



**HARMONIZATION ALERT, a publication of Public Citizen, seeks to promote open and accountable policy-making relating to public health, natural resources, consumer safety, and economic justice standards in the era of globalization.**

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## **FOOD SAFETY**

**Topic:** *Genetically Modified Organisms*

**Contact:** For more information on the U.S. position on labeling of GMOs, contact Theresa Thomas, U.S. Codex Committee on Food Labeling, Food and Drug Administration, at (202) 205-4210.

Genetically Modified Organisms (GMOs) are living organisms created through genetic engineering. Scientists transplant the genes of one species into another species to try to transfer “desirable” characteristics.<sup>1</sup> For example, scientists have transplanted fish genes into tomatoes in an attempt to make them less susceptible to freezing.<sup>2</sup> Multi-national corporations, such as Monsanto, Novartis, Dupont, and Avantis, have applied this process primarily to agricultural crops, including cotton, soya, and corn. They argue these genetic changes improve resistance to

disease, pesticides, and herbicides, enhance nutritional value, and increase yield.<sup>3</sup> GM crops already have been planted in the U.S. for harvest and for test purposes without containment measures to prevent exposure to the broader environment.

Consumer groups, environmentalists, and scientists have pointed out several serious problems such genetic tinkering may cause. First, crops engineered to resist pesticides and herbicides promote reliance on specific chemicals, generally non-organic pest control chemicals, by forcing farmers to buy the

type of pesticide or herbicide to which the crops are designed to be resistant.<sup>4</sup> For example, Monsanto, manufacturer of the popular Roundup line of herbicides, genetically engineers cotton seeds to resist only its herbicides. In 1998, Monsanto bought two of the world's top ten seed companies and is now the second largest seed company in the world.<sup>5</sup>

Second, critics warn that crops engineered to resist pesticides and herbicides could pass those traits on to weeds, resulting in herbicide and pesticide-tolerant "superweeds".<sup>6</sup> Scientists in the U.S. and Denmark have shown that an herbicide-tolerance gene readily passed from cultivated canola plants to closely-related wild plants, like wild mustard, in nearby fields.<sup>7</sup> Development of such "superweeds" would force farmers to use more and more herbicides to control plant pests, with unknown effects on the environment and potential risks to food and worker safety.

Third, critics note that GMOs may upset biological diversity. According to a report written for the British government, if GMOs eradicate weeds and insects, species that depend on them for food or habitat, including such birds as the corn bunting, partridge, and skylark, will suffer.<sup>8</sup> Researchers funded by the British government found that plants genetically engineered to resist aphids had serious effects on the fertility and life-span of ladybirds, which feed on aphids.<sup>9</sup> Furthermore, crops engineered to resist insect pests also may be toxic to harmless or beneficial insects, such as green lacewings and springtails, thereby reducing insect diversity.<sup>10</sup>

Fourth, genetically modified foods can pose serious threats to consumers with allergies and specific dietary requirements because of ethical, religious, or cultural beliefs. For example, people allergic to shellfish could have a reaction to strawberries with transplanted shrimp genes used to enhance their color. And persons of the Islamic or Jewish faiths and vegetarians may not want to eat plants with transplanted pig genes.

Fifth, GMOs might pose human health risks. British scientist Dr. Arpad Pusztai first suggested this after he conducted a study on the effects of genetically modified potatoes on rats. He found that rats fed the altered potatoes suffered stunted internal organ growth and weakened immune systems.<sup>11</sup>

Because of these potential problems, other countries have hesitated to allow imports of GMOs or have required products containing GMOs to be labeled. For example, the European Parliament adopted an amendment allowing European Union nations to ban GMOs in "environmentally sensitive" areas.<sup>12</sup> The

Supreme Court of India recently prohibited trials of genetically modified cotton until rules ensuring protection of the environment, human health, and biological diversity are implemented.<sup>13</sup> In December 1998, Australian and New Zealand health ministers recommended that genetically modified foods be labeled.<sup>14</sup>

Representatives of 140 nations met in Cartagena, Colombia, in February 1999 to forge a Biosafety Protocol covering GMOs. The overwhelming majority desired a treaty that would permit countries to prohibit imports of GMOs, require segregation of genetically modified grain from conventional grain, and make producers of GMOs legally liable for any environmental or economic damage.<sup>15</sup> However, the U.S.-led "Miami Group," composed of major exporters of GMOs, including Canada, Argentina, Chile, and Australia, blocked adoption of the treaty by refusing to include commodities (e.g. soya beans, corn) in the negotiations, citing trade concerns.<sup>16</sup> According to a statement from the European Commission, "This would in practice mean excluding 99 percent of the genetically modified organisms that the protocol is supposed to cover."<sup>17</sup>

The U.S. wanted to write into the protocol World Trade Organization (WTO) rules requiring nations prohibiting GMOs to base their decisions on "sound science."<sup>18</sup> The U.S. proposal raised the specter of a WTO challenge nearly any time a nation restricts GMOs. For example, after the EU rejected a Monsanto application for two genetically engineered cotton seeds, Frank Loy, U.S. Undersecretary for Global Affairs, reserved the right to challenge the decision in the WTO because, he claimed, the EU's decision was not based on "sound science."<sup>19</sup> The U.S. also seeks to ban labeling of genetically modified foods, claiming labels would prejudice its producers and amount to an illegal trade barrier.<sup>20</sup> It has threatened a WTO challenge.

WTO rules, which place the burden of proof on countries seeking health safeguards, would force the importing countries to prove that GMOs are **unsafe**, rather than requiring exporting countries to prove that GMOs are safe. Since so little conclusive research has been done on the effects of GMOs on the environment, biological diversity, and human health, many countries have based their restrictions on the precautionary principle or consumer demand, neither of which are tolerated under WTO rules.

At the April 1999 meeting of the Transatlantic Consumer Dialogue (TACD), more than 60 U.S. and EU consumer groups adopted a consensus resolution demanding mandatory labeling of all genetically

engineered foods and food ingredients based on complete traceability of GMOs throughout the production, processing, and distribution chain. The

TACD also called for further testing of GMOs and their potential consequences for human health, biodiversity, and the environment.

## WORLD TRADE ORGANIZATION

**Topic:** *Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement)*

**Contact:** Submit 20 copies of written comments on the agenda of the WTO's third ministerial conference (to be held in Seattle, Washington, November 30 - December 3, 1999) to Gloria Blue, Executive Secretary, Trade Policy Staff Committee, Office of the U.S. Trade Representative, Room 122, 600 17<sup>th</sup> Street, N.W., Washington, D.C. 20508. For procedural questions, contact Ms. Blue at (202) 395-3475. For all other questions concerning the WTO negotiations, contact the USTR's Office of WTO and Multilateral Affairs at (202) 395-6843.

**Deadline:** Written comments must be received by noon on May 26, 1999.

The SPS Agreement is the part of the General Agreement on Tariffs and Trade (GATT) that sets criteria WTO member nations must follow regarding policies designed to protect human, animal, or plant life from pests, diseases, and toxins in foods, beverages, or animal feed. It also covers labeling and packaging laws related to food safety. The entire WTO agriculture agreement is up for review at the November 1999 WTO Ministerial in Seattle as part of the "built-in" agenda.

The SPS Agreement is separated into 14 Articles. Article 2.1 defines World Trade Organization (WTO) member nations' basic rights: "Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement."<sup>21</sup> Article 2.2 defines Members' basic obligations, requiring SPS measures to be applied "only to the extent necessary to protect human, animal or plant life or health, . . . based on scientific principles, . . . and not maintained without sufficient scientific evidence. . . ."<sup>22</sup>

Article 3 requires Members to harmonize their SPS measures by basing them on international standards, such as the food safety and pesticide residue level standards set by the Codex Alimentarius Commission. SPS measures which are based on such international standards are presumed to be GATT-legal. However, SPS measures that achieve a higher level of human, animal, or plant protection than relevant international standards must pass a series of tests to be

proved not to be illegal trade barriers. One such test requires a "scientific justification."<sup>23</sup> A Member has "scientific justification" only if it analyzes available scientific data and determines that the international standard is insufficient to attain its "appropriate level of sanitary or phytosanitary protection."<sup>24</sup>

Article 4 requires Members to accept the SPS measures of other Members as equivalent, even if they are different, if the exporting Member can prove to the importing Member that its measures reach the importing Member's appropriate level of protection. The key is a Member's "appropriate level of protection," defined as "the level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory."<sup>25</sup> This definition gives the appearance that WTO Members have unfettered discretion to set their own level of protection.

Yet, as noted above, SPS Article 3 requires Members to base their SPS measures on international standards and specifically states that international standards are presumed to be GATT-legal. If a Member wishes to maintain an SPS measure that provides more consumer protection than the relevant international standard, it must bear the burden of proving "scientific justification." Given the burden of proof falls on the Member with the more protective standard, that Member must prove a negative, that the international standard is **unsafe**. This is the reverse of U.S. regulatory requirements. For example, the FDA

requires companies wishing to introduce a product to prove that the product is safe before the FDA will allow the product on the market.

The SPS Agreement's terms eviscerate the precautionary principle, which requires proof of safety before a product which poses potential risks is allowed on the market. The precautionary principle is based on the premise that science does not always provide the information or insights necessary to take protective action effectively or in a timely manner, and that undesirable and potentially irreversible effects may result if action is not taken until science does provide such insights. The precautionary principle allows countries to protect their citizens from potential, but scientifically-uncertain, harm.

In the 1950s, for instance, the FDA exercised the precautionary principle in the case of thalidomide, a drug approved in some European countries for use by pregnant women to prevent nausea that ended up causing thousands of severely deformed babies. The FDA refused to approve the use of thalidomide in the U.S. until it had proof that the drug was safe, a decision that prevented countless birth defects in the U.S.

In addition, the phrase "appropriate level of protection" itself leaves the door open to challenges.<sup>26</sup> The word "appropriate" in that phrase is unnecessary, except as a basis for a WTO challenge of a Member's SPS regulation. If a Member's level of protection is not based on international standards, it is automatically subject to challenge as not "appropriate."

Finally, the SPS Agreement exalts the role of science beyond its appropriate use, attempting to eliminate all "non-science" factors from standard-setting. Despite the value of science in policy-making,

scientific uncertainties concerning the health threats posed by exposure to chemicals remain. Moreover, political judgments play a central role in policy-making regarding risk. While science informs policy decisions, it is ultimately a legislative body that must make the political decision about how much risk society will face. Thus, if citizens desire a zero-risk policy regarding certain hazards, a legislature could pass a zero-risk law, simply banning a substance that might pose a small risk in small doses. However, under the SPS Agreement, such policy judgments are not permitted.

SPS Article 5 outlines the procedures Members must follow when assessing risk and determining their appropriate levels of protection. It repeatedly cautions Members to take into account possible negative trade effects when setting their appropriate level of protection. For example, Article 5.4 reads: "Members should, when determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing negative trade effects."<sup>27</sup> Article 5.6 adds: "Members shall ensure that such [SPS] measures are not more trade-restrictive than required. . . ."<sup>28</sup>

The WTO cases involving the EU's ban on beef hormones and Japan's testing requirements for fruit demonstrate how the SPS Agreement's rules undermine the precautionary principle and nations' sovereign power to protect their citizens from potential harm. In both cases, the WTO panels held that protective regulations amounted to trade barriers. The next health/environmental law the U.S. challenges in the WTO may be the EU's ban on genetically modified foods, described in greater detail above.

**Topic:** *Agreement on Technical Barriers to Trade (TBT Agreement)*

**Contact:** See the above information under the SPS Agreement.

The TBT Agreement is the part of the General Agreement on Tariffs and Trade (GATT) that sets criteria WTO Members must follow concerning standards, technical regulations, and conformity assessment rules. Its provisions apply to all products, including industrial and agricultural products, but not to sanitary and phytosanitary (SPS) measures. The overarching purpose of the Agreement is to make Members' standards-setting processes transparent, albeit to other Members, not to consumer and environmental groups, and to make national standards uniform.

The TBT Agreement requires Members to use international standards if such standards "exist or their completion is imminent." The Agreement requires Members to use international standards as the basis for their technical regulations and standards, unless the international standards would not be appropriate "because of fundamental climatic or geographical factors or fundamental technological problems."<sup>29</sup> If a Member adopts a standard "which may have a significant effect on trade of other Members," the Member must justify the standard to other Members upon request.<sup>30</sup> However, if a Member's standard

conforms with the relevant international standard, "it shall be rebuttably presumed not to create an unnecessary obstacle to international trade."<sup>31</sup>

The TBT Agreement also requires WTO member nations to treat imported and domestic products alike. It prohibits Members from adopting or applying standards and technical regulations in ways that create "unnecessary obstacles to international trade."<sup>32</sup> Members must maintain regulations fulfilling "legitimate objectives" - defined as "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment"<sup>33</sup> - in the least trade-restrictive manner possible, while taking into account the risks non-fulfilment of such regulations would create.<sup>34</sup> However, in assessing such risks, the only factors Members may consider are "available scientific and technical information, related processing technology or intended end-uses of products."<sup>35</sup>

As with the SPS Agreement, the TBT rules give almost absolute authority to international standards-setting organizations, such as the Codex Alimentarius Commission (Codex) and the International Organization for Standardization (ISO). Although official representation at Codex is through governments, it has been dominated by corporate interests, to the exclusion of consumer interests. For example, one study found that twenty-six percent of all participants on Codex working committees, which establish food safety standards, represented corporate interests while less than one percent represented consumer interests.<sup>36</sup>

The list of corporations with formal roles as members of country delegations at Codex included Nestle, Coca-Cola, Bayer, Monsanto, Pfizer, Kraft, BASF, Pepsico, M&M Mars, Dupont, Shell, Tyson Foods, Hershey, and Dole.<sup>37</sup> Many large transnational agribusiness and chemical corporations with representatives on member nations' Codex delegations have more representatives than some developing nations. Not surprisingly, consumer groups have criticized Codex for promoting trade rather than protecting health and the environment.<sup>38</sup>

The ISO is a private-sector body made up of industry representatives that, until a few years ago, developed technical standards (e.g. the standard size of a light bulb) for industry. However, it recently began producing environmental standards under a program called ISO 14000. Even though the TBT Agreement designates ISO standards by name as presumptively

trade-legal, consumer groups, and even government officials, have been excluded from ISO's standards-developing process.

In fact, according to a report for the European Environment Bureau, ISO's standards drafting committee is "made up principally of executives from large international corporations, national standards-setting firms and consulting firms."<sup>39</sup> The report continues, the ISO "has belatedly invited delegates from governments and citizen's groups; but has used this invitation, and the limited participation that ensued, to claim an openness while ignoring their substantive input."<sup>40</sup>

In addition, the TBT Agreement requires Members to consider accepting the standards of other Members as "equivalent," even if they differ, if they adequately meet the objectives of their own standards.<sup>41</sup> However, the very concept of determining whether different standards are "equivalent" has been criticized. For instance, the Community Nutrition Institute (CNI), a consumer organization focusing on food safety issues, calls equivalence determinations "bureaucratic guesswork," arguing that there is no objective basis for the claim that different standards can meet the same goals.<sup>42</sup>

Finally, the TBT Agreement requires member nations to ensure that their local governmental bodies, which, in the U.S., includes state, county, and municipal governments, comply with the Agreement's terms.<sup>43</sup> This is not an issue, when state regulations mirror the corresponding federal regulations. However, a few states, most notably California, employ public referendums to pass consumer and environmental protection standards that are more stringent than federal or international standards.

While no such state standards have been challenged under the TBT Agreement, the threat exists. For example, in 1998 the EU and Japan filed a complaint with the WTO against a Massachusetts selective purchasing law, claiming that it violated the part of the GATT treaty covering government procurement. The WTO formed a Dispute Settlement Body to hear the complaint, but the countries suspended their complaint after a U.S. court struck down the Massachusetts law under the U.S. Constitution. While the complaint was not based on the TBT Agreement, it shows that state, county, and municipal laws and regulations may be challenged under the international trade treaties.

## FEDERAL REGISTER ALERTS

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**Topic:** *Genetically-Engineered Rice*  
**Action:** Petition for Determination of Non-regulated Status  
**Venue:** Animal and Plant Health Inspection Service (APHIS)  
**FR Cite:** 64 Fed. Reg. 3924 (January 26, 1999)  
**Deadline:** Written comments must be received on or before March 29, 1999  
**Contact:** For more information, Dr. David Heron, Biotechnology and Biological Analysis, PPQ, APHIS, Suite 5B05, 4700 River Road Unit 147, Riverdale, MD 20737-1236; Tel.: (301) 734-5141. To get a copy of the petition, contact Ms. Kay Peterson at (301) 734-4885 or by e-mail at Kay.Peterson@usda.gov. Submit an original and 3 copies of written comments to Docket No. 98-126-1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

On November 25, 1998, AgrEvo USA Company submitted a petition to the U.S. Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) seeking a determination of non-regulated status for rice (named "Liberty Link" Rice Transformation Events) which the company has genetically engineered to tolerate the herbicide glufosinate. APHIS is soliciting public comment on whether this rice poses a plant pest risk. If APHIS approves the petition, it will no longer regulate "Liberty Link" rice, which means AgrEvo will be able to plant the rice without any restrictions.

APHIS currently regulates the rice because it contains gene sequences from a plant pathogen and thus is considered a possible plant pest. The Federal Plant Pest Act defines a "plant pest" as any living organism "which can directly or indirectly injure or

cause disease or damage in any plants or parts thereof, or any processed, manufactured or other products of plants." APHIS interprets the plant pest language very broadly, applying it to damage to crops, native plants, and organisms that may be beneficial to plants (e.g. honeybees). AgrEvo has conducted field trials of "Liberty Link" rice under APHIS supervision since 1997 and claims these trials show the rice does not pose a plant pest risk.

At the close of the comment period, APHIS will review the data submitted by AgrEvo along with all the written comments it receives and any other relevant information. Based on this information, APHIS will either deny the petition or approve it in whole or in part. Then APHIS will publish a Federal Register notice announcing its decision.

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**Topic:** *Child Restraint Systems*  
**Action:** Review of Federal Motor Vehicle Safety Standards  
**Venue:** National Highway Traffic Safety Administration (NHTSA)  
**FR Cite:** 64 Fed. Reg. 4834 (February 1, 1999)  
**Deadline:** Written comments must be received on or before April 2, 1999  
**Contact:** For more information, Nita Kavalauskas, Office of Regulatory Analysis and Evaluation, Office of Plans and Policy, National Highway Traffic Safety Administration, Room 5208, 400 Seventh Street, SW, Washington, DC 20590; Tel.: (202) 366-2584; Fax: (202) 366-2559. Submit one original and two copies of written comments to Docket Management, Room PL-401, 400 Seventh Street,

SW, Washington, DC 20590. Comments must refer to Docket No. NHTSA-99-5025 and should not be more than 15 pages long.

NHTSA is reviewing the Federal Motor Vehicle Safety Standard No. 213 for Child Restraint Systems to determine whether to retain, rescind, or modify it. The rule sets minimum performance standards for child restraint systems in motor vehicles and aircraft.

Specifically, the rule establishes requirements for child restraint systems such as the height and width of the seat back surface, padding on surfaces contacted by the child's head, the locations of surfaces in front of the seated child, belt buckles and their releases, and seat belt material. The rule requires manufacturers to place a permanent label on each restraint system, stating the heights and weights of children for whom the restraint system will protect, warning of the possible risks of using rear-facing child restraint systems in the front seat of vehicles with passenger-side air bags, and listing the manufacturer's address and the U.S. Government's Auto Safety Hotline toll-free number. It also requires manufacturers to supply,

at the time of sale of the restraint system, a postage-paid registration card so that the manufacturer can notify the purchaser in the event of a recall.

NHTSA is required by the Regulatory Flexibility Act to periodically review rules to determine if they have a significant economic impact on a substantial number of small businesses. The agency determined that the child restraint system standard may have such an impact, and is requesting comments from interested parties on the following subjects: (1) the benefits and utility of the rule in its current form; (2) the continuing need for the rule; (3) the rule's complexity; (4) whether and to what extent the rule overlaps, duplicates, or conflicts with other federal, state, and local rules; (5) any new technological or economic developments affecting the ability of affected manufacturers to comply with the standard; and (6) alternatives to the rule that would minimize impacts on small businesses while maintaining NHTSA's safety objectives.

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**Topic:** *Motor Vehicle Content Labeling*  
**Action:** Notice of proposed rulemaking  
**Venue:** National Highway Traffic Safety Administration (NHTSA)  
**FR Cite:** 64 Fed. Reg. 6021 (February 8, 1999)  
**Deadline:** Written comments must be received by April 9, 1999  
**Contact:** For more information on non-legal issues, Henrietta Spinner at (202) 366-4802, or Office of Planning and Consumer Programs, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590; on legal issues, Edward Glancy at (202) 366-2992, or Office of the Chief Counsel, National Highway Traffic Safety Administration, 400 Seventh Street, SW, Washington, DC 20590. Submit two copies of written comments to Docket Management, Room PL-401, 400 Seventh Street, SW, Washington, DC 20590. Comments should refer to Docket No. NHTSA-98-5064, and should not be more than 15 pages long.

NHTSA is proposing to amend its regulation implementing the American Automobile Labeling Act (AALA), which requires passenger motor vehicles to be labeled with information specifying their domestic and foreign parts content. Congress recently amended the AALA, and NHTSA reports that its proposed changes to the regulation would make it consistent with Congress's amendments.

NHTSA's proposed changes are mostly technical. For example, current NHTSA regulations specify that equipment is considered 100 percent U.S./Canadian if it contains at least 70 percent value added in the U.S. or Canada ("roll up" provision), but is considered zero percent U.S./Canadian if it contains less than 70 percent value added in the U.S. or Canada ("roll down" provision). NHTSA is proposing to

eliminate the “roll down” provision and require suppliers whose equipment contains less than 70 percent U.S./Canadian content to value, and report, the U.S./Canadian content of their products to the nearest five percent. For instance, a supplier whose product contained 48 percent U.S./Canadian value would report to the manufacturer a U.S./Canadian content of 50 percent.

In addition NHTSA is proposing to allow automobile manufacturers to voluntarily place on

vehicles labels specifying U.S./Canadian content based on the assembly plant in which the vehicle was assembled. NHTSA also proposes to default the value of small parts (such as nuts, bolts, and screws) to the country where the automobile is assembled. Currently, these small parts are not considered in determining parts content. NHTSA proposes to apply these amendments to all model year 2000 automobiles that are offered for sale to consumers on or after June 1, 1999.

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**Topic:** *EPA Pesticide Guidelines*  
**Action:** Notice of Public Availability  
**Venue:** Environmental Protection Agency (EPA)  
**FR Cite:** 64 Fed. Reg. 5796 (February 5, 1999)  
**Contact:** Dr. Stephen C. DeVito, Office of Pesticide Programs, Health Effects Division (7509C), Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460; Tel.: (703) 308-9584; Fax: (703) 308-7157; devito.steve@epamail.gov. To get a copy of this document electronically, visit [www.epa.gov/pesticides](http://www.epa.gov/pesticides), select “TRAC”, and find the entry entitled “Guidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity.” To get a copy via fax, use a faxphone to call (202) 401-0527 and select item 6055 or follow the automated menu.

EPA has made available to the public its “Guidance for Identifying Pesticide Chemicals and Other Substances That Have a Common Mechanism of Toxicity.” This document describes the approach the EPA will use for identifying and classifying pesticides and other substances that cause a common toxic effect by a common mechanism in order to assess the cumulative toxic effects of such substances on human health.

More specifically, the document describes: (1) the specific steps EPA will take to identify mechanisms of toxicity of pesticides and other substances that cause a common toxic effect; (2) the types of data that EPA needs to do so; (3) how EPA will use this data in reaching conclusion regarding commonality of toxicity mechanisms; and (4) the criteria EPA will use for categorizing pesticides and other substances to assess cumulative risk.

**Topic:** *U.S./E.C. Mutual Recognition Agreement (MRA)*  
**Action:** Notice of Public Availability  
**Venue:** Food and Drug Administration (FDA)  
**FR Cite:** 64 Fed. Reg. 5302 (February 3, 1999)  
**Deadline:** Written comments may be submitted at any time  
**Contact:** For more information, or to submit written comments, contact John F. Stigi, Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850; Tel.: (301) 443-6597; Fax: (301) 443-8818. To get a copy of this document electronically, visit [www.fda.gov/cdrh](http://www.fda.gov/cdrh) and find the entry entitled

“Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).”

The FDA has made available to the public its “Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA).” Under the MRA, the FDA has agreed to designate private organizations as “conformity assessment bodies” (CABs) - third parties authorized to perform premarket and quality system evaluations of companies that produce medical devices. The FDA document provides guidance for organizations designated as CABs.

The MRA, which went into effect on December 7, 1998, provides for a 3-year transition period. After that time, the FDA and the European Community (E.C.) will endorse premarket and quality

system evaluation reports of medical devices manufacturers provided by private CABs. In effect, private organizations will be performing the inspection and quality/safety management duties that previously were performed by governmental bodies.

The FDA stresses that “in order to establish confidence in the conformity assessment process,” CABs will be required to participate in “rigorous” exercises to demonstrate their ability to conduct evaluations adequately. However, health groups, such as Public Citizen’s Health Research Group, have criticized the FDA for allowing private, third-party organizations to perform evaluations of manufacturers making any product regulated by the FDA, especially medical devices.

**Topic:** *Labeling of Irradiated Foods*  
**Action:** Proposed Rule  
**Venue:** Food and Drug Administration (FDA)  
**Deadline:** Written comments must be received by May 18, 1999  
**Contact:** Patricia A. Hansen, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C Street, SW, Washington, DC 20204; Tel.: (202) 418-3093. Submit written comments to: Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852; or by e-mail to [FDADockets@bangate.fda.gov](mailto:FDADockets@bangate.fda.gov).

The FDA is soliciting public comment on whether changes should be made to FDA regulations requiring irradiated foods to be labeled as such. Currently, the regulations require retail packages or displays of irradiated foods to conspicuously display both the logo for irradiation and a statement such as “treated by irradiation.” The FDA is asking whether such labeling should be less prominently displayed - for instance by placing the irradiation statement in the list

of ingredients.

Pro-irradiation groups have argued for such less-prominent labeling, and even for no labeling, claiming irradiation has been deemed safe. They believe the labels prevent consumer acceptance of irradiated foods. However, others argue that consumers need conspicuous labeling to make informed choices among products.

**Topic:** *Irradiation of Meat and Meat Products*  
**Action:** Proposed Rule

**Venue:** Food Safety and Inspection Service (FSIS)  
**FR Cite:** 64 Fed. Reg. 9089 (February 24, 1999)  
**Deadline:** Written comments must be received by April 26, 1999  
**Contact:** Daniel L. Engeljohn, Director, Regulation Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture at (202) 720-5627. Submit one original and two copies of written comments to FSIS Docket # 97-076P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12<sup>th</sup> Street, SW, Washington, DC 20250-3700.

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) is proposing to change its meat and poultry inspection regulations to allow the voluntary use of radiation to treat refrigerated or frozen uncooked meat, meat byproducts, and certain other products to reduce food-borne microbial pathogens (such as Salmonella and E. coli), eliminate insects, and increase shelf-life. Food irradiation is the process of subjecting food to high levels of radiant energy, including microwave, ionizing, and infrared radiation; and visible and ultraviolet light. The FSIS also is proposing labeling requirements for irradiated meat products.

The Federal Food, Drug, and Cosmetic Act (FFDCA) classifies irradiation as a "food additive," and since the Food and Drug Administration (FDA) is responsible for determining whether food additives are safe, the FSIS had to wait until the FDA authorized food irradiation before it could propose these amendments. On December 3, 1997, the FDA authorized the use of irradiation for several meat and meat byproducts, including ground beef, hamburger, poultry, liver, kidneys, and pork. The FDA concluded that irradiation was effective in reducing microbial pathogens in raw meat, would not pose toxicological or microbiological risks, and would not affect the nutritional content of these products.<sup>44</sup> Thus, the FSIS proposes to amend its meat inspection regulations to conform with the FDA's decision.

The FSIS also proposes to require packaged meat and meat products irradiated in their entirety to be labeled with the radura symbol and a "disclosure statement" indicating the meat was irradiated, such as "irradiated chicken" or "pork treated by irradiation." The radura symbol would have to be placed

"prominently and conspicuously" on the label, and the statement would have to "appear as a qualifier contiguous to the product name."<sup>45</sup> For unpackaged meat and meat products entirely irradiated, the FSIS would require the symbol and disclosure statement to be prominently and conspicuously displayed to consumers on a bulk container or in some other appropriate manner. If an establishment uses irradiated meat as an ingredient in a multi-ingredient product, it would have to include in the ingredient section one of the above disclosure statements (e.g. "irradiated pork"). However, the disclosure statement would not have to be any more prominent than the other listed ingredients.

The FSIS assumes that the use of irradiation will decrease pathogens, and the resulting human illnesses, by 25% over the next 20 years, which would translate into economic benefits ranging from \$56.5 million to \$138 million. The FSIS admitted that initially consumer acceptance of irradiated meat products "may be slow."<sup>46</sup> However, the agency believes that as consumers become informed about the safety of irradiated meat, acceptance will increase at a rate equal to the assumed reduction in food-borne illnesses.

The FSIS emphasizes that the use of irradiation will be voluntary: "The meat industry will not be required to have their products irradiated, nor will consumers be forced to purchase irradiated meat products." However, it was a member of the meat industry, Isomedix, Inc., that initially petitioned the FDA to authorize food irradiation, and, if all meat and poultry processors decide to irradiate their products, consumers **will** be forced to purchase irradiated meat.

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**Topic:** *Implementation of the U.S. - E.U. Pharmaceutical Mutual*

*Recognition Agreement*

- Action:** Establishment of a public docket and FDA contact points
- Venue:** Food and Drug Administration (FDA)
- FR Cite:** 64 Fed. Reg. 11376 (March 9, 1999)
- Deadline:** Written comments may be submitted at any time
- Contact:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. FDA also will publish information concerning the implementation of the MRA on its web site at [www.fda.gov](http://www.fda.gov), under the "International" heading.

For more information on human drug good manufacturing practices (GMPs), contact Brian J. Hasselbalch, Division of Manufacturing and Product Quality (HFD-325), Office of Compliance, Center for Drug Evaluation and Research, FDA, 7520 Standish Pl., Rockville, MD 20855-2737, Phone - (301) 827-7285, Fax - (301) 594-2202, E-mail - [hasselbalch@cder.fda.gov](mailto:hasselbalch@cder.fda.gov).

For more information on animal drug GMPs, contact Judith A. Gushee, Office of Surveillance and Compliance (HFV-232), Center for Veterinary Medicine, FDA, 7500 Standish Pl., Rockville, MD 20855-2773, Phone - (301) 827-0150, Fax - (301) 594-1807, E-mail - [jgushee@bangate.fda.gov](mailto:jgushee@bangate.fda.gov).

For more information on human biologic GMPs, contact Jennifer A. Thomas, Office of Compliance and Biologics Quality (HFM-600), Center for Biologics Evaluation and Research, FDA, 1401 Rockville Pike, Rockville, MD 20852-1448, Phone - (301) 827-6190, Fax - (301) 594-1944, E-mail - [thomasj@cber.fda.gov](mailto:thomasj@cber.fda.gov).

For more information on 510(k) medical devices, contact Eric J. Rechen, Office of Device Evaluation (HFZ-402), Center for Devices and Radiological Health, FDA, 9200 Corporate Blvd., Rockville, MD 20850, Phone - (301) 594-2186, Fax - (301) 594-2977, E-mail - [ejr@cdrh.fda.gov](mailto:ejr@cdrh.fda.gov).

For more information on device quality systems and GMPs, contact Kimberly A. Trautman,

Office of Compliance (HFZ-340), Center for Devices and Radiological Health, FDA, 2094 Gaither Road, Rockville, MD 20850, Phone - (301) 594-4646, Fax - (301) 594-4672, E-mail - [kat@cdrh.fda.gov](mailto:kat@cdrh.fda.gov).

For more information on third-party program administrative matters and general MRA matters, contact John F. Stigi, Division of Small Manufacturers Assistance (HFZ-220), Office of Health and Industry Programs, Center for Devices and Radiological Health, FDA, 1350 Piccard Dr., Rockville, MD 20850, Phone - (301) 443-7491, Fax - (301) 443-8818, E-mail - [jfs@cdrh.fda.gov](mailto:jfs@cdrh.fda.gov).

Under the terms of the Mutual Recognition Agreement (MRA) between the U.S. and the European Union, which went into effect on December 7, 1998, an importing country's agency (e.g. FDA in the U.S.) may endorse pharmaceutical GMP inspection reports and quality system audits provided by exporting countries' agencies determined to be equivalent to the importing country's agency. In addition, an importing country's agency may endorse medical device product evaluation reports performed by exporting countries' third-party conformity assessment bodies (CABs). In other words, under the MRA, the FDA is abdicating its authority to inspect foreign pharmaceutical manufacturers not only to foreign nations' agencies but also to private, third-party organizations, if the FDA determines their requirements and inspection practices are equivalent to FDA's.

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## UPCOMING MEETINGS/EVENTS

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- Event:** *U.S. Codex Committee on Food Labeling (CCFL) Meeting*
- Date:** March 16, 1999, 1:30-4:30 p.m.
- Location:** Food and Drug Administration, Room 1813, 200 C Street, SW, Washington, DC.

**Contact:** Theresa Thomas at (202) 205-4210 (Tel.), or (202) 205-4594. If you plan on attending the meeting, you must RSVP no later than March 10, 1999.

This U.S. Codex Committee is holding a public meeting to review and discuss the agenda items scheduled for consideration at the 27<sup>th</sup> Session of the CCFL, which will take place April 27-30 in Ottawa, Canada. The Committee also will begin the selection process for members of the U.S. Delegation, which is limited to 25 members, to the CCFL.

U.S. Codex has distributed the proposed U.S. positions on several of the items coming before the CCFL at the 27<sup>th</sup> Session: The Labeling of Foods That Can Cause Hypersensitivity; The Guidelines for the Production, Processing, Labeling, and Marketing of

Organically Produced Foods; The Labeling of Foods Obtained Through Biotechnology; The Labeling of Prepackaged Foods; and The Guidelines on Nutrition Labeling.

This will be the last meeting of the U.S. CCFL before the 27<sup>th</sup> Session of the CCFL in Ottawa. Thus members of the public wishing to make comments at this meeting should be prepared to submit written copies of their comments. For more information on the 27<sup>th</sup> Session of the CCFL and the items on its agenda, see the notice below.

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**Event:** *27<sup>th</sup> Session of the Codex Committee on Food Labeling*  
**Dates:** April 27-30, 1999  
**Location:** Main Conference Room, Government Conference Centre, 2 Rideau Street, Ottawa, Canada  
**Contact:** Ron B. Burke, Director, Bureau of Food Regulatory International and Interagency Affairs, Health Protection Branch, Health Canada, HPG Bldg., Room 200, Tunney's Pasture, Ottawa K1A 0L2, Canada; Telefax: 613.941.3537. The Session will be conducted in English, French, and Spanish. Those planning on attending should RSVP by March 26, 1999.

The Session is open to Member Nations and Associate Members of the United Nations and the World Health Organization, and to observers. Member Nations and Associate Members of the UN and the WHO which are not members of Codex will be allowed to attend as observers only. Individual citizens and representatives of non-governmental organizations who are not part of their government's delegation will not be allowed to attend, even as observers.

The proposed agenda items for the Session include: Draft Guidelines for the Production, Processing, Labeling, and Marketing of Organically Produced Foods; Draft Amendments to the General Standard for the Labeling of Prepackaged Foods; Proposed Draft Recommendations for the Labeling of

Foods obtained through Biotechnology (also known as "genetically modified foods"); Proposed Draft Amendment to the Guidelines on Nutrition Labeling; Proposed Draft Recommendations for the Use of Health Claims; Proposed Draft Recommendations for Sport and Energy Drinks; and Proposed Draft Guidelines for the Use of the Term "Vegetarian."

The government members of the U.S. Delegation will be staying at Les Suites Hotel Ottawa, 130 Bresser Street from Sunday, April 25 through Friday, April 30. The U.S. Delegation will meet with interested parties on Monday, April 26, at 6 p.m. in the "Byward Suite" in the Les Suites Hotel Ottawa to discuss comments, concerns, and developments that may affect the CCFL Session.

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**Event:** *U.S. Codex Committee on General Principles Meeting*  
**Date:** March 17, 1999, 1:00 - 4:00 p.m.

**Location:** Room 107-A, Jamie L. Whitten Building, U.S. Department of Agriculture, 1400 Independence Avenue, SW, Washington, D.C. 20250-3700.

**Contact:** Patrick J. Clerkin, Associate U.S. Manager for Codex, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue, SW, Washington, D.C. 20250-3700; Tel.: (202) 205-7760; Fax: (202) 720-3157.

This U.S. Codex Committee is holding a public meeting to provide information and receive comments on agenda items up for discussion at the Fourteenth Session of the Codex Committee on General Principles (CCGP), which will be held in Paris, France, April 19 - 23, 1999. The CCGP deals with procedural and general matters referred to it by the full Codex Alimentarius Commission, including the general principles defining the purpose and scope of Codex, the development of guidelines, and the nature

of Codex standards.

Specific issues to be discussed at the March 17<sup>th</sup> meeting include: (1) special treatment of developing nations; (2) definitions and principles for risk analysis; (3) measures for facilitating consensus; (4) review of the Technical Barriers to Trade Agreement; (5) review of the role of science and the extent to which other factors should be taken into account in risk analysis; and (6) revision of the procedural manual.

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**Event:** *Public Meeting on the Equivalence Evaluation Process*

**Date:** April 14, 1999, 9:00 a.m. to 3:00 p.m.

**Location:** Washington Plaza Hotel, 10 Thomas Circle, NW (at Massachusetts Avenue and 14<sup>th</sup> Street), Washington, D.C. 20009, (202) 842-1300.

**Deadline:** Written comments should be received by May 11, 1999

**Contact:** Mark Manis, Director, International Policy Division, Office of Policy, Program Development, and Evaluation at (202) 720-6400 or by e-mail at mark.manis@usda.gov

The Food Safety and Inspection Service (FSIS) is holding a public meeting to discuss the equivalence evaluation process. FSIS is also announcing the publication of a document, entitled "FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Regulatory Systems," describing its process for evaluating foreign meat and poultry inspection systems to determine whether they are equivalent to the U.S. system. Copies of this document are available from the FSIS Docket Clerk, Room 102 Cotton Annex, 300 12<sup>th</sup> Street, SW, Washington, D.C. 20250-3700, or from the FSIS web site at [www.fsis.usda.gov](http://www.fsis.usda.gov). Written comments on this document must refer to Docket #99-009N and be submitted in triplicate to the FSIS Docket Clerk at the above address or by fax at (202) 205-0381.

"Equivalence" is a concept applied to the evaluation of sanitary and phytosanitary measures taken by nations to protect human, animal, or plant life or health. Article 4 of the Sanitary and Phytosanitary Agreement (SPS Agreement), to which the U.S. is a signatory, requires importing nations to accept exporting nations' SPS measures as equivalent if the exporting nations objectively demonstrate that their measures achieve the importing nations' "appropriate level of protection." In other words, the U.S. must accept as equivalent to its own food inspection system the food inspection systems of other WTO member nations that have been demonstrated to provide the same level of health protection, even if they are different.

## NOTES

1. Matthew Stilwell and Brennan Van Dyke, *An Activist's Handbook on Genetically Modified Organisms and the WTO*, Center for International Environmental Law, Mar. 1999, at 2.
2. *Id.*, at 5.
3. *Id.*, at 3.
4. *Id.*
5. "Motivated to Modify Foods," *New Straits Times* (London), Mar. 10, 1999, at A4.
6. U.S. Consumer's Choice Council, Letter to The Honorable Frank Loy, Under Secretary for Global Affairs, U.S. Department of State, Feb. 9, 1999.
7. *Id.*
8. Charles Clover and George Jones, "Government Stifled Report on GM Risks," *The Daily Telegraph* (London), Feb. 17, 1999.
9. James Meikle and Paul Brown, "Friend in Need. . .The Ladybird, an Agricultural Ally Whose Breeding Potential May Be Reduced by GM Crops," *Guardian* (London), Mar. 4, 1999.
10. U.S. Consumer's Choice Council Letter, *supra*, note 6.
11. "Top Scientist Backs Calls for GM Safety Screen," *Guardian* (London), Mar. 9, 1999.
12. "Member States Should Be Able to Ban GM Crops in Sensitive Areas, Parliament Says," *International Environment Reporter*, Feb. 17, 1999, at 143.
13. Frederick Noronha, "India's High Court Stops Field Trials of Biotech Cotton," *Environment News Service*, Feb. 23, 1999.
14. "Australian, New Zealand Health Ministers Recommend Labeling of Genetically Modified Foods," *World Food Chemical News*, Jan. 6, 1999, at 1.
15. Ricardo Maldonado, "Biotech Industry Discusses Trade," *Associated Press*, Feb. 22, 1999.
16. "EU Accuses US, Others of 'Extreme' Positions That Will Block Biosafety Protocol," *International Environment Reporter*, Feb. 17, 1999, at 136.
17. *Id.*
18. *Id.*, at 137.

19. “Member States Reject Application for Two Genetically Modified Cotton Seeds,” *International Environment Reporter*, Feb. 17, 1999, at 138.

20. Sean Poulter, “Blank Out Labels, Says U.S.,” *UK Daily Mail*, Feb. 11, 1999.

21. World Trade Organization, *Agreement on the Application of Sanitary and Phytosanitary Measures*, Art. 2, para. 1, available at [www.wto.org/wto/goods/spsagr.htm](http://www.wto.org/wto/goods/spsagr.htm) as of Mar. 12, 1999.

22. *Id.*, at Art. 2, para. 2.

23. *Id.*, at Art. 3, para. 3.

24. *Id.*, at Footnote 2.

25. *Id.*, at Annex A (Definitions), para. 5.

26. The Agreement also refers to this as “acceptable level of risk.” Again, the word “acceptable” is unnecessary, except to subject a Member’s level of risk to a WTO challenge if it provides more consumer protection than the relevant international standard.

27. *Id.*, at Art. 5, para. 4.

28. *Id.*, at Art. 5, para. 6.

29. *Id.*, at Art. 2.4.

30. *Id.*, at Art. 2.5.

31. *Id.*

32. OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, *THE TEXT OF THE WORLD TRADE ORGANIZATION AND FINAL ACT EMBODYING THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS (1994)* at Art. 2.2, p. 118.

33. *Id.*, at Art. 2.2.

34. *Id.*, at Art. 2.3.

35. *Id.*, at Art. 2.2.

36. NATALIE AVERY, MARTINE DRAKE, AND TIM LANG, *CRACKING THE CODEX: AN ANALYSIS OF PARTICIPATION ON CODEX ALIMENTARIUS COMMISSIONS WHICH SET INTERNATIONAL FOOD STANDARDS (1993)*, at 1.

37. *Id.*, at 19.

38. See Community Nutrition Institute, *Comments on Draft Guidance on Equivalence Criteria for Food*, Jul. 16, 1997, at 2-3.

39. Benchmark Environmental Consulting, *ISO 14001: An Uncommon Perspective - Five Public Policy Questions for Proponents of the ISO 14000 Series* (Nov. 1995), report produced for the European Environment Bureau, at 13.

40. *Id.*, at 11. One of the five questions asked in this report is “Can ISO 14001 become an international trade standard without operative participation from governments or NGOs?” The answer is “Yes.” *Id.* The report also notes, “Decision-making in ISO is by member associations and firms. Other participants, while they may be invited and are recorded as ‘participants’ in a ‘consensual’ decision-making process, do not have voting rights.” *Id.*, at 12.

41. WTO TEXT, *supra* note 29, at Art. 2.7.

42. Community Nutrition Institute, *Comments on Agenda for U.S. Position on Draft Guidelines for Development of Equivalence Agreements*, Jan. 11, 1999, at 2.

43. WTO TEXT, *supra* note 29, at Art. 3.1.

44. *See* 64 Fed. Reg. 9090.

45. 64 Fed. Reg. 9093.

46. 64 Fed Reg. 9098.