

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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INVASIVE SPECIES

- Topic:** *New Equivalency Provisions for Irradiation of Imported Fruits and Vegetables*
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On May 26, 2000, the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) proposed a new rule to allow the use of irradiation of imported fruits and vegetables as a treatment to control fruit flies and mango seed weevils.¹ A number of countries already have notified APHIS of their intent to use irradiation on produce exported to the U.S. when the rule becomes final, among them Brazil, Costa Rica, Guatemala, Mexico, Turkey, New Zealand and Australia.²

In comments on the proposed rule, the Organic Consumers Association and others pointed out that the rule failed to address important questions about monitoring and inspection of overseas operations.³ In response, APHIS published a supplement to the proposal on March 15, 2002.⁴ The supplement is designed to incorporate the

“equivalency” provisions of the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) into the pending regulation. Article 4.1 of the SPS Agreement requires countries to “accept the sanitary or phytosanitary measures of other Members as equivalent, even if those measures differ from their own ...”⁵ This provision has been read to mean that different, and possibly less protective regulatory systems and standards in other countries can be declared “equivalent” to the U.S. regulatory system. Such equivalency agreements are designed to allow goods produced under “equivalent” systems to cross borders without reinspection by the importing country.

The supplement to the proposed rule on fruit and vegetable irradiation would require APHIS to enter into “irradiation treatment framework equivalency work plans”

with plant protection agencies in other countries. The purpose of the work plans is to set out the type and extent of monitoring that will be required for each country's irradiation program, and to assign responsibility for inspection on a country-by-country basis. If adopted, this new policy could turn over APHIS' oversight responsibility for protecting the U.S. from potentially-devastating invasive pests to the plant protection agencies of other countries. Despite this significant shift, APHIS has not said if it plans to develop an equivalency policy for public comment, nor has it committed to making the work plans publicly available prior to their implementation.

Irradiation is currently approved by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) for limited uses, among them killing pathogens in meat, eggs, spices and seasonings; inhibiting sprouting in potatoes; and destroying arthropod pests.⁶ Irradiation currently is approved by USDA to reduce pathogens and extend the shelf-life of meat and poultry products, to control Mediterranean fruit flies in areas of infestation in the U.S., and to control pests on various fruits and vegetables shipped from Hawaii to the mainland.⁷ In a new section entitled "Phytosanitary Treatments," the proposed APHIS rule sets minimum radiation dosage requirements to control eleven listed species of fruit fly and one species of mango seed weevil, in amounts ranging from .1 to .25 kGy.⁸ In addition, the proposed rule sets certain requirements for the operation of facilities performing irradiation and for the packaging and handling of irradiated foods, and adds irradiation as a permitted treatment listed in APHIS' Plant Protection and Quarantine Treatment Manual. [See, "Irradiation of Imported Fruits and Vegetables," *Harmonization Alert*, May/June 2000.] The supplement to the proposed rule would add two new sections to the regulation: (1) Monitoring and interagency agreements; and (2) indicators and tests to identify irradiated fruits and vegetables.⁹

Monitoring and Interagency Agreements: The proposed rule includes many of the same elements required by APHIS' existing regulations governing irradiation to control Mediterranean fruit flies and pests on Hawaiian produce: (1) Irradiation facilities must be approved by APHIS; (2) In order to be approved, facilities must be capable of administering the required minimum dose, meet certain construction requirements concerning physical barriers and separation of treated items, and enter into compliance agreements with APHIS; (3) Dosimetry systems (measurement instruments to determine dosage) and their associated standards and procedures, must comply with certain American Society for Testing and Materials standards; and (4) Treatment must be monitored by an "inspector."¹⁰

However, there are several significant differences between the existing rules governing irradiation of domestic produce and the proposed rule regarding irradiation of imported produce. For instance, APHIS is required to approve facilities that irradiate domestic produce annually, but the proposed rule does not require annual re-certification of facilities that irradiate produce for export to the U.S.¹¹ For facilities that irradiate domestic produce, APHIS monitors adherence to the compliance agreement, but the supplement to the proposed rule requires that the country's plant protection service where the irradiation facility is located agree to monitor compliance and report violations to APHIS.¹² Finally, the regulations governing irradiation of Hawaiian produce define "inspector" as an employee of APHIS or a state regulatory official who has certain qualifications, but the proposed rule defines "inspector" as an employee of APHIS "or other person, authorized by the Administrator in accordance with law to enforce the provisions of the regulations."¹³

Not only will imports be treated differently from domestic products under the proposed rule, but products from different countries will be subjected to differential treatment on a country-by-country basis. The stated intent of the new section on monitoring and interagency agreements in the supplement to the proposed rule is to allow APHIS to provide differing levels of inspection and monitoring, depending on its assessment of situations in different countries. The level of oversight could range from intermittent monitoring of operations and inspection of records to a continual APHIS presence at facilities and regular inspection of untreated and treated fruits and vegetables. Three agreements must be in place between APHIS and the plant protection service of the other country before goods may be brought into the U.S. under this rule:

(1) an "irradiation treatment framework equivalency work plan" in which APHIS and the foreign plant protection service each identify any requirements that apply to the importation of irradiated fruits and vegetables into their respective countries, the type and amount of inspection, monitoring, or other activities that will be required, and any other conditions that must be met to allow importation;

(2) an annual "facility preclearance work plan" detailing the activities that APHIS and the foreign plant protection service will carry out in connection with each irradiation facility to verify its compliance, such as frequency of visits by inspectors, methods for reviewing facility records, and methods for verifying compliance with requirements for separation of articles, packaging, and labeling;

(3) and, a trust fund agreement requiring the

foreign plant protection service to pay, in advance of each shipping season, all costs that APHIS estimates it will incur in providing monitoring and inspection services.¹⁴

Under the proposed rule and supplement, the oversight to which imported produce sold in the U.S. is subjected would not be required to be identical to the oversight to which domestic produce is subjected. For example, the facilities in which Hawaiian produce is irradiated are required to be approved annually by APHIS.¹⁵ Treatments must be conducted under the actual observation of an inspector.¹⁶ Although the regulations allow inspectors to be either APHIS employees or Hawaii state regulatory officials, in practice APHIS has retained responsibility for monitoring treatment at the one irradiation facility now in operation in Hawaii and actually is present in the plant on an almost daily basis.¹⁷ By contrast, under the proposed rule, a facility in another country that has once been certified by APHIS only would have to be re-certified upon the occurrence of certain specified events. Responsibility for monitoring treatment of imported produce could be transferred to the plant protection service of the country in which an irradiation facility is located and the frequency of inspection would be determined by negotiation between the agencies of the two countries.¹⁸

USDA already has a poor track record in making equivalence determinations and in monitoring imports from countries whose systems have been classified as equivalent. USDA's Food Safety and Inspection Service (FSIS) is charged with ensuring that meat, poultry, and egg products are safe, wholesome, and accurately labeled. In 1999, FSIS rated 36 countries eligible to export meat to the U.S. after classifying their inspections systems as "equivalent" to the U.S. system. When the program was evaluated by the USDA's own Inspector General in June 2000, significant deficiencies were found, including the following: 1) USDA granted equivalency status to six countries before performing onsite reviews, contrary to U.S. policy; 2) 19 countries were allowed to ship meat into the U.S. even though they had not certified that all their facilities complied with U.S. standards; and 3) USDA allowed thousands of pounds of meat from delisted plants into the U.S. because its database was not kept up to date. [See, "USDA Releases Report Criticizing FSIS Process for Determining Equivalence," *Harmonization Alert*, May/June 2000.]

Irradiation of Foods is the Subject of On-going Controversy:

Use of irradiation faces significant opposition because of safety concerns that have yet to be adequately addressed by national and international regulatory bodies. Public Citizen has requested that USDA withdraw the proposed rule. The subject of food irradiation is highly controversial. Discussions about revisions to standards for irradiated foods currently are

underway at the Codex Alimentarius Commission, the international standards-developing body empowered to set food safety standards that are presumptively legal under the WTO. The Philippines has proposed eliminating the current radiation dose limit of 10 kGys.¹⁹ Several European Commission countries want to await the results of ongoing studies into the safety of cyclobutanones, unique radiolytic products that do not occur naturally in any food and that have been linked to genetic and cellular damage to human and rat cells.²⁰ Due to the volume of comments received, the Codex committee has suspended its discussions and established a drafting group.²¹

In addition to the health and safety issues raised by the use of radiation, virtually all types of food, including fruits and vegetables, suffer significant loss of vitamins and other nutrients when exposed to radiation. For example, potatoes irradiated at 0.1 kilogray have been found to suffer a loss of beta-carotene of up to 50 percent.²² The vitamins most sensitive to radiation are A, B1 (thiamin), C and E.²³ The fact that irradiation extends the shelf-life of many fruits and vegetables increases the likelihood of loss of nutrients.²⁴

Inspection Duties Turned Over to Federal Regulators: It is unclear how APHIS will make the initial determinations about the extent of monitoring to be required for each country and about the respective responsibilities to be assigned to its own or another nations' inspectors. It is also unclear whether APHIS intends to seek public comment about these decisions. Unlike FSIS, the National Highway Traffic and Safety Administration and other agencies that make equivalence determinations, APHIS has not published an equivalence policy for public comment.²⁵ APHIS has not yet developed the list of criteria that will be used to judge equivalence.²⁶ An APHIS import specialist describes their work on equivalence as "new" and "evolving," and does not anticipate that the agency will create an equivalency policy nor publish the criteria it will use to determine equivalence in the Federal Register for public comment.²⁷ APHIS has not developed a draft work plan, and intends to develop the work plans on a country-by-country basis. In addition, APHIS considers it to be the responsibility of the plant protection services in non-English speaking countries to provide interpreters.²⁸ The issue of who pays for the significant cost of translating documents is an important one that has been highly controversial in other equivalency negotiations, namely the FDA's 1998 Mutual Recognition Agreement with the European Union.

If adopted, the proposed rule and supplement could erode food safety by opening the door to irradiated produce that has not even been found to meet the requirements of the U.S. food and agriculture regulatory system. Moreover, APHIS' sloppy implementation of the equivalency provisions of the WTO's SPS Agreement

could significantly undermine government accountability and public participation in the regulatory process.

— Winifred De Palma for *Harmonization Alert*

FOOD SAFETY

Topic: *U.S. Meat Inspection in Crisis as U.S. Continues Aggressive Effort to Export Hazard Analysis and Critical Control Point Program Internationally*

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On July 18, 2002, ConAgra Beef Company of Greeley, Colorado, recalled 19 million pounds of ground beef from super market shelves as 41 people in 12 states were sickened with E. Coli.²⁹ E. Coli 0157:H7 is a virulent form of bacteria present in the feces of slaughtered cattle. The recall was the latest in a series of events which have led a number of U.S. consumer groups to the conclusion that the U.S. meat inspection system is in crisis. Yet, despite repeated evidence that this current system is fundamentally flawed, the U.S. government is continuing an aggressive effort to export the system to the rest of the world through the harmonization requirements of the World Trade Organization (WTO).

Second Largest Recall in U.S. History: The ConAgra recall is the second largest in U.S. history. A series of fumbles and delays by the U.S. Department of Agriculture (USDA) raises serious questions about whether the outbreak could have been prevented and whether USDA officials are committed to the enforcement of U.S. food safety requirements at giant slaughter and processing operations.

Although USDA confirmed that the Greeley plant had a problem with E. Coli contamination when test results came back positive on ConAgra meat June 11 and 13, USDA continued testing and delayed notifying the company until two weeks later.³⁰ In those weeks, contaminated ground beef was distributed to retailers and was purchased by an untold number of consumers. On June 19, 2002, for instance, the Safeway grocery chain which had purchased ConAgra beef launched a six-day buy-one-get-one-free sale on ground beef.³¹ ConAgra did not initiate a recall of 354,000 pound of meat until June 30, 2002 (19 days after the first positive test) and expanded the recall to 19 million pounds on July 18, 2002.³²

While the two-week delay was reported widely and generated embarrassing press for the Department of Agriculture, Public Citizen has discovered that, in fact, USDA was informed as early as February 2002 of E. Coli contamination at the Greeley plant. John Munsell, owner

of Montana Quality Foods and Processing, a small meat grinding company, was notified by a USDA lab that meat his company was processing tested positive for E. Coli on February 19, 20, 21.³³ Munsell immediately started a trace-back of the meat and discovered that all the meat was from the same manufacturer, with the same batch number, processed on the same date.³⁴ Munsell then sent a series of e-mails to the USDA office in Minnesota urging them to take action. One email from Munsell stated that if the information was not acted upon, the result could be "a consumer sickness in America potentially much greater than what happened with Jack-in-the-Box."³⁵ (In 1993, an E. Coli outbreak swept through Jack in the Box restaurants in four western states. 700 people were sickened and four died.)

The USDA's 1996 meat inspection program called the Hazard Analysis and Critical Control Point (HACCP) program calls for zero tolerance of E. Coli and requires the random sampling of processors for the presence of the bacteria. However, after much correspondence and a meeting with USDA, Munsell discovered several other USDA policies about which he was unaware. For instance, Munsell uncovered that: USDA believed it could not classify E. Coli as an adulterant until it was actually *in* processed food; as a consequence, USDA frequently holds the company which does the final processing solely responsible for the adulteration; and, federal inspectors who discover a contaminated ground beef sample are not permitted to trace back and document the actual source of the contamination.³⁶

Public Citizen and the Government Accountability Project (GAP) called for a congressional investigation into the incident. "USDA prides itself on basing all its decisions on 'sound science.' This whistleblower's experience illustrates that a lot more than sound science is involved in USDA decision making. USDA seems to be protecting giant packers at the expense of small food processors and consumers. It may be hard to believe, but it is clearly USDA policy to obstruct

inspectors' ability to follow the science, get to the bottom of the problem, and save lives. "HACCP needs a major overhaul before it can legitimately be called a 'science-based' system," said Felicia Nestor, Food Safety Project Director, for the Government Accountability Project (GAP), a group which assists government whistleblowers.³⁷

Widespread and Systemic Problems with HACCP: The ConAgra recall is only the latest indicator of a more widespread and systemic problem with the HACCP system. Significant changes were made to the way the U.S. government regulated the federal meat inspection system when HACCP was instituted in 1996. Under the new regime, slaughter, processing and packing plants rather than U.S. government inspectors were encouraged to take on the responsibility for determining where in their production system hazards are most likely to occur and for controlling them. The role of government inspectors changed significantly. Today, inspectors spend less time inspecting product and more time inspecting the paperwork.³⁸ In addition, under HACCP, inspectors have less authority to require corrective action when they see a problem.³⁹ As part of the new regulatory system, the U.S. government launched a new salmonella testing program in an effort to see how well plants were controlling for microbiological hazards.

HAACP's promise was that scientific tools would be used to dramatically increase consumer protection. However, the evidence is mounting that USDA's program is riddled with significant flaws. While USDA's Food Safety Inspection Service (FSIS) has consistently touted the success of the program, new reports cast doubt on the agency's data.

One month before the ConAgra recall, Public Citizen and the GAP published a report entitled ***Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program.*** The report found that the government's own data does not support the assertion that the food supply has become safer for consumers of ground beef because of the HACCP program.⁴⁰ The report also found that the federal government's main microbial testing program was riddled with holes. Poor training and policy confusion among the staff resulted in large quantities of potentially contaminated ground beef moving through the system and landing on supermarket shelves.

The report discovered that when USDA analyzed the salmonella testing data, it failed to account for all failed "sample sets" indicating salmonella contamination. The agency's failure to take all the data into account suggested a drop in salmonella contamination when actually there was a slight rise. Using this method, the agency announced that salmonella contamination in ground beef had dropped from 7.5 percent to 5.8 percent,

when a complete set of the test results demonstrate that salmonella increased slightly to 7.6 percent.⁴¹

In addition, the Public Citizen/GAP study found that many of the largest ground beef plants in the United States repeatedly flunked salmonella tests but were permitted to continue sending ground beef stamped as government-approved to market.⁴² The authors obtained testing data from January 26, 1998, when the HACCP program began, through October 1, 2001. During the period analyzed, the USDA allowed failing plants to send product to market long after the sixth positive salmonella test (which means that the plant failed the set). In quantifying this delay, the study found that USDA waited a cumulative total of nearly 1,000 weeks after the sixth positive without informing plant operators of the problems or requiring them to take corrective action.⁴³ In large plants, USDA waited a cumulative total of 121 weeks before taking action.⁴⁴ During that time, the USDA knowingly allowed an estimated 218 million pounds of potentially contaminated ground beef - enough for about a billion hamburgers - to enter the market bearing the USDA seal of approval before it informed plant managers of the need for corrective action.⁴⁵

"The report shows that our confidence in the microbial testing system of HACCP has been misplaced and premature. Dirty meat from the plants in this report is reaching consumers, killing them and making them sick. It's a shame that nine years after Jack in the Box, USDA still can't get it right," said Donna Rosenbaum, food safety consultant with Food Safety Partners, and co-founder and former executive director of Safe Tables Our Priority (STOP).⁴⁶

GAO Slams HACCP and HIMP Implementation: Concerns about the HACCP program further increased when a draft U.S. General Accounting Office (GAO) study on the failure of HACCP to protect consumers from unsafe meat was leaked and made newspaper headlines on July 10, 2002. According to the *New York Times*, the leaked document described a system that was "poorly designed, badly supervised and riddled with problems."⁴⁷

The report confirmed Public Citizen's findings that often there were extensive delays in the enforcement of the requirements of the salmonella program. While HACCP regulations require that plants take immediate action to meet salmonella performance standards after a failure, the GAO found that on average, FSIS waited three months after a second set of test failures before launching an in-depth investigation.⁴⁸ In addition, the agency gave plants an average of one year and a half to remedy the contamination problems rather than demanding an immediate clean up.⁴⁹ In that time, potentially contaminated product continued to leave the plants.

The draft GAO study also reported that its in-depth review of a small portion of slaughter and processing plants indicated that 94 percent of the HACCP plans reviewed failed to meet regulatory requirements, and 80 percent had inadequate verification of critical control points.⁵⁰ Even after experiencing positive tests for microbiological contamination, 32 percent of plants failed to identify in their HACCP plans "microbiological contamination" as a hazard that was reasonably likely to occur.⁵¹

The draft GAO report also found that even when plants experienced multiple, serious non-compliance violations, they were rarely closed down. At one plant for instance, inspectors issued 155 noncompliance records for fecal contamination, but no further action was taken.⁵² In 60 instances when the government told the plant that they would suspend inspection services and force the plants to close, in 95 percent of those cases (57 of the 60 cases) the suspension was placed in abeyance meaning the plant quickly resumed normal operations.⁵³

The findings of this draft GAO report followed another report formally released by the same agency in December 2001 which was highly critical of a HACCP-pilot program for poultry.⁵⁴ Under the HACCP-based Inspection of Meat and Poultry or "HIMP" program, company employees are tasked with most of the duties of a federal inspector. In addition, line speeds are greatly increased which makes it difficult for company inspectors to take a look at each carcass as is required by law.

The December 2001 GAO report expressed doubts that the new HIMP system represented an improvement over the old. The report found that none of the 11 plants studied met all required organoleptic standards for safety and quality and only one met the USDA's zero tolerance standard for E. Coli.⁵⁵ In addition, five of 11 chicken processing plants had higher rates of salmonella contamination than prior to the implementation of the HIMP program.⁵⁶ Moreover, tests found higher rates of defects, such as ingesta and feathers, on chickens processed by many of the plants.⁵⁷ The report also found that USDA does not require training for plant employees taking over the duties of government inspectors, even though it requires extensive training of federal inspectors.⁵⁸ In contrast, an Australian program touted as a model for HIMP requires 600 hours of training for plant employees.⁵⁹

The report concluded that significant design flaws and methodological limitations compromised the overall validity and reliability of the data used by USDA to conclude that the project was a success.⁶⁰ The oversight office was particularly critical of the fact that USDA did not use a control group, did not randomly select participating plants, and did not take into account important variables like the addition of a chemical wash at

the end of the line to remove microbiological contamination.⁶¹

"Notwithstanding the project's design problems, which we believe make the results unreliable, we found that, so far, the data themselves do not conclusively demonstrate that modified inspections are at least equal to traditional inspections," GAO concluded.⁶²

These latest reports follow a damning analysis of HACCP published in June 2000 by the USDA's own Office of the Inspector General. [See, "USDA Releases Report Criticizing FSIS Process for Determining Equivalence," *Harmonization Alert*, May/June 2000.] That report listed serious problems with the manner in which USDA was implementing the HACCP program domestically and was highly critical of the manner in which USDA was judging foreign countries' meat inspection systems to be equivalent to the U.S. system.

U.S. Continues Aggressive Strategy to Get HACCP adopted internationally: Despite the raft of recent studies and large recalls which have exposed the significant flaws in the U.S. system, the U.S. government is continuing international efforts to export HACCP principles around the world. Both the European Union (EU) and the Codex Alimentarius in Rome are moving toward the adoption of HACCP policies for meat inspection purposes.

The U.S. already requires nations that export meat to the U.S. to adopt HACCP as part of the exporting countries regulatory system.⁶³ Utilizing the WTO's equivalency rules, which encourage nations with differing standards to declare each others standards "equivalent" for trading purposes, many European countries already have been judged "equivalent" and eligible to export meat to the U.S.⁶⁴ Their product is marked USDA approved, just as domestic meat. As part of an extensive effort to address recent food scares in Europe and to be consistent with its trading obligations, the European Commission is developing HACCP requirements for all EU nations.

On July 14, 2002, the European Commission approved adopted a package of five proposals that would require EU nations to adopt a uniform HACCP policy for meat inspection purposes and would revamp a large number of official controls relating to hygiene of food of animal origin for human consumption.⁶⁵ The HACCP proposal was comprised in the so-called "hygiene package" of food safety measures proposed in the action plan of the Commission's January 2000 White Paper on Food Safety.⁶⁶ Because a number of European governments have risen and fallen due to food safety scandals in Europe in recent years, the proposal takes the form of Council and Parliament Regulation rather than an EU Directive. Regulations have more weight and are

subject to more thorough democratic review and debate. Once adopted by the European Parliament and the European Council, the regulations will replace an existing EU Directive on the hygiene of foodstuffs (ECC 93/43) and sixteen product-specific Council Directives, and if approved would enter into force in January 2004.⁶⁷

The European HACCP plan is similar to the U.S. plan in that it limits the role of the government employees and enhances the role of company employees. The Federation of Veterinarians of Europe has protested this aspect of the proposal, while expressing support for HACCP principles. The Federation has objected to plant employees serving as auxiliary inspectors.⁶⁸ The veterinarians also express concern about a provision that allows smaller plants to get around the requirement that veterinarians be present for ante- and post-mortem inspections.⁶⁹

Some U.S. consumer groups view the EU proposal as having some advantages to the U.S. system. Rod Leonard of the Community Nutrition Institute notes that the EU proposal gives government veterinarians the power to use science to determine when meat and poultry is contaminated and should be condemned. According to Leonard, this is not happening under HACCP in the U.S.⁷⁰

"HACCP was sold as a scientific program to institute microbial testing, but in the U.S. it has become a tool for limiting the role of federal inspectors. As the HIMP program illustrates, the end goal is to eliminate the role of government in plants all together," said Leonard. Along with the federal meat inspectors union, Community Nutrition Institute has been involved in a federal lawsuit to overturn the HIMP pilot project and restore the role of the federal inspector in HIMP plants.⁷¹

Meanwhile, at the Codex Alimentarius Commission (Codex), the U.S. government continues to promote the adoption of HACCP around the world. At the 50th Session of the Executive Committee in June 2002,

proposed "Revised Draft Guidelines for the Application of the HACCP System" were advanced from Step 5 to Step 6 of the 8 Step Codex process.⁷² The Codex is one of the international standard-setting bodies recognized by both NAFTA and the WTO for setting global food standards. It was established in 1962 by the World Health Organization and the U.N. Food and Agriculture Organization to facilitate international trade in food and agriculture products. The proposal to revise HACCP guidelines to give more "flexibility" to small establishments was a work product of the Codex Committee on Food Hygiene which is chaired by the U.S. government.⁷³ The task of the committee is to draft basic provisions on food hygiene which will be applicable to all food groups. Codex is currently soliciting comments on this proposal from Codex governments, and the U.S. government is soliciting comments from U.S. industry and other interested parties with a deadline of October 15, 2002.⁷⁴

The discussion of HACCP at the Codex raises several concerns. First, many consider it premature for developing nations to be discussing instituting a HACCP system when neither the public funding nor regulatory structures may have been developed yet for any strong mandatory system for meat inspection and meat hygiene, but more developed countries may also have something at stake. The harmonization rules of the WTO specifically recognize Codex as setting the world's presumptively "trade-legal" food safety standards. Countries maintaining a food safety regulation system with a higher level of consumer protection than those endorsed by the Codex could find their regulations challenged at the WTO by other countries that view them as barriers to trade.

The U.S. government repeatedly assures its trading partners that the U.S. has the highest food safety standards in the world. However, the escalating number and severity of food product recalls in the U.S. during this 4th year of the HACCP implementation is a basis for concern and on-going analysis.

FEDERAL REGISTER ALERTS

For more timely notice of these alerts, please visit our web site at www.harmonizationalert.org and sign up for one of four listserves. The full texts of these notices are available at http://www.access.gpo.gov/su_docs/aces/aces140.html. 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

Nominations for Membership on the National Advisory Committee on Microbiological Criteria for Foods (FSIS)

67 Fed. Reg. 31177 (May 9, 2002)

Notice.

International Standard Setting Activities of the Codex (FSIS)

67 Fed. Reg. 37760 (May 30, 2002)

Notice.

Environmental Impact Statement for the Importation of Wood Packaging Material (APHIS)

67 Fed. Reg. 52893 (August 14, 2002)

Notice of intent to prepare an environmental impact statement, scope of study, and notice of public meetings.

International Sanitary and Phytosanitary Standard-Setting Activities (APHIS)

67 Fed. Reg. 54615 (August 23, 2002)

Notice.

Department of Health and Human Services

International Conference on Harmonisation; Stability Data Package for Registration in Climatic Zones III and IV (FDA)

67 Fed. Reg. 40951 (June 14, 2002)

Notice.

International Conference on Harmonisation; Draft Guidance on Q1E Evaluation of Stability Data (FDA)

67 Fed. Reg. 40949 (June 14, 2002)

Notice.

International Conference on Harmonisation; Draft Guidance on S7B Safety Pharmacology Studies (FDA)

67 Fed. Reg. 40950 (June 14, 2002)

Notice.

International Conference on Harmonisation; Draft Guidance on Electronic Common Technical Document Specification (FDA)

67 Fed. Reg. 40948 (June 14, 2002)

Notice.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (FDA)

67 Fed. Reg. 42790 (June 25, 2002)

Notice.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (FDA)

67 Fed. Reg. 43332 (June 27, 2002)

Notice.

Agency Information Collection Activities; Submission for OMB Review (FDA)

67 Fed. Reg. 47821 (July 22, 2002)

Notice.

Preparation for the International Conference on Harmonization Meetings in Washington, DC (FDA)

67 Fed. Reg. 51589 (August 8, 2002)
Notice of public meeting.

Department of Transportation

Advisory Guidance on Packaging and Shipper Responsibilities (RSPA)

67 Fed. Reg. 31974 (May 13, 2002)
Advisory guidance.

Special Conditions; The Lancair Company, Model LC40-550FG-E Airplane (FAA)

67 Fed. Reg. 39262 (June 7, 2002)
Final special conditions.

Special Conditions Issued for Airbus Model A340-500 and -600 Series Airplanes (FAA)

67 Fed. Reg. 44018 (July 1, 2002)
Final Special Conditions.

Federal Communications Commission

Conducted Emission Limits for Radio Frequency Devices

67 Fed. Reg. 45666 (July 10, 2002)
Final rule.

Office of the United States Trade Representative

Initiation of Environmental Review of Doha Multilateral Trade Negotiations

67 Fed. Reg. 34750 (May 15, 2002)
Notice and request for comments.

WTO Dispute Settlement Proceeding Regarding Japanese Measures Affecting the Importation of Apples

67 Fed. Reg. 40977 (June 14, 2002)
Notice; request for comments.

Environmental Protection Agency

Oxadixyl Tolerance Revocations

67 Fed. Reg. 45639 (July 10, 2002)
Final Rule.

Endocrine Disruptor Methods Validation Subcommittee Under the National Advisory Council for Environmental Policy and Technology

67 Fed. Reg. 45720 (July 10, 2002)
Notice.

Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

67 Fed. Reg. 50430 (August 2, 2002)
Notice.

Benomyl Tolerance Revocations

67 Fed. Reg. 46900 (July 17, 2002)
Final Rule.

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1. 65 Fed. Reg. 34113 (May 26, 2000).
 2. *Harmonization Alert* telephone interview with Donna L. West, Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, USDA, Jun. 24, 2002. SureBeam, a subsidiary of the U.S. defense contractor Titan Corporation, whose irradiation technology is already used to treat Hawaiian produce, has entered into a deal with Tech Ion Industrial Brasil to build one of the largest irradiation networks in the world and has also entered into deals to build irradiation facilities in Australia, Japan and Saudi Arabia. *Irradiation in Brazil, Fruit Basket of the World*, Public Citizen, Critical Mass Energy and Environment Program, Feb. 22, 2002.
 3. Organic Consumers Association, *Comments re Docket No: 98-030-1*, Jun. 26, 2000; Ralph T. Ross, PhD, *7 CFR Parts 305 and 319 (Docket No: 98-030-1): "Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables: Proposed Rule [sic]*, Jul. 14, 2000.
 4. 67 Fed. Reg. 11610 (2002).
 5. World Trade Organization SPS Agreement, Dec. 15, 1993, Art. 4.1 in Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT Doc. MTN/FA 33 I.L.M. 9 (1994).
 6. 21 CFR 179.26. The maximum allowed dose of radiation for disinfestation of arthropod pests in food is 1 kGy. 179.26(b).
 7. Meat and poultry - 9 CFR 424.22; Mediterranean fruit flies - 7 CFR 301.78; Hawaiian produce - 7 CFR 318.13.
 8. 67 Fed. Reg. 11610, 11613-14 (2002).
 9. Under current law, individual irradiated fruits and vegetables are not required to be labeled at the retail level and the proposed rule and supplement do not change this. For foods not in packages, current law requires a label with the statement "Treated with Radiation" or "Treated by Irradiation," and the radiation logo, on the bulk container or on a counter sign or card. 21 CFR 179.26(c)(2). Irradiated food may soon also be referred to as "pasteurized" under the farm bill that went into effect on May 13, 2002. The bill amends the Federal Food, Drug and Cosmetic Act [21 U.S.C.A. §343(h)] to permit use of the term "pasteurized" for foods that have been subjected to a "safe process or treatment" that is as long-lasting and as protective of public health as pasteurization and that is "reasonably certain" to eliminate the most resistant microorganisms of public health significance. Once a notice is sent to HHS of intent to call a process or treatment "pasteurization", the burden is on HHS to establish that the process or treatment does not meet the required standards. Unless HHS determines, within 120 days, that the process or treatment does not meet the standards, the term "pasteurization" may be used. In addition, the farm bill directs HHS to propose "appropriate" revisions to the current rule on labeling irradiated foods and creates a short-cut to judicial review, Security and Rural Investment Act of 2002, H.R. 2646, Sections 10808 and 10809. The new section of the proposed rule that requires indicators to identify irradiated produce is intended to aid in enforcement activities by providing a "quick check" to confirm that particular cartons have been irradiated. APHIS gives examples such as phosphor-based technology to be used with a "light-pen" detector, or a bar code that changes color when irradiated. The potential migration of chemicals from irradiated packaging materials has not been assessed by the USDA. Implementing the proposed rule without a safety assessment of irradiated packaging material would put the USDA in non-compliance with the Federal Food, Drug, and Cosmetic Act, 21 CFR Part 170.
 10. Mediterranean fruit flies - 7 CFR 301.78; Hawaiian produce - 7 CFR 318.13; proposed rule re imports - 65 Fed. Reg. 34113 (2000), new 7 CFR 305.
 11. Mediterranean fruit flies - 7 CFR 301.78-5(c)(1)(iv); Hawaiian produce - 7 CFR 318.13-4f(b)(2)(iv); proposed rule re imports - 65 Fed. Reg. 34113, 34123 (2000), new 7 CFR 305.2(e).
 12. 65 Fed. Reg. 34113, 34123 (2000), new 7 CFR 305.2(d).
 13. Hawaiian produce - 7 CFR 318.13.-1; proposed rule re imports, 65 Fed. Reg. 34113, 34123 (2000), new 7 CFR 305.2(f).
 14. 67 Fed. Reg. 11610, 11613 (2002), 7 CFR 305.2(f).
 15. 7 CFR 318.13-4f (b) (2) (iv).
 16. 7 CFR 318.13-4(b).
 17. *Harmonization Alert* telephone interview with Ed Uyeda, APHIS, Hawaii, Jul. 12, 2002.
 18. Moreover, international standards are currently under consideration that could substantially increase the likelihood of deference to the regulatory systems of other countries. At its May 2002 meeting, the Standards Committee of the International Plant Protection Convention Secretariat approved draft standards for the use of irradiation as a phytosanitary measure. These standards, which are now being circulated to member countries for comment, will be the presumptively WTO-legal international standards adopted. The draft standards or "guidelines" call for less direct observation of radiation treatments than APHIS currently requires for treatment of Hawaiian produce and would lodge significant oversight responsibility with the exporting countries' regulatory systems. For example, Guideline 6.3 states that "[d]irect, continuous supervision of treatments should not be necessary provided treatment programmes are properly designed ..." and specifies that "[t]he degree of verification required for a facility is determined by: ... the monitoring and certification programme as administered by the NPPO [National Plant Protection Organization] of the country where treatments are conducted" (emphasis added). Guidelines for Use of Irradiation as a Phytosanitary Measure, Report of the Standards Committee, First Meeting, Rome, Italy, 13-17 May 2002.
 19. Report of the 34th Session of the Codex Committee on Food Additives and Contaminants, Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Mar. 2002.
 20. Although the FDA's upper dose limit for fruits and vegetables of 1 kGy is well below the disputed Codex limit, a type of cyclobutanone has been detected in irradiated mangoes after 14 days of storage at doses as low as .1 kGy. *Hidden Harm, How the FDA is Ignoring the Potential Dangers of Unique Chemicals in Irradiated Food*, A Special Report by Public Citizen and The Center for Food Safety, Dec., 2001, at 9. 0.1 kGy is the dose set in the proposed rule for elimination of mango seed weevils. The proposed rule on irradiation of imported fruits and vegetables sets a minimum required dosage that is designed to eliminate pests. The FDA's maximum dosage requirement is mentioned only in a footnote that refers to FDA's role in regulating irradiation of food, 65 Fed. Reg. 34113, 34123 (2000).
 21. Report of the 34th Session of the Codex Committee on Food Additives and Contaminants, Joint FAO/WHO Food Standards Programme Codex Alimentarius Commission, Mar. 2002.
 22. Public Citizen, *The Great Vitamin Robbery, What Irradiation Does to the Nutrients in Your Food*, Feb. 13, 2002, citing Janave, M.T. and Thomas, P. "Influence of post-harvest storage of potato carotenoids." Potato Research, 22:365-9, 1979, cited in Kilcast, 1994.

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23. Public Citizen, *Comments Re: Docket No. 98-030-3, "Irradiation Phytosanitary Treatment of Imported Fruits and Vegetables,"* Apr. 12, 2002, citing data of Janave and Thomas (1979), cited in Kilcast, D. "Effect of irradiation on vitamins", *Food Chemistry*, 49:157-164 (1994).
24. Irradiation can extend shelf-life substantially, doubling it for some products. *Harmonization Alert* telephone interview with Danila Oder, Food Irradiation Coordinator, Organic Consumers Association, Jul. 16, 2002.
25. See, for example, FDA Draft Guidance on Equivalence Criteria for Food, 62 Fed. Reg. 30593 (Jun. 4, 1997); FSIS Equivalence Evaluation Process for Foreign Meat and Poultry Food Regulatory Systems, 64 Fed. Reg. 12281 (Mar. 12, 1999).
26. E-mail to *Harmonization Alert* from Dr. Paul Gadh, Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, USDA, Aug. 2002.
27. *Harmonization Alert* telephone interview with Donna L. West, Import Specialist, Phytosanitary Issues Management, PPQ, APHIS, USDA, Jun. 24, 2002.
28. *Id.*
29. Allison Sherry and David Migoya, "Meat Recall Information Kept Hidden," Denver Post, Aug. 4, 2002.
30. Allison Sherry, "USDA Inspectors Slow to Reveal Suspicions about Possibly Contaminated Beef," Denver Post, Jul. 7, 2002.
31. Allison Sherry, "USDA Inspectors Slow to Reveal Suspicions about Possibly Contaminated Beef," Denver Post, Jul. 7, 2002.
32. USDA, Food Safety and Inspection Service, "Colorado Firm Recalls Beef Trim And Ground Beef Products For Possible E. Coli O157:H7," Recall Release FSIS-RC-055-2002, Jul. 19, 2002.
33. Email, John W. Munsell, to Nathaniel Clark, USDA Feb. 25, 2002 available on Public Citizen's web page www.citizen.org.
34. Email, John W. Munsell, to Nathaniel Clark, USDA Feb. 26, 2002 available on Public Citizen's web page www.citizen.org.
35. Email, John W. Munsell, to Nathaniel Clark, USDA Feb. 26, 2002 available on Public Citizen's web page www.citizen.org.
36. Email, John W. Munsell, to Denny Rehberg, Conrad Burns, Max Baucus, May 5, 2002 available on Public Citizen's web page www.citizen.org.
37. *Harmonization Alert* telephone interview with Felicia Nestor, Government Accountability Project, Aug. 5, 2002.
38. Public Citizen Report, *Jungle 2000: Is America's Meat Fit to Eat?*, Sep. 2000 at 48-49.
39. Public Citizen Report, *Jungle 2000: Is America's Meat Fit to Eat?*, Sep. 2000 at 22-23.
40. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at i.
41. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at iii.
42. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at ii.
43. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at ii.
44. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at ii.
45. Public Citizen, *Hamburger Hell: The Flip Side of the USDA's Salmonella Testing Program*, May 2002, at ii.
46. Public Citizen, "Government's Ground Beef Testing Program Leaves Consumers Vulnerable to Dangerous Bacteria," Press Release, May 23, 2002.
47. Marian Burrows, "Federal Audit Departments Meat and Poultry Inspection System," *New York Times*, Jul. 10, 2002.
48. Government Accounting Office, Draft Report on HACCP, at 14, on file with Public Citizen.
49. Government Accounting Office, Draft Report on HACCP, at 15, on file with Public Citizen.
50. Government Accounting Office, Draft Report on HACCP, at 4, on file with Public Citizen.
51. Government Accounting Office, Draft Report on HACCP, at 4, on file with Public Citizen.
52. Government Accounting Office, Draft Report on HACCP, at 13, on file with Public Citizen.
53. Government Accounting Office, Draft Report on HACCP, at 16, on file with Public Citizen.
54. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 4, 26.
55. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 4, 26.
56. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 28.
57. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 28.
58. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 4.
59. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 21.
60. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 3.
61. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 3.
62. Government Accounting Office, *Weaknesses in Meat and Poultry Inspection Pilot Should be Addressed Before Implementation*, GAO-02-59, Dec. 2001, at 4.
63. USDA Office of Policy, Program and Development, and Evaluation International Policy Division, FSIS Process for Evaluating Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Mar. 1999.
64. Austria, Belgium, Denmark, France, Germany, Italy, Netherlands, Northern Ireland, Spain, Sweden, United Kingdom.
65. Commission of the European Communities, Final Proposal for a Regulation of the European Parliament and of the Council, SANCO/1190/2001 Rev. 8, Jul. 2002.

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66. Commission of the European Communities, White Paper on Food Safety, COM (1999) 719, Jan. 2000.
67. Commission of the European Communities, Final Proposal for a Regulation of the European Parliament and of the Council, SANCO/1190/2001 Rev. 8, Jul. 2002.
68. Federation of Veterinarians of Europe, "Commission Communication, Draft Proposal for a Regulation of the European Parliament and Council Laying Down Detailed Rules for the Organization on Official Controls on Products of Animal Origin Intended for Human Consumption," FVE/01/098/20/09/01, Aug. 20, 2001, at 1.
69. Federation of Veterinarians of Europe, "Commission Communication, Draft Proposal for a Regulation of the European Parliament and Council Laying Down Detailed Rules for the Organization on Official Controls on Products of Animal Origin Intended for Human Consumption," FVE/01/098/20/09/01, Aug. 20, 2001, at 2.
70. *Harmonization Alert* telephone interview with Rod Leonard, Aug. 5, 2002.
71. *Harmonization Alert* telephone interview with Rod Leonard, Aug. 5, 2002.
72. Report on the Fiftieth Session of the Executive Committee of the Codex Alimentarius Commission, FAO Headquarters, Rome 26-28 June 2002, ALINORM 03/3A, Appendix II. The proposal itself can be found in The Report of the Thirty-Fourth Session of the Codex Committee on Food Hygiene, Bangkok, Thailand, 8-13 October 2001, Appendix III.
73. U.S. Chair of this Codex Committee is Dr. Karen Hulebak, Deputy Administrator, Office of Public Health and Science, FSIS, USDA, Phone (202) 720-2644, Fax (202) 690-2980.
74. Comments should be directed to Dr. Michael Wehr, Office of Constituent Operations, U.S. FDA, Room 1B-065, HFS 550, 5100 Paint Branch Parkway, College Park, MD 20740, Phone (301) 436-1725, Fax (301) 436-2618.



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