXICOLOGY, <http://legacy.library.ucsf.edu/tid/hmp15d00/pdf?search=%22kirschman%20excellence%20research%22>.

companies on calcium lignosulfonate and hence did not participate in the discussion.⁹⁹

The selection of members for the U.S. delegation to Codex is similarly opaque. For example, the USDA Food Safety Information Service noted that for the 36th Session of the Codex Alimentarius Commission in 2013 “[t]he United States was represented by Delegate Mary Frances Lowe, U.S. Manager for Codex, eight governmental advisors, three non-governmental advisors, and two former chairs of the CAC.”¹⁰⁰

Under current federal regulations, FDA largely relies on interested persons and domestic constituencies to guide the Codex standard adoption and implementation process.¹⁰¹ While the FDA Commissioner has broad authority to introduce Codex standards, including deviations, the Commissioner’s decision to do so does not explicitly require an independent assessment of potential conflicts of interest on relevant WHO/FAO committees informing relevant health measures like pesticide residues and acceptable daily intakes of food additives or their elements. In fact, the regulations strongly hint that it will be inclined to adopt standards that garner sufficient domestic consensus, whether or not that consensus includes consumer advocacy or public health opinion.¹⁰² Similarly, while the U.S. Codex Office is technically within the USDA’s Food Safety and Inspection Service, FDA’s broad consumer protection mandate and specific authorization with respect to Codex give it authority to make participation in U.S. delegations more transparent.

C. CODEX AND THE WELFARE OF DEVELOPING COUNTRIES

The relationship between Codex and the welfare of developing countries has emerged as one of its most contested roles. Codex is managed and funded by wealthy countries that have a significant interest in what it declares to be international standards that both protect consumers and facilitate trade. Whether intentionally or not, the standards promoted by these countries necessarily impose resource barriers to low- and middle-income countries and even participation in Codex processes can be cost prohibitive. In 2003, former Director-Generals of both the WHO and FAO launched the Codex Trust Fund (“Trust Fund” or “Fund”) to assist developing nations join and participate in Codex processes.¹⁰³ The Trust Fund sought \$40 million over a period of 12 years to assist the transition required by developing nations to meet the organization’s food safety, quality, and fairness standards.¹⁰⁴ By the end of 2013, only \$18.77 million was donated from 15 countries.¹⁰⁵ Trust Fund donation information is open to the public, and the Fund is audited internally and externally per WHO regulations.¹⁰⁶

⁹⁹ Sixty-Ninth Meeting of the Joint FAO/WHO Expert Committee on Food Additives, Rome, Italy, June 17-26, 2008, *Evaluation of Certain Food Additives*, at 1, WHO TECHNICAL REP. SERIES NO. 952 (2009).

¹⁰⁰ *36th Session of the Codex Alimentarius Commission*, USDA, <http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/recent-delegation-reports/delegate-report-36th-session-cac> (last updated Sept. 4, 2013).

¹⁰¹ Review of Codex Alimentarius Food Standards, 21 CFR § 130.6(c) (2012).

¹⁰² *See id.*

¹⁰³ *Codex Alimentarius: FAO/WHO Trust Fund for Participation in Codex*, CODEX ALIMENTARIUS, <http://www.codexalimentarius.org/faowho-trust-fund/en/> (last updated Mar. 3, 2015). Dr. Gro Harlem Brundtland (WHO) and Dr. Jacques Diouf (FAO) launched the fund during the 25th session of Codex. *Id.*

¹⁰⁴ *Id.*

¹⁰⁵ *Codex Trust Fund: Donor Contributions*, WHO, http://www.who.int/foodsafety/areas_work/food-standard/codextrustfund/en/index1.html (last visited May 5, 2015). The list of donating countries and

Codex's standards, especially good manufacturing processes, inspection, import and export control, and other aspects of its mission are expensive to implement and poor countries often lack the resources to comply or participate.¹⁰⁷ These decisions may indeed reflect trade-restrictive efforts by wealthy but resource disadvantaged countries. Certain kinds of infestations for the same crop may require lighter or heavier applications of insecticides, pesticides or rodenticides resulting in climactically favored nations to urge lower thresholds for pesticide tolerance and less favored nations to urge higher levels with objective scientific evidence unable to resolve disagreements definitively.¹⁰⁸ But even when trade-restrictiveness and consumer health do not hang so starkly in the balance, it is often not Codex standards that stand in the way of greater low- or middle-income countries' exports to Europe and North America, but regulatory and private-sector measures that exceed what Codex recommends.¹⁰⁹ Indeed, as Ching-Fu Lin has effectively described, the greatest threat to developing countries may not be Codex standards but the more stringent, privately driven standards put in place between large retailers in North America and Europe and preferred growers and manufacturers in developing countries.¹¹⁰

With respect to Codex's role as an agent charged, at least nominally, with the redistribution of global wealth (i.e., its standards should accommodate the aspirations of developing countries with strong agricultural sectors that might lift themselves out of poverty with agricultural exports), it is not obvious that FDA has much, if any, of a role to play. As a threshold matter, FDA's domestic mandate counsels against any accommodation of international food safety standards purely for sake of global poverty alleviation.¹¹¹ Yet FDA's current stated strategies for its global offices are articulated largely in terms of compliance at facilities whose products are destined for the U.S. market.¹¹² FDA employees in the India Office, for example, focus on inspections of products destined for the United States, and coordinate with the U.S. Department of Agriculture and the Foreign Agricultural Services to more easily inspect manufacturing and processing facilities in India that are producing goods destined for the United States.¹¹³ While the FDA's International Food Safety Capacity Building Plan emphasizes bilateral partnerships with Codex, it focuses its efforts with respect to its international offices on exchanges of information, providing information technologies, and establishing criteria for mutual recognition.¹¹⁴ Its specific objective with respect to Codex is to provide training on food safety and best practices.

organizations were as follows: Australia, Canada, European Commission, Finland, France, Germany, India, Ireland, Japan, Malaysia, Netherlands, New Zealand, Norway, Sweden, Switzerland, and the United States. *Id.* India and Malaysia have transitioned to become donor countries. *Id.*

¹⁰⁶ See *Codex Trust Fund: Background*, WHO, http://www.who.int/foodsafety/areas_work/food-standard/codextrustfund/en/ (last visited May 5, 2015).

¹⁰⁷ Gumisai Mutume, *New Barriers Hinder African Trade*, AFR. RENEWAL, <http://www.un.org/africarenewal/magazine/january-2006/new-barriers-hinder-african-trade> (last visited May 5, 2015).

¹⁰⁸ Beacham, *supra* note 67, at 11.

¹⁰⁹ Mutume, *supra* note 107 ("The EU, however, frequently chooses to ignore Codex recommendations and is often much stricter" (internal quotation marks omitted)).

¹¹⁰ Ching-Fu Lin, *Global Food Safety: Exploring Key Elements for an International Regulatory Strategy*, 51 VA. J. INT'L L. 637, 661-62 (2011).

¹¹¹ Cf. Margaret A. Hamburg, *Improving the World Through Improved Food Safety*, FDA VOICE (Dec. 13, 2012), <http://blogs.fda.gov/fdavoices/index.php/2012/12/improving-the-world-through-improved-food-safety/> ("Serendipitously, our self-interest coincides with a humanitarian imperative." (emphasis added)).

¹¹² See *FDA's International Posts: Improving the Safety of Imported Food and Medical Products*, FDA, <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm185769.htm> (last updated Apr. 29, 2015).

¹¹³ *Id.*

¹¹⁴ See FDA, *supra* note 2, at 21.

Conversations with foreign counterparts at FDA overseas offices are therefore aimed at facilitating inspections, exchanging information both informally and through formally negotiated agreements, and minimizing friction arising from regulatory incongruities.¹¹⁵

But the increase in overseas presence and the inevitable role of developing and low-income countries in the U.S. food supply provides FDA an opportunity to collaborate on Codex standards with greater frequency and depth than before FSMA. Although Section 305 of FSMA requires consultation with U.S. agencies that do not share FDA's robust consumer protection mandate, the provisions with respect to Codex are embedded within a broader statutory requirement to "develop a comprehensive plan to expand the technical, scientific, and regulatory food safety capacity of foreign governments, and their respective food industries".¹¹⁶ FDA is therefore urged to examine Codex standards within the context of its foreign partnerships, which are now limited to about 20 countries.¹¹⁷ Investing in its foreign offices as collaborative points in the Codex standard setting process is valuable not only to FDA's and Codex's credibility but also to FDA's role as regulatory measures are increasingly scrutinized under international trade and investment rules. FDA, in the near future, will need to prepare an institutional infrastructure for dealing with WTO or other international judicial bodies that reject or order the modification of the regulations it adopts. Working ahead of finalized Codex rules will help minimize investment or trade-based challenges. Indeed, certain provisions of the 2009 Family Smoking Prevention and Tobacco Control Act related to flavorings added to cigarettes were recently dealt a blow by the WTO, and even though that ruling was specific to a statutory mandate, Indonesia's challenge would have been equally applicable to an FDA finding as to mentholated cigarettes.¹¹⁸ As the next set of trade agreements are finalized—many of which deal with liberalized trade in agricultural goods—FDA will need to take an active approach to Codex's work as its regulatory options may be constrained by challenges based on Codex standards.

IV. CONCLUSION

This article has advocated that FDA use its new powers under FSMA to inform its Codex work, urging food labeling standards to offer flexibility for advances in nutrition and behavioral science, bringing greater transparency, and working with partners through its overseas offices to anticipate Codex's role as trade in agricultural goods and foodstuffs liberalizes. In a more general sense, FSMA will allow FDA to grapple actively with the changes facilitated by international trade and investment agreements that will inevitably constrain and shape its regulatory role. Because FSMA envisions FDA as a truly global consumer protection agency, adopting measures to better advance public health science; shedding light on international regulatory processes; and working to forge ground-level relationships will not only advance its traditional domestic mission, but lead to stronger and better regulation in a globalized, interdependent food system.

¹¹⁵ See FDA, *supra* note 112.

¹¹⁶ FDA Food Safety Modernization Act, Pub. L. No 111-353, § 305(a), 124 Stat. 3885, 3958 (2011).

¹¹⁷ See FDA, *supra* note 2, at 21.

¹¹⁸ Dispute Settlement, *United States—Measures Affecting the Production and Sale of Clove*, WT/DS406 (Oct. 3, 2014).