FOOD SAFETY

Topic: Codex Poised to Pass Global Food Equivalency Rules at July Meeting

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The Codex Alimentarius Commission (Codex) in Rome is poised to approve international guidelines to facilitate trade in food products under the equivalency provisions of the World Trade Organization’s Sanitary and Phytosanitary (WTO SPS) Agreement. The Codex was established as an international standard-setting body in 1962 by the World Health Organization and the U.N. Food and Agriculture Organization to set international commodity product standards and food safety standards to promote trade in food. The WTO SPS Agreement governs trade in food and sets regulatory constraints that WTO nations must abide by when creating policies designed to protect human, animal or plant life from pests, diseases and toxins in food, beverages, or animal feed.

Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems are slated for final approval and adoption at the June 30-July 7, 2003, Codex Alimentarius Commission meeting. If passed by the Codex General Assembly, these Guidelines could serve to undermine differing
domestic policies on equivalency around the world. This is due to the fact that Codex standards were elevated to a new role by the WTO SPS agreement, which specifically recognizes Codex as setting the world’s presumptively “trade-legal” food safety standards and makes these international standards the point of reference in any WTO food safety dispute.

Once in place, nations denied food equivalency decisions due to inadequate food safety standards or enforcement could use the Codex Guidelines as additional ammunition in launching a WTO complaint, moving the decision making on the issue out of the hands of food safety officials and into the hands of a closed-door trade tribunal that puts the interest of facilitating trade above all other concerns.

“Equivalency” and “Harmonization” in Global Trade: Both the WTO and the North American Free Trade Agreement (NAFTA) oblige member governments to engage in equivalency. For instance, Article 4.1 of the WTO SPS agreement states that “Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member’s appropriate level of sanitary or phytosanitary protection.”

Under these pacts, equivalency is mandatory. A WTO member country “shall accept” another member country’s food safety measures if the exporting country demonstrates that its standards achieve the importing country’s appropriate level of protection. Although the importing country makes the determination of equivalency, denial of equivalency can be challenged as a barrier to trade in the powerful dispute resolution system of the WTO. Such challenges have occurred before. In 1993 for instance, a trade tribunal operating under the U.S.-Canada Free Trade Agreement (the precursor to NAFTA) forced Puerto Rico to accept Canadian “ultra-high temperature milk” in an equivalency challenge regarding Puerto Rico’s requirement for milk to be pasteurized even though Puerto Rico did not think the milk met the standards of its domestic Pasteurized Milk Ordinance.

Once “equivalence” is agreed to, the standards of the exporting party apply. In other words, different standards for the same food product exist side-by-side at the same time. Each is legal in the United States. One set of standards applies to food produced in the United States. These standards have been adopted by a U.S. regulatory agency to implement a U.S. law enacted by Congress. Citizen input into these standards has been assured by the federal Administrative Procedure Act - requiring notice and opportunity for public comment; the Freedom of Information Act - permitting citizen access to the records of government agencies; the Government in the Sunshine Act - ensuring that important agency meetings are publicly noticed; and the Federal Advisory Committee Act - requiring balanced representation on government advisory committees. Compliance with the U.S. standards by producers of the affected product is secured through the monitoring and enforcement mechanisms of U.S. law.

In contrast, another set of “equivalent” standards has been agreed to by the U.S. regulatory agency at the request of a foreign country, on the basis of a claim that the foreign country’s standards achieve the same level of protection as the standards that the U.S. agency itself selected after consideration of the opinions of its own experts, representatives of public interest groups, industry and academia, and the affected public.

The WTO-required equivalency idea has been criticized by consumer groups and food safety advocates. The Transatlantic Consumer Dialogue, for instance, made up of over 65 consumer organizations in the United States and Europe, passed a resolution on equivalency which states that “the very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety.”

Government agencies and consumer groups have also been critical of the U.S. Department of Agriculture (USDA) Food Safety and Inspection Service performance in this area. Since 1995, USDA has certified 43 foreign country inspection systems as equivalent to the U.S. system. In June 2000, USDA’s own Office of the Inspector General issued a lengthy report sharply critical of the way the agency was handling equivalency decisions, concluding the agency had “reduced its oversight short of what is
prudent and necessary for the protection of the consumer." The Washington-based consumer group Center for Science in the Public Interest has criticized the agency’s lack of oversight and enforcement with regard to its equivalency agreement with Mexico and has characterized equivalency as “a method by which nations can create exemptions to each others’ food safety laws to advance trade rules.”

In addition to calling for equivalency agreements, NAFTA and the WTO both oblige member governments to base their domestic rulemaking on specified international standards and on international standard-setting techniques. For example, the WTO SPS Agreement requires that countries “base their sanitary and phytosanitary measures [food standards] on international standards, guidelines or recommendations.” This process is called “harmonization” by its proponents.

Theoretically, international harmonization could occur at the lowest or highest levels of public health or environmental protection or somewhere in between. Unfortunately, the actual provisions in NAFTA and the WTO requiring harmonization are likely to result in the lowering of the best existing domestic public health, social, economic justice, natural resource conservation and environmental standards around the world. This is the case because, under NAFTA and the WTO, international standards serve as a ceiling that countries cannot exceed rather than as a floor that all countries must meet. The agreements provide for the challenge of any domestic standards that go beyond international standards in providing greater citizen safeguards, but contain no provisions for challenging standards that fall below the named international standard.

Thus, the provisions in NAFTA and the WTO promoting harmonization are likely to serve only as a one-way ratchet downward on domestic standards. Challenges of domestic standards that exceed international standards are resolved in the binding dispute resolution system built into these agreements, which is closed to public participation or observation. Weak or vague international equivalency rules, like those being developed at the Codex, could serve to undermine domestic equivalency rules if those rules are more stringent or provide better safeguards for consumers and public health.

**Codex Accelerates Equivalency Rules at the Behest of the WTO:** The development of internationally-harmonized equivalency rules in the Codex was accelerated at the behest of the WTO. The promise of the establishment of these rules is being used by developed nations as an inducement to prompt developing nations to go along with their demands in the wider, multilateral negotiations now under way at the WTO. Currently, developed nations are pushing for a major new WTO expansion, including the launch of negotiations of four new binding agreements covering the so-called “Singapore issues” of procurement, competition, investment and trade facilitation. In contrast, developing nations mainly oppose any expansion of WTO rules and seek full implementation of the benefits they were promised in previous WTO agreements.

At the 2001 WTO Ministerial Meeting in Doha, Qatar, equivalency was officially listed as an implementation issue that would further existing WTO commitments for more and speedier market access by developing countries, deserving the focused attention of all WTO members. While developed WTO member countries were willing to commit to deregulation in this context, potentially undermining public health and safety, they rejected market access concessions, such as steep cuts in the subsidies currently paid to agribusiness which effectively shut many poor countries of food trade and undermine domestic food security in poor countries.

In October 2001, the WTO’s SPS Committee issued an official communiqué to the Codex demanding that it expedite international equivalency rules it had been working on for many years. The WTO’s involvement in the process clearly illustrates that the primary rationale for equivalency is one of trade facilitation. Ensuring a safe and wholesome food supply for the protection of consumers around the world is a lesser concern.

The Codex Committee on Food Import/Export Inspection and Certification Systems (CCFICS) approved a set of international equivalency guidelines for trade in food products, including meat, at its December 2002 meeting in Adelaide, Australia. Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems were
moved to final step of the Codex eight-step process and are slated for final approval by the General Assembly at the June 30-July 7, 2003, Codex Alimentarius Commission meeting.¹⁵

Codex defines equivalency as “the capability of different inspection and certification systems to meet the same objectives.”¹⁶ Equivalency agreements “may result in reducing the importing country’s rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin.”¹⁷ The Codex Guidelines establish a multi-step process for determining equivalence. However, the Guidelines are solely process-oriented and fail to cover key issues such as the types of information that must be taken into account when determining equivalency.

After multiple meetings, the countries participating in CCFICS were unable to agree on the types of information to be taken into account when judging equivalence. They thus postponed this politically hot topic by suggesting that such a list could be developed later as an annex to the agreement.¹⁸ Such a list should cover not only the specific aspects of meat slaughter and inspection standards to be compared, but also other aspects of law, regulation and practice, such as the adequacy of a nation’s SPS budget and a nation’s track record of enforcement and product recalls. Without including this full range of comparisons, meat produced under widely differing systems could be judged to be “equivalent” for trading purposes, undermining consumer protection across the globe.

During its development, a number of U.S. and international consumer groups commented on the significant shortcomings of the Codex proposal. In October 2002, Consumers International pressed unsuccessfully for the development of at least three annexes to the agreement: the first would specify the kinds of information requested by importing countries that would be used to make and maintain a judgment of equivalence; the second would outline the terms for onsite visits by importing country authorities to verify if and how the exporting countries’ application of SPS measures meets importing country requirements; the third would specify the kinds of technical assistance to be provided by importing countries to assist exporting countries in satisfying importing country requirements.¹⁹ No such annexes were included in the final proposal.

Worse, the proposed Codex equivalency policy inappropriately creates a new limit on the criteria and information that can be supplied and should be requested for the determination of equivalence “to that which is necessary for this purpose.”²⁰ This clause inserts a new “necessity test” into the document, inappropriately limiting the criteria that importing countries may want to utilize in a determination of equivalence, and encouraging trade challenges against criteria deemed by an exporting nation to be more than strictly “necessary.” In the context of a WTO or NAFTA complaint, this language is likely to expose the judgement by a country’s food safety experts about what is necessary to second-guessing by trade officials operating in a closed-door trade tribunal.²¹

In a similar vein, while the U.S. government demands science-based decision making in other contexts (most notably in with its ongoing battle with the EU over its new regulations for genetically modified foods), the Codex equivalency Guidelines do not require that risk assessments be performed by exporting country’s measure to objectively demonstrate that their measures achieve the appropriate level of protection demanded by importing countries. However, if a denial of equivalency ends up being challenged in the WTO, it is extremely likely that the importing country will be required to provide the science to prove that the exporting country’s measure is inadequate. This has occurred in other WTO disputes, most notably the WTO beef hormone case, where the burden of proof fell upon the defendant European Union to scientifically justify its more consumer-protective regulation on a number of different artificial beef hormones vis à vis weaker or nonexistent Codex standards.

Consumer groups also recommended that the Codex policy explicitly note that nations are free to introduce and maintain domestic standards with a higher level of protection. In other words, countries are not locked into Codex standards. In contrast, the Codex Guidelines state that “to facilitate a judgement of equivalence between countries and promote harmonization of food safety standards, Codex member nations should base their sanitary measures on Codex standards and related texts.”²² The ability
of countries to maintain different standards under constraining WTO rules is only referenced in a footnote to this text. Given that Codex sanitary standards regarding meat inspection contain significant deviations from U.S. law (Codex meat inspection standards, for instance, allow company self-inspection of meat), a requirement to rely on international standards raises the specter of the United States being required to determine equivalency with countries that do not have the budget to pay for government meat inspectors, and therefore rely on the food industry to police itself or face WTO or NAFTA trade challenges for failing to do so.

Finally, while the equivalency procedure seems to be a cooperative one between importing and exporting nations, in fact, it could cause an enormous resource drain on importing countries. Importing countries are obligated to engage in lengthy equivalency negotiations with any WTO or Codex member country that asks to initiate this process. If the importing country ultimately refuses to establish an equivalency agreement, that decision could be challenged under WTO rules.

**Codex Guidelines Could Undermine More Rigorous Domestic Equivalency Rules:** The Codex Guidelines apply to all trade in food and as a consequence may have ramifications for every U.S. agency regulating products destined for the dinner plates of U.S. consumers.

Four U.S. agencies have some responsibility for the safety of the U.S. food supply: the USDA’s Food Safety and Inspection Service (FSIS) regulates meat, poultry and processed eggs; the Food and Drug Administration (FDA) regulates all other food, shell eggs and contaminants in animal feed and drug residues in animals for human consumption; the Environmental Protection Agency (EPA) has a role in regulating pesticides and genetically engineered foods; and the Animal and Plant Health Inspection Service (APHIS) regulates animal health and animal imports.

In 1994, the Uruguay Round Agreements Act passed Congress. This bill made the U.S. part of the WTO and implemented key WTO agreements as binding federal law. In addition to rewriting large swaths of U.S. law, the Uruguay Round Agreements Act made statutory changes to the Federal Meat Inspection Act and the Poultry Products Inspection Act that in 1995 resulted in a minor, seemingly insignificant change to the U.S. meat and poultry regulations, when the words “equal to” were replaced with the word “equivalent.” Shortly thereafter, FSIS decided that all 37 countries that had previously been found eligible to export meat to the U.S. under a standard requiring importing governments to adopt identical meat inspection standards were at least “equivalent” to U.S. standards, so they were automatically judged to be equivalent. It was not until four years later, in 1999, that FSIS published a short and not-very-detailed draft policy for making equivalency determinations. USDA responded to public comments on this policy in December 1999, but never promulgated the policy as a formal agency rule.

In other words, before the WTO, foreign meat inspection systems were required to produce meat destined for export to the U.S. utilizing sanitary and quality standards the same as those of the United States. U.S. government inspectors had to certify that foreign processing plants met U.S. standards in order for such a facility to send food to the U.S. After the Uruguay Round Act, the meat industry in foreign nations could maintain differing standards, certify their own plants for export, and still be eligible to export into the U.S. As explained by FSIS officials, “since 1995 the United States, along with other members of the World Trade Organization, has shifted its emphasis from ‘compliance’ with importing country inspection requirements to ‘equivalence’ in conformance with our obligations under the [WTO Sanitary and Phytosanitary] SPS Agreement,” which governs trade in food.

Consumer groups have watched USDA embrace the notion of equivalency with a great deal of concern. Even with its $1 billion annual budget, USDA has failed to implement its broad-brush equivalency policy in a manner that ensures the safety of the U.S. meat imports. This was dramatically illustrated by a USDA Office of the Inspector General Report published in June 2000 that found:

- FSIS granted equivalency status to six countries for their Hazard Analysis and Critical Control Point program without conducting onsite reviews.
Seven establishments that had lost their eligibility certification were found to have shipped 4,625,363 pounds of meat and poultry into the U.S.;30

Nineteen plants that had not been recertified as meeting U.S. standards were allowed to continue to export meat to the U.S.;31

Regulatory requirements that countries provide annual certifications of plants and residue test plans were not enforced;32 and,

FSIS had no clear procedures for determining if another country’s alternative testing methods were equivalent.33

The imprecise Codex policy is similar to the approach developed by USDA in March 1999. As a consequence, it is perhaps less likely to conflict with the poor USDA policy than undermine future, hopefully more consumer protective, policies at other U.S. agencies.

For instance, FDA proposed but never implemented an equivalency policy back in 1997,34 so currently it has no food equivalency policy for the foods under its jurisdiction. In July 2002, the Washington-based consumer group Center for Science in the Public Interest (CSPI) sent a letter to the FDA, the U.S. Codex delegation leader for the Codex Guidelines, pointing out that the Guidelines were a far cry from a draft equivalency regulation the FDA proposed in 1997.35 The draft policy clearly stated that to assure the imported foods were as safe and wholesome as domestically produced foods, U.S. standards “would not be relaxed to facilitate a finding of equivalence.”36 By contrast, the Codex Guidelines do not provide any assurances that standards will not be relaxed. In addition, the FDA draft policy requires ongoing verification, including import checks at the border, while the Codex Guidelines state that “importing parties may be able to reduce the frequency and extent of verification measures following a judgement of equivalence.”37

The FDA draft policy states that the U.S. will conduct one or more on-site visits to verify that foreign regulatory systems, including plant inspection systems, are functioning as indicated in the paper review. Rather than recommending such site visits be a regular part of verification and monitoring, the Codex Guidelines merely suggest that the exporting country provides access to enable its inspection system to be examined by the importing party.38

Further, while U.S. law requires that FDA publish notice of any equivalency decision prior to any determination of equivalency, the Codex Guidelines merely suggest that governments consult with interested parties “to the extent practical and reasonable,”39 providing no assurances that consumers or other interested parties will truly have a voice in the process.

The existence of the Codex Guidelines not only may have ramifications for every U.S. agency that regulates food, but it will have significant ramifications for consumers around the globe. Nations without their own policy on equivalency will be pressured to utilize the Codex’s vague process on equivalency. Nations with more stringent domestic equivalency processes could be challenged at the WTO for creating barriers to trade, given the weaker Codex rules. In other words, if a nation is denied an equivalency agreement with any other nation and decides to challenge that determination in the binding dispute resolution bodies of the WTO or NAFTA, that nation’s process for determining equivalency could itself become a WTO-adjudicable issue over and above whatever specific sanitary measures or meat inspection standards were at issue.

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**FEDERAL REGISTER ALERTS**

The full texts of these notices are available at [http://www.gpoaccess.gov/fr/index.html](http://www.gpoaccess.gov/fr/index.html). For instance, for a document cited as 66 Fed. Reg. 52752 (August 30, 2001), search the 2001 Federal Register for "page 52752" (quotation marks required) and choose the correct title from the results list.
Department of Agriculture

Codex Alimentarius Commission: 35th Session of the Codex Committee on Food Additives and Contaminants
Notice of Public Meeting Request for Comments.

Codex Alimentarius: Meeting of the Codex Committee on Residues of Veterinary Drugs in Foods
Notice of Public Meeting and Request for Comments.

Codex Alimentarius Commission: 25th Extraordinary Session of the Codex Alimentarius Commission
Notice of Public Meeting and Request for Comments.

Codex Alimentarius Commission: 4th Session of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology
Notice of Public Meeting and Request for Comments.

Listeria Risk Assessment Technical Meeting (FSIS)
Notice of Availability and Announcement of Public Meeting.

Importation of Cooked Meat and Meat Products Relating to Rinderpest and Foot-and-Mouth (APHIS)
Final Rule.

Recognition of Animal Disease Status of Regions in the European Union (APHIS)
Final Rule.

Announcement of and Request for Comment on FSIS’ Tentative Determinations on the Availability of Salmonella Test Results (FSIS)
Notice and Request for Comments.

Codex Alimentarius Commission: 3rd Session of the Codex Ad Hoc Intergovernmental Task Force on Fruit and Vegetable Juices
Notice of Public Meeting and Request for Comments.

Environmental Protection Agency

Bifenthrin; Pesticide Tolerance (OPP)
Final Rule.
Department of Health and Human Services

*Preparation for International Conference on Harmonisation Meetings in Tokyo, Japan, Including Progress on Implementation of the Common Technical Document and Update on New Topics (FDA)*
Notice of Public Meeting.

*International Conference on Harmonisation; Guidance on Q1D Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products; Availability (FDA)*
Notice and Request for Comments.

*Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (FDA)*
Notice of Proposed Rulemaking.

*International Conference on Harmonisation; Revised Guidance on Q3A Impurities in New Drug Substances; Availability (FDA)*
Notice and Request for Comments.

*Food Additives Permitted for Direct Addition to Food for Human Consumption; Vitamin D3 (FDA)*
Final Rule.

*Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule (FDA)*
Proposed Rule and Request for Comments.

*Safety Reporting Requirements for Human Drug and Biological Products (FDA)*
Proposed Rule.

Notice.

*International Conference on Harmonisation; Annual Guidance Agenda (FDA)*
Notice.

*Draft Guidance for Industry on Submitting Marketing Applications According to the ICH/CTD Format (FDA)*
Notice of Reopening of Comment Period.
Department of Transportation

**Design Standards for Fuselage Doors on Transport Category Airplanes (FAA)**
Notice of Proposed Rulemaking.

**Glare from Headlamps and Other Front-Mounted Lamps (NHTSA)**
Request for Comments.

**Harmonization Aviation Initiatives (FAA)**
Notice of Public Meeting and Request for Comments.

**Harmonization with the United Nations Recommendations, International Maritime Dangerous Goods Code, and International Civil Aviation Organization’s Technical Instructions**
Final Rule.

Notice of Activities and Request for Comments.

Department of Labor

**Testing and Evaluation by Independent Laboratories and Non-MSHA Product Safety Standards (Mine Safety and Health Administration)**
Final Rule.

Office of the United States Trade Representative

**Request for Comments on the Operation and Implementation of the World Trade Organization’s Agreement on Technical Barriers to Trade**
Notice and Request for Comments.

**Request for Comments on Employment Impact of United-States Morocco Free Trade Agreement**
Request for Comments.

**Request for Public Comment on Employment Impact of Proposed United States-Central America Free Trade Agreement**
Request for Comments.

**Request for Information Concerning Labor Rights in Morocco and Its Laws Governing Exploitative Child Labor**

**Request for Information Concerning Labor Rights in Singapore and Its Laws Governing Exploitative Child Labor**


**NOTES**

5. 5 U.S.C. §552.
6. 5 U.S.C. §552b.
7. 5 U.S.C. Appx. §1.
11. WTO SPS Agreement, Art. 3.1.
13. At the Doha Ministerial meeting, the WTO produced a statement on implementation that lists equivalency as one of the issues on which progress needs to be made. Ministerial Declaration and Decisions: Implementation Issues and Concerns, Decision of 14 of Nov. 2001, WT/MIN (01)/17, at para. 3.3.
17. *Id* at 2.
27 9 CFR §327.2.
30 Id., at Section III, at 37.
31 Id., at Section III, at ii.
32 Id.
33 Id., at Section III, at 31.
34 Center for Science in the Public Interest, letter to Dr. Catherine W. Carneval, Director Office of Constituent Operations, Center for Food Safety and Applied Nutrition, FDA, Jul. 30, 2002.