

# FDA's Consideration of Codex Alimentarius Standards in Light of International Trade Agreements

LUCINDA SIKES \*

## I. INTRODUCTION

Recent international trade agreements have altered radically the status of standards set by the Codex Alimentarius Commission, an international food standard-setting organization composed of more than 150 national governments. Codex standards were designed originally to facilitate smooth trading negotiations and to serve as a minimum floor of acceptable food quality for less developed countries. With the adoption of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT)<sup>1</sup> in 1994, however, Codex standards have become the presumptive international standards for food safety and labeling.

For example, food safety standards are subject to the Uruguay Round's Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement).<sup>2</sup> This agreement governs, among other things, measures intended to protect human or animal life or health from risks arising from additives, contaminants, toxins, or disease-causing organisms in foods, beverages, or feedstuffs; and measures intended to protect human life or health from risks arising from diseases carried by animals, plants, or products thereof. Under the SPS Agreement, regulatory requirements that exceed Codex standards may be challenged as trade barriers. While the SPS Agreement does not require the adoption of Codex standards as national standards, it does require that a country have a scientific justification to establish or maintain more stringent standards. Moreover, food labeling requirements fall under the terms of the Uruguay Round's Agreement on Technical Barriers to Trade (TBT Agreement),<sup>3</sup> which encourages the harmonization of technical regulations. While the TBT Agreement does not specifically refer to Codex standards, Codex qualifies as an international standard-setting body under the TBT agreement when Codex elaborates and adopts international standards not related to SPS food safety matters. Pursuant to these recent agreements, other countries may challenge a Food and Drug Administration (FDA) safety standard as a trade barrier if the standard exceeds the requirements set by Codex. Thus, Codex standards have new significance for food safety and labeling in the United States.

In response to these international changes, FDA currently is considering whether the agency should amend its regulations governing procedures for the review and evaluation of Codex standards.<sup>4</sup> Any amendments to FDA regulations should comply with three fundamental principles: 1) the paramount goal of FDA's consideration of

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\* Ms. Sikes is a staff attorney with Public Citizen Litigation Group, Washington, D.C. This article is based on comments submitted to the Food and Drug Administration in response to an Advance Notice of Proposed Rulemaking on Consideration of Codex Alimentarius Standards, 62 Fed. Reg. 36,243 (July 7, 1997).

<sup>1</sup> Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125 [hereinafter Final Act].

<sup>2</sup> Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, *in* Final Act, *supra* note 1, 33 I.L.M. at 1381.

<sup>3</sup> Agreement on Technical Barriers to Trade, Apr. 15, 1994, *in* Final Act, *supra* note 1, 33 I.L.M. at 1427.

<sup>4</sup> 62 Fed. Reg. at 36,248.

Codex standards should be to safeguard public health in the United States; 2) FDA should adopt only those Codex standards that would improve (or equally maintain) public health and consumer protection in the United States; and 3) FDA should maintain the domestic, democratically accountable policymaking process. Based on these principles, this article addresses the significant problems in the Codex standard-setting process and offers specific suggestions to ensure that FDA's consideration of Codex standards does not undermine the public health.

## II. STANDARD-SETTING BY CODEX

The Codex Alimentarius Commission is an international standard-setting body established jointly in 1962 by the United Nations World Health Organization (WHO) and the United Nations Food and Agriculture Organization (FAO) to facilitate international trade of food.<sup>5</sup> At its inception, Codex set identity standards (descriptive standards for foods) so that traders around the world would have a common understanding, for example, of what was "peanut oil." The 162 member countries of Codex, including the United States, are encouraged to accept and implement Codex-approved food standards, but are not obligated to do so. Historically, Codex standards have not been considered safety standards, and FDA did not accept them as such.<sup>6</sup> The SPS Agreement and the TBT Agreement, however, have given Codex and its standards heightened status and responsibility. Yet, significant problems in how Codex operates raise concerns that this new role is not justified.

### A. *Codex Was Created to Promote International Trade and Employs Procedures That Jeopardize the Safety of the U.S. Food Supply*

Codex is poorly suited to establishing global food safety standards because it has two competing mandates: to promote international trade and to protect public health.<sup>7</sup> In contrast with FDA,<sup>8</sup> Codex has no overarching mandate to protect public health. There is no codified standard requiring Codex to apply precautionary principles or spelling out precisely how Codex is to assess whether consumer health is protected adequately.<sup>9</sup> Codex threatens to trump U.S. standards that are based solely on public health, such as the Delaney Clause (which uses a zero-risk standard providing that no risk of cancer is permitted for exposure to carcinogens in food).<sup>10</sup>

Codex sets health and safety standards by majority vote of its member countries. Codex gives each member country an opportunity to vote on each standard, even if a country has a self-interest in a less protective standard. Thus, a country may give greater weight to economic factors than to public health protection. France and other European countries that sell nonpasteurized cheese, for example, object to any Codex dairy standards that would require pasteurization,<sup>11</sup> and pottery-producing nations

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<sup>5</sup> Statutes of the Codex Alimentarius Commission, Art. I, in *FAO/WHO FOOD STANDARDS PROGRAMME, PROCEDURAL MANUAL OF THE CODX ALIMENTARIUS COMMISSION* (1995).

<sup>6</sup> 21 C.F.R. § 130.6 (1997).

<sup>7</sup> *FAO/WHO FOOD STANDARDS PROGRAMME, INTRODUCING CODEX ALIMENTARIUS 3* (1990).

<sup>8</sup> 21 U.S.C. § 393(b). The FDA Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2295, establishes a mission statement for the agency. FDA's substantive mission is "to protect the public health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). The mission statement also directs the agency to participate in international harmonization efforts, but the law attaches no substantive component to this directive. *Id.* § 393(b)(3).

<sup>9</sup> FDA, however, is subject to such codified standards. *See, e.g.*, 21 U.S.C. §§ 342, 346.

<sup>10</sup> 21 U.S.C. §§ 348(c)(3)(A), 360b(d)(1)(H), 376(b)(5)(B).

<sup>11</sup> *CODX ALIMENTARIUS COMM'N, REPORT OF THE TWENTY-SECOND SESSION OF THE CODX ALIMENTARIUS COMMISSION, Codex Doc. ALINORM 97/37 ¶ 97 [hereinafter 22D SESSION REPORT].*

such as Portugal and Spain object to stringent lead standards.<sup>12</sup> Not surprisingly, the United States (which often has more protective safety standards than other Codex members) is outvoted; if countries with less protective safety standards voted to accept higher standards, their products would be banned from international trade. Thus, the system is designed to maintain weak Codex standards.

Indeed, the United States lost some key battles at the last Commission meeting, held in June 1997. For example, the Commission adopted *Guidelines for the Design, Operation, Assessment and Accreditation of Food Import and Export Inspection and Certification Systems* by a vote of forty-six to sixteen.<sup>13</sup> Under these guidelines, company employees may operate food inspection systems. In contrast, the United States requires that government-paid officials conduct inspections. The United States opposed adoption of the Codex guidelines, arguing that “it was highly inappropriate for such broad based and significant Guidelines to be adopted before member countries had the opportunity to consider their legal impact on national legislation in the light of the [World Trade Organization] Agreements.”<sup>14</sup>

Similarly, the Commission adopted a standard for “natural mineral waters” by a vote of thirty-three to thirty-one.<sup>15</sup> The United States had objected strenuously that this “standard ignores public health protection by prohibiting any antimicrobial treatments and creates a barrier to international trade by including unnecessary and inappropriately restrictive requirements which are contrary to the General Principles of Codex Alimentarius, adopted by the Commission to protect public health and facilitate international trade.”<sup>16</sup>

### B. Codex Standard-Setting Lacks Public Participation

Codex operates without adequate mechanisms for obtaining public input or maintaining public accountability. Meetings of the Codex Executive Committee are closed, even when the agenda includes decisions on risk management or other important policy issues. Observers also are excluded from the meetings of the two expert committees that perform the scientific evaluations that support Codex standards: the Joint FAO/WHO Expert Committee on Food Additives and the Joint FAO/WHO Committee on Pesticide Residues. While nongovernmental organizations are allowed to attend the Commission’s meetings, relevant background documents rarely are provided with adequate lead-time; procedural rulings by the Codex Secretariat preclude full dissemination of consumer perspectives to participants. Moreover, the Commission makes certain decisions in private sessions. For example, the decision to accept maximum residue limits for growth-promoting hormones in meat production — a subject of great interest to consumer groups in many countries — was made by secret ballot at the Commission’s July 1995 meeting.<sup>17</sup>

Thus, Codex procedures are completely at odds with the open and participatory manner in which FDA sets safety standards in the United States. Domestically, the

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<sup>12</sup> *Id.* ¶ 115.

<sup>13</sup> *Id.* ¶ 44.

<sup>14</sup> *Id.* ¶ 45.

<sup>15</sup> *Id.* ¶ 90.

<sup>16</sup> *Id.* ¶ 91.

<sup>17</sup> See Consumers International, Position of Consumers International for the Twenty-Second Session of the Codex Alimentarius Commission Re: Involvement of Non-Governmental Organizations in the Work of Codex Alimentarius Commission (June 1997) (position paper) (discussing significant barriers to consumer participation in Codex proceedings and making recommendations for improvements).

Administrative Procedures Act<sup>18</sup> ensures that the public has notice and the opportunity to comment on proposed rules, while the Federal Advisory Committee Act<sup>19</sup> guarantees that advisory committees are balanced and open to the public. Codex follows no such democratically accountable policymaking process.

In recent years, some consumer and environmental organizations have attended Codex meetings and have sought to make Codex more open and participatory. Consumer and environmental representation, however, remains sporadic, and Codex has not significantly reformed its processes to ensure more meaningful public participation.<sup>20</sup>

In contrast, industry historically has been involved in the Codex standard-setting process. For example, representatives from Coca-Cola, Pepsi Cola, Monsanto, and Pfizer, as well as from trade groups such as the International Dairy Federation, the International Council of Grocery Manufacturers Associations, the International Organization of the Flavour Industry, the International Soft Drink Council, and the International Glutamate Technical Committee, attended the June 1997 Codex meeting.<sup>21</sup> A 1993 study reported that over eighty percent of the nongovernmental participants on national delegations to recent Codex committees represented industry, while only one percent represented public interest organizations.<sup>22</sup> Of the thirty-seven nongovernmental organizations that participated in the 1997 Codex meeting, only three represented the public interest community.<sup>23</sup> While many of the delegations of member countries included industry advisors, only three countries — the United States, Germany, and Norway — included consumer representatives on their delegations.<sup>24</sup>

### C. *The Rationale and Process for Codex Decisionmaking Needs Strengthening*

According to a report released by the Office of the U.S. Coordinator for Codex Alimentarius (U.S. Codex) in February 1995, "aspects of the scientific and administrative procedures followed in the elaboration of [Codex health and safety standards] warrant attention[,] for example[,] their transparency, their consistency between and within committees, and their adequacy of data requirements."<sup>25</sup> U.S. Codex identified three concerns regarding the scientific basis for Codex decisionmaking:

- the basic scientific approaches employed in the expert committees' evaluations need clearer articulation and public review;
- the relationships among the technical experts, governments, and nongovernmental organizations need to be examined and clarified; and
- systematic processes need to be established for continuous reassessment and updating of the scientific approaches and the data evaluations themselves.<sup>26</sup>

<sup>18</sup> Pub. L. No. 79-404, 60 Stat. 237 (1946) (codified as amended at 5 U.S.C. §§ 551 et seq. (1994)).

<sup>19</sup> Pub. L. No. 92-463, 86 Stat. 770 (1992) (codified as amended at 5 U.S.C. app. II).

<sup>20</sup> At the most recent Codex meeting, the Commission considered the involvement of nongovernmental organizations in its work and concluded that the Secretariat, in consultation with independent nongovernmental consumers' organizations, should prepare a paper on enhancing the role of such organizations in the Codex process for consideration at the next session of the Commission in 1999. See 22D SESSION REPORT, *supra* note 11, ¶¶ 155-59.

<sup>21</sup> *Id.* app. I, at 75-82.

<sup>22</sup> NATALIE AVERY ET AL., CRACKING THE CODEX: AN ANALYSIS OF WHO SETS WORLD FOOD STANDARDS I (Nat'l Food Alliance 1993).

<sup>23</sup> 22D SESSION REPORT, *supra* note 11, app. I, at 75-82.

<sup>24</sup> *Id.* app. I, at 32-73. Norway paid for a consumer representative (from the Consumer Council of Norway) to attend.

<sup>25</sup> OFFICE OF THE U.S. COORDINATOR FOR CODEX ALIMENTARIUS, U.S. CODEX STRATEGIC PLAN 8 (1995).

<sup>26</sup> *Id.* at 8-9.

U.S. Codex also established a goal that “within five years, with the support of U.S. Codex, Codex Alimentarius decisions will be widely recognized and fully accepted as being based on strong, consistent scientific principles.”<sup>27</sup>

In an apparent effort to achieve this goal at the June 1997 Codex meeting, the U.S. delegation emphasized that the risk analysis process should be transparent and that “it was extremely important that results of risk assessment be published to be available for others to obtain information and/or to confirm their own evaluations.”<sup>28</sup> While Codex currently is developing an action plan for the development and application of risk analysis principles and guidelines in all Codex activities, Codex deferred making firm recommendations for the adoption of definitions for risk assessment policy and risk profile until its next session, to be held in 1999.<sup>29</sup>

#### D. Codex Standards Often Are Weaker Than U.S. Standards

The existing problems in the operation of Codex standard-setting — the inherent conflict posed by Codex’s dual mandate to promote international trade while protecting consumer health, as well as the need for Codex to address standard-setting as a democratic policymaking process in which openness and effective participation are central — have resulted in standards that are often less protective than FDA standards. No comprehensive comparison of FDA and Codex standards has been conducted recently. A 1997 report by the Center for Science in the Public Interest, however, pointed to five areas in which Codex standards fall below existing FDA and U.S. Department of Agriculture regulatory requirements: pasteurization of dairy products, food additives, mineral content of bottled water, meat inspection, and lead contamination.<sup>30</sup>

Moreover, in 1991, the U.S. General Accounting Office (GAO) conducted a comparison of U.S. pesticide standards to Codex pesticide standards.<sup>31</sup> Many pesticide tolerances or maximum residue levels (MRLs) could not be compared directly because the standards were defined differently. For those that could be compared, however, GAO found that among the pesticides that the Environmental Protection Agency had rated as probable carcinogens, the United States had lower MRLs (a more stringent standard) in fifty-five percent of the cases.<sup>32</sup> Thus, acceptance of Codex’s less stringent standards in the United States would increase possible exposure to cancer-causing residues.<sup>33</sup> Indeed, a 1994 analysis by Public Citizen and the Environmental Working Group found that adopting Codex tolerances for pesticides when they are higher than U.S. tolerances would increase allowable cancer risk twelve times over current U.S. levels.<sup>34</sup>

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<sup>27</sup> *Id.* at 11.

<sup>28</sup> 22D SESSION REPORT, *supra* note 11, ¶ 166.

<sup>29</sup> *Id.* at ¶¶ 162-67.

<sup>30</sup> CENTER FOR SCIENCE IN THE PUBLIC INTEREST, INTERNATIONAL HARMONIZATION OF FOOD SAFETY AND LABELING STANDARDS 10-28 (1997).

<sup>31</sup> U.S. GENERAL ACCOUNTING OFFICE, INTERNATIONAL FOOD SAFETY: COMPARISON OF U.S. AND CODEX PESTICIDE STANDARDS (1991) (GAO/PEMD-91-22).

<sup>32</sup> *Id.* at 4.

<sup>33</sup> *Id.* at 35.

<sup>34</sup> PUBLIC CITIZEN & ENVIRONMENTAL WORKING GROUP, TRADING AWAY U.S. FOOD SAFETY 70 (1994).

### III. FDA'S CONSIDERATION OF CODEX STANDARDS

Congress has made clear that FDA's obligation to protect the public from adulterated and misbranded food has not been reduced or modified by the United States' participation in international trade agreements. In approving and implementing the Uruguay Round trade agreements, Congress explicitly provided that "[n]othing in this Act shall be construed . . . to amend or modify any law of the United States, including any law relating to . . . the protection of human, animal, or plant life or health."<sup>35</sup> Moreover, the Statement of Administrative Action written by the Clinton Administration and approved by Congress when it implemented the Uruguay Round agreements specifically lists the Federal Food, Drug, and Cosmetic Act (FDCA)<sup>36</sup> as a federal environmental and health measure that is not amended or modified by the agreements.<sup>37</sup> Accordingly, FDA may not adopt Codex standards that do not comply with the statutory requirements set forth in the FDCA.

FDA's primary goal in consideration of Codex standards, as in all of its international harmonization activities, should be to preserve and enhance the agency's ability to accomplish its public health mission.

FDA procedures for review of Codex standards should ensure that the agency is exercising its own independent judgment (uninfluenced by international trade pressures) when it considers whether a particular Codex standard will improve public health in the United States. The review should guarantee that 1) the relevant science on which the Codex standard was based is valid and independent from industry influence; 2) the Codex standard reflects the most modern science and consumer protection concerns, including precautionary principles; 3) the factual and scientific bases for the Codex standard are part of the record made available to the public; and 4) the standard maintains the flexibility to respond to emerging health hazards and other new information.

FDA should consider adopting only Codex standards that provide a greater level of protection than current U.S. standards or that address concerns not yet regulated by FDA. For example, in 1991, GAO determined that Codex standards had lower (more stringent) MRLs for carcinogenic pesticides than did the United States in twenty-seven percent of the comparable cases.<sup>38</sup> FDA should review Codex standards such as these, which would increase consumer protection. Codex standards that are adopted domestically would need to be reviewed at least once every three to five years to ensure that the standard still offers the appropriate level of health and consumer protection.

To identify other Codex standards for review, FDA should look to those FDA regulations that need updating and revision, and consider any relevant Codex standards in conjunction with a review of such regulations. For example, FDA intends to review its regulations pertaining to identity, quality, and fill of containers for standardized food to take into account the impact of the Nutrition Labeling and Education Act of 1990<sup>39</sup> and to simplify the regulations where practicable.<sup>40</sup> As part of this re-

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<sup>35</sup> Uruguay Round Agreements Act, Pub. L. No. 103-465, § 102(a)(2), 108 Stat. 4809, 4815 (1994) (codified at 19 U.S.C. § 3512).

<sup>36</sup> Pub. L. No. 75-717, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301 et seq.).

<sup>37</sup> HOUSE COMM. ON WAYS AND MEANS, 103D CONG., 2D SESS., URUGUAY ROUND TRADE AGREEMENTS, TEXT OF AGREEMENTS, IMPLEMENT BILL, STATEMENT OF ADMINISTRATIVE ACTION (Comm. Print vol. I), reprinted in 1994 U.S.C.C.A.N. 4040, 4063.

<sup>38</sup> U.S. GENERAL ACCOUNTING OFFICE, *supra* note 31, at 4.

<sup>39</sup> Pub. L. No. 101-535, 104 Stat. 2353 (1990).

<sup>40</sup> 60 Fed. Reg. 67,492 (Dec. 29, 1995).

view, FDA should consider any relevant Codex standards. Whenever FDA plans to issue a new FDA regulation (or to revise an existing regulation), the agency also should review any relevant Codex standards.

FDA is considering focusing its resources for review of Codex standards on standards adopted since 1993.<sup>41</sup> Codex standards adopted from 1993 forward are intended to reflect the new role of Codex standards under the SPS and TBT Agreements, while those adopted previously were intended to provide product standardization and guidance to developing nations. Thus, post-1993 Codex standards are more likely to be upheld by the World Trade Organization (WTO) in a trade challenge. FDA should make sufficient resources available to conduct necessary scientific studies and defend its position before WTO.

FDA should not assume, however, that standards adopted since 1993 are better than those adopted previously. Because of the significant problems in the way that Codex sets standards, it is wrong to assume that post-1993 Codex standards are more likely to deserve adoption as U.S. safety standards than pre-1993 Codex standards. As U.S. Codex recognized in 1995, it is unlikely that routine acceptance of Codex standards will be appropriate until at least the year 2000.

Ideally, within the next five to ten years . . . Codex standards would be

- established through a more transparent and fully participatory process;
- based on stronger, more consistent scientific principles; and
- fully protective of health in all countries.<sup>42</sup>

Thus, in the future FDA might give priority to consideration of Codex standards adopted after a certain date, because those standards would reflect a Codex standard-setting process that was more open and participatory, based on stronger science, less tainted by purely economic considerations, and fully protective of health. At this time, however, it would be premature for FDA to focus review on post-1993 standards.

In future Codex proceedings, FDA should object strongly to any Codex standards that are weaker than FDA standards. Indeed, the new U.S. strategic plan calls for FDA employees who participate in Codex proceedings to determine whether acceptance of a Codex standard would affect the health and safety of American consumers.<sup>43</sup> FDA not only should ascertain when Codex standards fall below U.S. requirements, but also should object to the approval of such standards by Codex and place on the record the agency's reasons for contesting Codex's proposed standard. If the United States cannot successfully block the development of weaker Codex standards, then it should record its position in the minutes and reports of Codex proceedings to establish a record that clearly demonstrates why the Codex standard does not sufficiently protect American consumers. This record will help discourage potential trade complaints and serve as a basis for a defense before WTO if necessary.<sup>44</sup>

Public participation in FDA's review of Codex standards is critical. FDA has proposed publishing a *Federal Register* notice when Codex adopts new standards. Such a notice would 1) describe the Codex standard and compare it to an FDA standard; 2) provide FDA's preliminary views on the Codex standard, including the standard's potential for acceptance by FDA and whether rulemaking would be necessary; 3) describe information needed to adequately evaluate the standard; 4) invite information on the relative importance of the standard to public health protection and

<sup>41</sup> 62 Fed. Reg. at 36,246.

<sup>42</sup> OFFICE OF THE U.S. COORDINATOR FOR CODEX ALIMENTARIUS, *supra* note 25, at 7.

<sup>43</sup> 62 Fed. Reg. 23,750 (May 1, 1997).

<sup>44</sup> See CENTER FOR SCIENCE IN THE PUBLIC INTEREST, *supra* note 30, at 34-35.

international trade; and 5) state the agency's preliminary plans to perform substantive review of the standard.<sup>45</sup>

This proposal is a sensible way to obtain preliminary public input on the priority to attach to the review and evaluation of particular standards. The notices also should be posted on the FDA's Internet Web page,<sup>46</sup> and the agency should take affirmative steps to ensure that consumer and health organizations, as well as interested academics receive this information. Moreover, the notices should be only one step in providing the public with the opportunity to participate in the standards process. At the front end, FDA should strive to improve public participation in the Codex standard-setting process itself, so that the public has input into Codex standards before they are finalized. Moreover, in those situations in which FDA decides to pursue adoption of a Codex standard, a separate notice should be published in the *Federal Register* and the public should have the opportunity to comment.

Currently, FDA regulations provide for review of Codex standards in one of the following three ways: 1) where an individual files a petition for adoption of a Codex standard and reasonable grounds are provided in the petition, FDA publishes the petition in the *Federal Register* for comment; 2) on FDA's own initiative, a proposal for adoption of a Codex standard is published in the *Federal Register*; and 3) after publication in the *Federal Register*, the public submits comments on whether a Codex standard should be adopted, and after reviewing the comments, FDA either publishes a proposal to establish a food standard or publishes a notice terminating consideration of the standard.<sup>47</sup>

These regulations should be clarified in three ways. First, the regulations should set forth the criteria FDA will use to decide whether to publish for comment a petition seeking adoption of a Codex standard. In light of FDA's public health mandate, FDA should require a petitioner to make a *prima facie* case that the adoption of a Codex standard would not lower current FDA standards or otherwise raise public health concerns. Only when the petition makes a *prima facie* case would FDA publish the petition for comment. Second, the regulation should provide that FDA would, on its own initiative, consider adoption of a Codex standard when the Codex standard provides a greater level of protection than a current FDA standard or addresses concerns not yet regulated by FDA; when a Codex standard is relevant to new or revised FDA regulations; or when a Codex standard would improve the public health or consumer protection. Third, the *Federal Register* notice provided for in the regulation,<sup>48</sup> at a minimum, should describe the Codex standard and its comparability to an FDA standard; provide FDA's preliminary views on the Codex standard, including the standard's potential for acceptance and whether rulemaking would be necessary; describe information the agency would need for adequate evaluation of the standard; invite information on the relative importance of the standard to public health protection; and state the agency's preliminary plans for substantive review of the standard. Based on the comments received, FDA either would decide to proceed with review of the Codex standard and publish a notice to that effect in the *Federal Register*, or decide against further review of the standard.

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<sup>45</sup> 62 Fed. Reg. at 36,247.

<sup>46</sup> See Food and Drug Admin., *Food and Drug Administration Home Page* (visited Apr. 30, 1998) <<http://www.fda.gov/>>.

<sup>47</sup> 21 C.F.R. §§ 130.6, 564.6.

<sup>48</sup> *Id.* § 130.6(b)(3).



#### IV. CONCLUSION

FDA's statutory mandate is to ensure public health. FDA should adopt Codex standards only when they will improve food safety and labeling in the United States. Given FDA's limited resources, FDA should focus on review of Codex standards that provide a greater level of protection than current FDA standards or address concerns not yet regulated by FDA, and that are relevant to new or revised FDA regulations. FDA should strive to improve public participation in the Codex standard-setting process itself and should provide the public with notice-and-comment opportunities when the agency is considering adoption of a Codex standard.

