

# THE WTO COMES TO DINNER

## U.S. Implementation of Trade Rules Bypasses Food Safety Requirements

A Special Report By  
Public Citizen's Global Trade Watch and  
Critical Mass Energy and Environment Program



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## EXECUTIVE SUMMARY

*“The very notion of equivalence allows for imprecise, subjective comparisons that are not appropriate when dealing with issues as important as public health and safety.”* Transatlantic Consumer Dialogue, February 2000<sup>1</sup>

Even as the U.S. government is increasingly concerned about the vulnerability of the food supply to bioterrorism and is being given new funds by Congress to shore up woefully inadequate border inspection capacity for potentially contaminated food, U.S. government officials are faced with a conflicting obligation contained in international trade agreements and enshrined in U.S. law – to facilitate trade and the unimpeded flow of goods via international “equivalency” agreements.

As a result, core requirements of U.S. food safety laws are being abrogated or amended in an effort to facilitate trade. In other words, a handful of agency officials are accepting others nations’ food safety policies as our own without congressional approval and often with little public notification and involvement. Though the American public has every reason to assume that they are protected by laws enacted by their elected representatives and enforced by administrative agencies in a publicly transparent and participatory fashion, this is not necessarily the case.

Equivalency is a fairly new concept in U.S. domestic law. The notion first arose in Europe in the context of the Common Market integration where the principal of mutual recognition ensures the free flow of goods across borders based on the recognition of differing national regulations as being equivalent to each other.<sup>2</sup> This idea was later enshrined as a key obligation of several World Trade Organization (WTO) Agreements and in the North American Free Trade Agreement (NAFTA). Equivalency is designed to allow foreign goods produced under different rules and regulations “free passage” into the importing country’s market without reinspection at the border. Once a foreign system or an individual foreign standard is declared “equivalent” to a domestic system or standard, products produced under that system must be treated as if they were produced under the domestic system or standard, even though the two systems may differ in significant ways. In other words, goods must be allowed entry that meet the *exporting* country’s laws and regulations even if they do not precisely meet the standards of the *importing* country. “Duplicative” border inspections are to be eliminated as the importing country relies on the exporting country to ensure that the product meets equivalent standards.

To implement these WTO and NAFTA equivalency mandates, U.S. agencies including the Food Safety and Inspection Service (FSIS) and the Animal Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA), as well as the Food and Drug Administration (FDA), and the National Highway Transportation and Safety Administration (NHTSA) are all engaged in equivalency determinations using a variety of differing policies and procedures, especially regarding public notice and consultation.

Neither USDA, nor any other U.S. government agency engaged in trade-related equivalency decisionmaking, has answered the fundamental paradox posed by this new trading concept: how can

something that is different be the same? When it comes to important public health and safety standards, most Americans would argue that “close” is simply not good enough.

The pressure for globalized agricultural trade is in large part being driven by the transnational agribusiness companies that are interested in operating in other nations because of cheap labor and production costs and weaker food safety and environmental regulations. As a publication by the U.S. Department of Agriculture’s Animal Plant Health Inspection Service states, “International commerce is increasingly the result of more commercial activities than just exporting or importing. Most of the top-ranked U.S.-based meat corporations are also investing overseas in processing or production. Market access, lower production costs, growth opportunities, and regulation drive international location decisions.”<sup>3</sup> The agency specifically points to lower labor and environmental compliance costs in nations like Mexico.<sup>4</sup> Meat industry giants such as Perdue Farms, Inc., Tyson Foods, Inc., Smithfield Foods, Conagra Foods, and Cargill, Inc. have all located plants abroad, many in order to send product right back to the U.S. market under “equivalent” standards.<sup>5</sup> Because it is becoming an increasingly international enterprise, the meat processing industry is interested in weakening governmental regulation of the slaughter and processing of meat and poultry products at home and abroad.

While the U.S. still has better safety controls than many nations, the drive to reduce standards is taking place in many arenas – from attempts to privatize meat inspection in the U.S. to international efforts to push third-party certification in lieu of government meat inspection and to harmonize least-common-denominator standards or recognize weaker standards as “equivalent” for trade promotion purposes.

While many U.S. agencies are engaged in equivalency decisions in a variety of food and product areas, FSIS, which regulates meat and poultry products, has gone the farthest in implementing the equivalency trading dictates of NAFTA and the WTO. As a consequence this briefing paper focuses on FSIS’ performance in this area.

FSIS oversees a group of U.S. laws and regulations that were first initiated almost 100 years ago to ensure the safety of the U.S. meat supply. Core elements of these laws include: mandatory sanitary standards for the processing of meat products, including standards for wholesome, unadulterated meat; enforcement by qualified federal meat inspectors whose impartiality is ensured by their status as government employees; visual inspection of each carcass by federal inspectors working in slaughter and processing plants; continuous inspection of slaughter and processing plants, meaning the presence of federal inspectors at all hours of operation; legal authority to keep potentially unsafe meat off the market; and more recently, sampling and microbial testing.<sup>6</sup>

FSIS first got its feet wet with equivalency with the 1989 Canada-U.S. Free Trade Agreement. Under this agreement, the two nations’ meat inspection systems were declared equivalent and a “streamlined” border inspection system was implemented. In February 1990, the two countries announced that they would take this new system one step further and proposed a one-year experiment with an “open border” which would eliminate all border inspections for meat imported from one country to another.<sup>7</sup> At the time, some FSIS officials interviewed by the Government Accounting Office questioned whether this

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move was in compliance with U.S. law on import inspection or whether it needed an act of Congress to drop all border controls, but the experiment proceeded.<sup>8</sup>

Shortly after U.S. and Canadian officials touted the agreement as “the first time in our countries’ history that we have been able to open our borders for food safety standards,” alarming warnings reached Congress about the results. Bill Lehman, a U.S. meat inspector with 26 years of experience blew the whistle on USDA for allowing contaminated Canadian meat into the country unchecked.<sup>9</sup> Jack Perrault, director of the International Import Inspection Service, condemned USDA for “giving up consumer protection for free trade.”<sup>10</sup> The brouhaha generated a number of negative press reports and congressional investigations, prompting USDA to abandon its “open border” with Canada, although a streamlined inspection system remains in effect between the U.S. and Canada to this day.<sup>11</sup>

In 1994, the Uruguay Round Agreements Act passed Congress. This bill made the U.S. part of the WTO, and implemented key WTO agreements as binding federal law. In addition to rewriting large swaths of U.S. law, the Uruguay Round Agreements Act made statutory changes to the Federal Meat Inspections Act and the Poultry Products Inspection Act that in 1995 resulted in a minor, seemingly insignificant change to the U.S. meat and poultry regulations, when the words “equal to” were replaced with the word “equivalent.”<sup>12</sup>

In other words, before the WTO, foreign meat inspection systems were required to produce meat destined for export to the U.S. utilizing sanitary and quality standards *the same as* those of the United States. U.S. government inspectors had to certify that foreign processing plants met U.S. standards in order for such a facility to send food to the U.S. After the Uruguay Round Act, the meat industry in foreign nations could maintain *differing* standards, certify their own plants for export, and still be eligible to export into the U.S.<sup>13</sup> As explained by FSIS officials, “since 1995 the United States, along with other members of the World Trade Organization, has shifted its emphasis from ‘compliance’ with importing country inspection requirements to ‘equivalence’ in conformance with our obligations under the [WTO Sanitary and Phytosanitary] SPS Agreement,” which governs trade in food.<sup>14</sup> Another official states, “if you revert to ‘the same as,’ then there’s even arguably a higher standard and a more difficult challenge to meet to gain entry [into U.S. markets].”<sup>15</sup>

Since 1995, FSIS has declared the meat inspection systems of 43 nations “equivalent” and eligible to export fresh meat or processed meat products into the U.S., although not all of these countries are currently exporting to the U.S. “Meat” is defined in U.S. regulation as product of cattle, sheep, swine and goats, although the vast majority of imported meat is beef.<sup>16</sup> In addition, five countries have been found equivalent for the importation of poultry. Not surprisingly, the amount of imported meat and poultry has grown, reaching over (4 billion pounds in 2002), an estimated 20% of the meat consumed in the U.S.<sup>17</sup> Moreover, the American consumer cannot distinguish these imports from meat produced under U.S. standards. Unbeknownst to consumers, in the meat sections of grocery stores all over the U.S., there are packets of beef and poultry bearing the USDA seal of approval that were produced in slaughterhouses and processing plants abroad that are not required to obey the same rules as U.S. facilities and in which no U.S. government inspector may ever have set foot. Yet, the appearance of the USDA grade stamp (which marks beef “choice,” “prime” or “select”) on certain meat packages as well as the inspection

stamp for certain meats processed in the U.S. misleads many consumers to believe that the beef is homegrown.<sup>18</sup> The lack of country-of-origin labeling is cause for concern, especially when one hamburger sold in the U.S. could potentially contain a veritable United Nations of meat as processors may mix beef from many nations in one batch.

Equivalency decisions are being made by a small number of bureaucrats in U.S. federal agencies. There is no congressional oversight of these decisions and information about how these decisions are made is very hard to obtain. For three years, USDA has been stalling on a series of Freedom of Information Act requests from Public Citizen and has attempted to charge the organization thousands of dollars for information that should be publicly available regarding how USDA makes equivalency decisions and how it addresses problems in other countries' inspection systems uncovered during country audits.

*What does FSIS have to hide?*

A review of those documents that are publicly available regarding equivalency decisions suggests that FSIS has reason to be nervous about public scrutiny of its activities. This report documents a sloppy *ad hoc* process for determining equivalency, so full of holes and omissions that U.S. consumers are exposed to increased risk.

In sum, Public Citizen found that under the WTO-required equivalency process:

**Equivalence Replaces Compliance:** Instead of explaining to other countries how to comply with U.S. standards, a handful of FSIS bureaucrats are now engaged in complex discussions about whether or not varying technical standards and differing rules and regulations are "close enough" to U.S. rules to provide the same level of protection for U.S. consumers as domestic inspection.

**Nations Not Compliant with Core Food Safety Law & Regulations Were Found "Equivalent:"** FSIS repeatedly authorized meat imports from nations whose standards did not meet U.S. regulatory requirements. When problems were discovered, FSIS gave countries a seemingly time-unlimited opportunity to address them. For instance, in violation of U.S. requirements for government meat inspection, Mexico was allowed to have company-paid meat inspectors year after year. Canada and the U.S. still have not agreed that differing sanitary standards, such as those governing *E. coli* testing, are in fact equivalent. Yet, Mexican and Canadian meat still flows into the U.S. and is stamped with the USDA seal of approval.<sup>1</sup>

**Paper Reviews Take Precedence Over Plant Inspections:** Under equivalence, instead of inspecting all plants seeking to export to the U.S. and officially certifying them for export, the U.S. determines if a country's meat inspection system is equivalent and then relies on regulators in other

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<sup>1</sup> In May of 2003, a case of bovine spongiform encephalopathy (BSE) or mad cow disease was discovered in Canada prompting the closing of the U.S. border to Canadian cattle and beef imports.

nations to inspect and approve plants as eligible to export to the United States. U.S. auditors perform “system” audits, which focus on reviewing documents describing a nation’s regulatory policy and sanitary procedures rather than a physical audit of each plant. One FSIS official described this as a “dramatic departure from the traditional audit approach”;<sup>19</sup> another said, “we used to approve plants, now we approve governments.”<sup>20</sup> As part of the system audit, U.S. inspectors visit a percentage of plants eligible to export and observe as foreign regulatory officials audit those plants. The percentage of plants inspected varies widely, and has dropped to as few as 2% in Canada. In addition, plants are notified well in advance of the inspection team’s arrival. Extensive problems with this system have already been documented. In June 2000, the USDA Office of the Inspector General reported that six countries were determined to be equivalent before on-site audits occurred and that agency bureaucrats, rather than audit teams and technical experts, were driving equivalency decisionmaking.<sup>21</sup>

**U.S. Relies on Exporting Country Regulators to Ensure the Safety of U.S. Imports:** Under equivalency, key food safety checks for meat to be consumed in the U.S. are turned over to regulators in other nations. Not only does FSIS rely on these regulators to approve and inspect plants for export and to test for microbiological hazards in slaughter and processing plants, but in the case of Canada, FSIS even relies on Canadian inspectors to choose which carcasses are to be examined by U.S. inspectors at the border without being taken off the truck.<sup>22</sup> The appropriateness of relying on the regulatory authority of other nations is called into question every time another coverup hits the papers, such as Britain’s mishandling of the “mad cow” crisis, Argentina’s delay in reporting a foot and mouth disease outbreak, the Belgian government’s coverup of dioxin-contaminated chicken, or even the recent outbreak of SARS in China that was not immediately reported to international officials.<sup>23</sup> Unfortunately, when millions of dollars in potential business losses are at stake, consumer health and safety has not always been given first priority.

**Border Checks Fail to Keep Pace with Imports:** FSIS has not dropped border checks of imported meat from equivalent nations. However, the extremely small amount of meat that is physically examined and the even smaller amount that is tested for microbial contamination may not be sufficient to ensure the safety of imports, especially when it is USDA policy not to retain the meat, but to let it into commerce while test results are pending.<sup>24</sup> In 1997, FSIS reported 75 full-time meat and poultry inspection workers at 200 facilities inspecting 2.5 billion pounds of meat and poultry – meaning each inspector monitored 33 million pounds of meat and poultry that year, or 91,000 pounds a day.<sup>25</sup> By 2001, the same number of inspectors monitored the import of 3.7 billion pounds of meat and poultry – increasing the per inspector rate to 49 million pounds per year or 135,000 a day.<sup>26</sup> In 2003, the same inspectors will have to examine well-over 4 billion pounds. More resources and personnel are needed to maintain inspection rates that will ensure consumer protection.

**Shifting Away from Border Inspection Based on Plant Performance to Random Sampling:** In 2002, USDA announced that it had made changes to the Automated Import Information System (AIIS), the computer system used to track and select meat and poultry imports for sampling at the border. Limited information is available about the new system, making it difficult to assess potential strengths and weaknesses. However, the system has been described as focusing on random sampling rather than sampling based on the performance of exporting plants. USDA has also said it wants to adopt the same

system that has been in use with Canada. The Canadian streamlined system has been sharply criticized as generating inspection rates as low as two hundredths of one percent, idling border inspectors who have the time and capacity to inspect more trucks than they are being assigned and not providing a true picture of the performance of Canada's inspection program.<sup>27</sup> One border inspector asserted "we could be inspecting much more product at no additional cost to the government or the consumer."<sup>28</sup> Indeed, newly available numbers demonstrate a profound drop in border inspections when the streamlined system was implemented for all meat imports in 2002. When the new system kicked in during the fourth quarter of 2002, it resulted in an astonishing 65% drop in the rate of meat and poultry inspected.<sup>29</sup>

**FSIS Fails to Look at Broader Issues of Consumer Protection:** Shockingly, FSIS has only recently begun assembling the documentation necessary for evaluating other countries' enforcement policies and performance as part of an equivalency determination.<sup>30</sup> Even though Mexico reported zero prosecutions or investigations in 2001, and in 2002 failed to demonstrate that required corrective actions had been taken, Mexico retains its equivalency status. Clearly a rigorous assessment of a nation's actual performance in enforcing its own standards must be part of any equivalency determination. Moreover, FSIS does not require that trading partners have the same whistle blower protections as U.S. law. These protections have benefitted the U.S. public countless numbers of times as government officials have alerted consumers to the presence of harmful food and consumer products, corruption, and lax agency oversight.<sup>31</sup> Nor does FSIS systematically examine the environmental practices of plants or the labor standards to which employees are subjected.

**Denial of Equivalency is Cause for a WTO Challenge:** FSIS officials have admitted that foreign governments that are unhappy with an FSIS denial of equivalency have recourse to the WTO dispute resolution process, where losing countries have the choice of either changing their policy or paying trade sanctions.<sup>32</sup> Decisions by U.S. government officials in this matter are now subject to oversight by trade tribunals operating behind closed doors whose goal is to facilitate trade, not to safeguard the interests of U.S. consumers. To date, the U.S. government has lost 33 of the cases filed against it at the WTO and has won only two of the cases filed against it.<sup>33</sup> The WTO can impose millions of dollars in sanctions against any nation found to violate its trade-promotion rules.

**U.S. Government Agencies Have Diverse Policies and Procedures for Equivalency:** U.S. agencies have developed diverse policies and procedures on equivalency, calling into questions the fairness and consistency of the policies. However, what these policies have in common is a lack of significant public consultation or even public access to information about the negotiations, undermining the legitimacy of such equivalency agreements. FDA has been engaged in equivalency discussions for years with the European Union (EU) in the context of a wide-ranging Veterinary Equivalency Agreement, yet has no policy on equivalency or on public participation on equivalency decisionmaking. Agencies also have different policies for public notification that equivalency is being considered or has been determined, and in some instances no public notice of equivalency decisions will be given at all. For instance, in 1999, USDA's FSIS reviewed the new Hazard Analysis and Critical Control Point meat inspection programs of 37 nations and declared 32 equivalent for meat importation purposes without giving advance notice to the public or an opportunity for the public to comment on these decisions.

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Because FSIS has gone further than any other U.S. agency in embracing and implementing a WTO equivalency policy, this paper will focus primarily on FSIS' performance in this area. This paper takes an in-depth look at publicly available FSIS documents regarding five of our top trading partners in fresh meat and meat products: Australia, Canada, Mexico, Brazil and Argentina. We selected these nations because there were indications of problems with the equivalency determinations for each of them.

A review of the publicly available audits of the performance of these nations in the meat inspection area reveals that regulatory systems that have been classified as equivalent by FSIS have not always complied with core requirements of U.S. food safety policy. A review of the FSIS system audits of these nations reveals that FSIS found to be "equivalent" systems with sanitary measures that differ from FSIS policy, and in some cases, actually violate the express language of U.S. laws and regulation.<sup>34</sup> For instance:

- C The U.S. law requiring meat to be inspected by independent government officials was violated by plants in *Brazil and Mexico*.
- C U.S. regulations requiring monthly supervisory reviews by foreign government officials were violated by *Argentina, Brazil, Canada, and Mexico*. Canada and Brazil are requesting an equivalency determination on this core requirement of U.S. regulation. Monthly reviews are vitally important to remind the meat industry that the meat inspector who works the line in the plant is backed by the weight of the government and to double check the work of meat inspectors on a regular basis.
- C Even though U.S. regulations require that a government official and not a company employee sample meat for *Salmonella* contamination, USDA approved company employees performing this task as part of equivalency determinations with *Brazil and Canada*.
- C Even though U.S. regulations require government samples to be tested at government laboratories, the U.S. approved testing by private labs as part of the equivalency determinations with *Brazil, Canada and Mexico*.
- C USDA's sanitary and zero tolerance policies for contaminants including feces, urine, and ingesta (stomach contents) was violated by *Australia, Canada and Mexico*.
- C Unapproved and/or improper testing procedures and sanitation violations have been re-identified by FSIS year after year for *Australia, Brazil, Canada and Mexico*, but the countries have retained their eligibility to export to the U.S.
- C After its regulatory system was designated equivalent, *Mexico* began using alternative procedures for *Salmonella* and *E. Coli* that had never been evaluated by FSIS.
- C *Australia and Canada* were allowed to export to the U.S. while utilizing their own methods and

procedures for such matters as *E. Coli* testing, post-mortem inspection, monthly supervisory reviews and pre-shipment reviews while awaiting a decision from FSIS on a request for an equivalency determination on these standards.

- C FSIS auditors and Canadian food safety officials continue to disagree about whether or not particular measures have already been found “equivalent” by FSIS, yet Canadian meat exports to the U.S. continued uninterrupted.
- C The regulatory systems of *Brazil and Mexico* were rated equivalent even though the countries pleaded insufficient personnel and monetary resources to explain their inability to carry out all required functions.

Because FSIS has refused to respond to Public Citizen’s Freedom of Information Act requests for correspondence and other documentation regarding these equivalency decisions, it is impossible to determine the current status of these issues and whether or not they have been resolved by regulators.

This report documents that the increasing level of imports due to these equivalency determinations, combined with foreign plant utilization of differing standards, the inadequate inspection of foreign plants by U.S. auditors and minimal border checks of the ensuing product, have and will continue to result in an abrogation of U.S. food safety standards. At a time when all governments must be more vigilant about increased risk of food contamination due to higher levels of trade, and even the possibility of terrorist biocontamination, government action is constrained by legally-binding trade promotion rules that elevate the swift and unfettered importation of meat and other commercial products over all other concerns.

To address this unacceptable abrogation of U.S. food safety policy, Public Citizen recommends:

- C Congress must intervene to change the underlying law and regulation so that USDA once again establishes that trading partners maintain the same standards as the U.S. to be eligible to export food products into the U.S. FDA must be given the similar authority to approve countries as compliant with U.S. standards for food production purposes and ban product from countries that are not compliant.
- C Congress must act to substantially increase border inspection activities. After the September 11, 2001 attacks, FDA and USDA received funds to increase border inspection activities. Yet, in 2003 FDA will only inspect 1.3% of food imports into the U.S., and recent changes in the USDA border inspection program indicate that there has been a dramatic drop off, from an 18% quarterly inspection rate to a 6% rate of inspection, deserving of congressional scrutiny and investigation.
- C USDA and FDA must be given more money for conducting rigorous overseas audits and the follow-up that is necessary to instruct foreign regulators on U.S. food safety policies and procedures. FSIS’s six auditors are woefully inadequate number of staff to annually confirm the

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equivalency status of 43 nations for fresh meat and five for poultry. FDA and USDA auditors should resume the practice of inspecting and certifying every foreign plant shipping product to the U.S. on an annual basis.

- C Congress and USDA should stop undermining the country-of-origin labeling (COOL) requirements that were passed as part of the 2002 Farm Bill. They should act to promptly implement the COOL provisions which are overwhelmingly supported by consumers who want more information about the food on their plates, not less.
- C Key WTO food and product agreements that inappropriately delve into regulatory issues via such trade promotion mechanisms as equivalency must be pared back. If the same domestic regulatory standard is applied to both domestic and imported food, the level of protection or enforcement is something those living with the results must decide – there is no trade issue if there is no discrimination.
- C The implementation of WTO-mandated equivalency mechanisms fundamentally undermines domestic democratic decisionmaking regarding food safety policy. All federal agencies engaged in international activities, must develop clear and consistent rules for public engagement in these activities to give U.S. consumers a voice through a participatory public process during multi-year negotiations and certainly before agreements are finalized.
- C In addition to requiring compliance and verification for imports, developed nations must live up to their responsibility to assist developing nations with the financial and technical assistance needed to secure the safety of their own domestic food supply as well as exports.



## **I. INTRODUCTION: TRADE RULES POSE NEW CHALLENGES FOR ENSURING THE SAFETY OF FOOD IMPORTS**

In the era of globalization, nations struggling to protect their citizens from food borne illness are attempting to address multiple hazards with limited resources. Some of these hazards are well-understood. Food borne pathogens, such as *E. Coli* 0157:H7, *Salmonella*, and *Listeria*, threaten to make ever-increasing numbers of people sick. As the *New England Journal of Medicine* argued succinctly, “with a global food supply, we worry less about the possibility that Grandmother’s potato salad will affect 80% of the people attending a church picnic than about the prospect that hundreds of thousands of people in many countries will be exposed to a single contaminated product.”<sup>35</sup>

Other food borne health threats with global impacts are less well understood. Scientists are still debating the root cause of the bovine spongiform encephelopathy, or “mad cow” disease, outbreak in the United Kingdom in 1986. This disease, which started in cows before jumping to humans, still has not run its course. The potential of the disease to spread to the far corners of the earth was only really understood 15 years after the outbreak and years after the export of British meat and cattle was halted, when it was disclosed that Britain continued to ship potentially contaminated animal feed to over 80 countries around the world.<sup>36</sup>

Bioterrorism is another new hazard to which the food safety community is only just beginning to respond. Since the September 11, 2001 attacks on New York and Washington, D.C., governments are accelerating their examination of vulnerabilities and beginning to shape a regulatory response. A September 2002 report prepared by the National Research Council, an arm of the National Academy of Sciences, caused a stir by documenting the multiple ways in which U.S. was vulnerable to agricultural bioterrorism.<sup>37</sup> “It is not a matter of ‘if,’ but ‘when,’” said R. James Cook, a committee member from Washington State University.<sup>38</sup>

Government officials, scientists and food safety groups not only fear the release into the U.S. of devastating agricultural pests or animal diseases such as foot and mouth, they are also concerned about the deliberate poisoning of food, such as ground beef, which has the potential to impact millions of consumers. Even the poisoning of a small amount of food would create an atmosphere of fear and panic.

Deliberate biocontamination of food has occurred before in U.S. history. For instance, in the 1980s, a cult poisoned salad bars with *Salmonella* bacteria sickening, 750 people in Oregon.<sup>39</sup> More recently, traces of ricin, a powerful and deadly poison derived from castor beans, were discovered in a London apartment building in January 2003.<sup>40</sup> The Central Intelligence Agency and British security officials are investigating the possibility that the ricin was being developed to poison food meant for British troops.<sup>41</sup>

At a hearing in Washington, D.C. shortly after the September 11, 2001 attacks, Health and Human Services Secretary Tommy G. Thompson testified to a U.S. House of Representatives Committee that he was “more fearful about [food safety] than anything else,” and that imports posed the highest

risk.<sup>42</sup> In January 2002, FDA issued non-binding industry guidelines making recommendations to prevent bioterrorism at plants producing foods regulated by the FDA at home and abroad. Under the guidelines, it is suggested that foreign and domestic plants take such steps as checking the immigration status of employees, color coding uniforms to determine who should be in what section of the plant, using photo IDs, inspecting employee lockers, cars and bags, and securing plant perimeters.<sup>43</sup> USDA issued similarly non-binding guidelines for U.S. plants, encouraging plants to “make a plan to manage risk,” screen hires, secure perimeters, hazardous materials, energy and water sources and make sure that production inputs such as feed and nutrients are safe.<sup>44</sup>

In June 2002, the President Bush signed the Public Health Security and Bioterrorism Preparedness and Response Act for products regulated by the FDA. For the first time, foreign and domestic plants that produce FDA-regulated foods for the U.S. market (such as fruits, vegetables, eggs, seafood, and dairy products) are subject to modest registration requirements.<sup>45</sup> In addition, the law requires importers to notify the FDA *before* bringing imports into the U.S. and allows the agency to detain contaminated foods.<sup>46</sup> These modest measures are geared more toward tracing back a product once a problem is found than seriously attempting to prevent a problem from crossing the border.

In the face of these increasing threats, nations struggling to protect their citizens from food borne illness are also faced with numerous challenges. Some of these challenges, such as industry pressure to weaken long-standing regulations and stymie new ones, are well-established. The food industry, with its army of lawyers and lobbyists plus millions in campaign contributions, fights the adoption of food safety controls in the courts, at government agencies and in Congress. Nothing deters them from the path of least regulation, not even the threat of a catastrophic bioterror incident.

For instance, the *Washington Post* reported last year that food “industry lobbyists persuaded lawmakers to water down or drop proposals from bioterrorism bills that would have substantially enhanced the FDA’s authority over domestic and foreign food processors.”<sup>47</sup> Industry is even adverse to a thorough examination of potential risks. For instance, a lobbyist for the National Food Processors Association expressed optimism to the *Associated Press* that the industry would be able to kill a proposed study in the Senate version of the Homeland Security Bill which would examine the deliberate rather than accidental contamination of food.<sup>48</sup> The study was not included in the final legislation signed by President Bush.

At the same time the food processing and meat industries are fighting to prevent further regulations in the food safety area, they are pushing an expensive, controversial technology of food irradiation as a solution for food borne illness and agricultural pests. This year, the industry pushed hard to get the U.S. government to purchase irradiated ground beef for the national school lunch program, and in October 2002, APHIS allowed imported fruit and vegetables to be irradiated for pests.<sup>49</sup>

In addition to the well-established challenges posed by industry self-interest, governments are increasingly facing tremendous pressure from trading partners who have been given new rights contained in legally-binding trade agreements to demand the weakening or elimination of food safety measures and the preclusion of new ones.

## *The WTO Comes to Dinner: U.S. Implementation of Trade Rules Bypasses Food Safety Requirements*

In 1993, Congress passed NAFTA, a comprehensive international trade and investment agreement covering Canada, the U.S. and Mexico. In 1994, Congress passed the Uruguay Round Agreements Act making the U.S. part of the now 145-member WTO which enforces dozens of different trade agreements, many of which constrain the domestic regulatory policies of signatory countries. Both pacts contain binding regulatory obligations, adopted into U.S. federal law by merit of congressional approval of the agreements. Taken in combination, the agreements not only give our trading partners new legal grounds to attack domestic laws and procedures as trade barriers, but constitute a deregulatory superstructure which undermines strong domestic policies to protect the food supply from pathogens and contaminants. NAFTA and the WTO are based on certain premises: 1) that domestic regulations should be constructed in the least trade restrictive manner possible; 2) that domestic standards should be “harmonized” (made to conform with international standards) or found to be “equivalent” (determined to be different, but “close enough” to a domestic standard) to facilitate cross border trade; 3) that domestic regulations not conforming to NAFTA or WTO constraints can be subject to challenge as barriers to trade in the powerful and binding dispute resolution bodies contained in these agreements. Countries that lose a NAFTA or WTO challenge must change the offending law or government action or face significant trade sanctions as a penalty.

These binding legal obligations empower U.S. trading partners to press for the elimination of U.S. regulations and standards they don’t like and to interfere in the promulgation of new ones. Thus, it is not surprising that numerous U.S. trading partners wasted no time in informing the U.S. that they viewed the modest registration requirements contained in the FDA’s bioterrorism legislation as potentially WTO-illegal barriers to trade. Argentina questioned whether the measures adopted by the FDA were consistent with U.S. obligations under the WTO’s food and product agreements.<sup>50</sup> The Swiss reminded the U.S. of their WTO obligations to pursue the least trade restrictive option available and challenged the prior notice requirement as discriminatory under trade law because it applied to foreign plants, but not to U.S. plants.<sup>51</sup> The EU charged that the registration requirement “would involve a major administrative burden and would create a serious barrier to trade.”<sup>52</sup> They requested that the U.S. provide for their review the WTO-required risk assessment which justified the measures taken, and suggested that some of the provisions of the law also contradicted the 1999 U.S.-EU Veterinary Equivalency Agreement.<sup>53</sup> Most significantly, the EU asked the U.S. to clarify how the increased border checks of food called for in the Bioterrorism Act aligned with the U.S. commitment to reduce border checks under the Veterinary Equivalency Agreement.<sup>54</sup>

Just at a time when the U.S. government should be strengthening border controls, it is coming under a barrage of pressure to drop such controls to conform with international harmonization and equivalency obligations imposed in trade agreements. Whether the U.S. will give way to these pressures is yet to be seen. The U.S. itself is a leading promoter of these international trade rules, and rarely fails to complain if a trading partner develops a food safety measure it believes goes beyond WTO or NAFTA constraints (as was evidenced by the recent filing by the U.S. of a WTO complaint against the EU’s policy on genetically engineered food and crops). In the end, if U.S. trading partners believe the new bioterrorism rules are more burdensome than necessary to achieve a WTO-permitted goal, they now have the option of challenging these new laws as a barriers to trade in the binding dispute resolution systems of the WTO or NAFTA.

There are three main sections to this briefing paper. In the first part, we review the concept of equivalency in international law and give a brief overview of U.S. agency procedures involving equivalency paying particular attention to agencies spotty performance in including giving public notice of equivalency negotiations and decisionmaking. In the second part, we focus on the performance of FSIS which, unlike other federal agencies, jumped into equivalency decisionmaking with an enthusiasm unparalleled by other federal agencies in the mid-1990's. We end with conclusions and recommendations. These sections are followed with three appendices: Appendix A covering new internationally harmonized equivalency rules being developed at the U.N. food standards body, the Codex Alimentarius Commission in Rome, at the behest of the WTO which could have a profound impact on U.S. policy in this area; Appendix B illustrating the diversity of agency procedures involving equivalency decisionmaking; and, Appendix C which is a model Administrative Procedures Act policy for notifying the public of agency involvement in international equivalency and harmonization negotiations and rule making activities.

## II. EQUIVALENCY IN CONTEXT

When NAFTA's implementing legislation and the Uruguay Round Agreements Act passed Congress in the early 1990s, huge swaths of U.S. domestic laws and policy were rewritten in one fell swoop. Because the agreements were passed under the special requirements of the "Fast Track" trade voting procedure, Congress was only allowed limited time to read, debate and vote on the lengthy bills. Because no amendments are allowed to Fast-Track trade bills, even the members of Congress who noticed and understood the arcane details, such as the harmonization and equivalency requirements, had no ability to fix the provisions that troubled them. After almost ten years of implementation of these pacts, we are reaching a point where we can begin to assess agency performance in executing the trade facilitation provisions required by these agreements and their implementing legislation.

NAFTA and the WTO both oblige member governments to make equivalency an aspect of their domestic regulatory systems. For instance, Article 4.1 of the WTO Sanitary and Phytosanitary (SPS) Agreement, which sets criteria that WTO nations must follow regarding policies designed to protect human, animal or plant life from pests, diseases and toxins in food, beverages, or animal feed states that, "Members shall accept the sanitary or phytosanitary measures of other Members as equivalent, even if these measures differ from their own or from those used by other Members trading in the same product if the exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection."<sup>55</sup> Similarly, Article 2.7 of the WTO Technical Barriers to Trade (TBT) Agreement, which sets parameters for WTO signatory countries' domestic standards for non-food products, states "Members shall give positive consideration to accepting as equivalent technical regulations of other Members, even if these regulations differ from their own..."<sup>56</sup>

Under these pacts, use of equivalence is mandatory. A WTO member country "shall accept" another member country's food safety measures if the exporting country demonstrates that its standards achieve the importing country's appropriate level of protection.<sup>57</sup> Although the importing country makes the determination of equivalency, denial of equivalency can be challenged as a barrier to trade in the powerful dispute resolution system of the WTO.<sup>58</sup> This has happened before. In 1993, for instance, a trade tribunal operating under the Canada-U.S. Free Trade Agreement (the precursor to NAFTA) forced Puerto Rico to accept Canadian "ultra-high temperature milk" in an equivalency challenge regarding Puerto Rico's requirements that milk be pasturized, even though the government of Puerto Rico did not think the milk met the standards of its Pasturized Milk Ordinance.<sup>59</sup>

Once "equivalence" is agreed to, the standards of the exporting party apply. In other words, different regulatory standards for the same food product exist at the same time, both of which are considered legal in the U.S. One set of standards has been adopted by a U.S. regulatory agency to implement a U.S. law enacted by Congress. Citizen input into these standards has been assured by an array of U.S. laws including: the Administrative Procedure Act,<sup>60</sup> requiring public notice and opportunity for public comment on proposed regulations or regulatory changes; the Freedom of Information Act,<sup>61</sup> permitting citizen access to the records of government agencies; the Government in the Sunshine Act,<sup>62</sup>

ensuring that important agency meetings are publicly noticed; and the Federal Advisory Committee Act,<sup>63</sup> requiring balanced representation on government advisory committees. Compliance with the U.S. standards by producers of the affected product is secured through the monitoring and enforcement mechanisms of U.S. law.

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

In addition to equivalency, there is another NAFTA and WTO-required trade facilitation mechanism that significantly affects domestic regulatory standards. In addition to calling for equivalency agreements, NAFTA and the WTO both oblige member governments to base their domestic standard-setting on specified international standards and on international standard-setting techniques. For example the WTO SPS Agreement requires that countries “base their sanitary and phytosanitary measures [food standards] on international standards, guidelines or recommendations,”<sup>64</sup> and specifically recognizes the standards set by the U.N. food standards body, the Codex Alimentarius Commission (Codex) in Rome as the world’s presumptively trade-legal standards.

This process is called “harmonization” by its proponents, and is especially relevant to this briefing paper because of a current proposal to create internationally harmonized standards for determining food equivalency at the Codex. This effort has been sanctioned by the WTO and is aimed at encouraging nations to develop the exact same procedure for determining equivalency and discouraging the diversity of procedures that a democratic, participatory process in different countries might create.

Final action on the Codex equivalency policy is slated for July 2003. Given that NAFTA and the WTO elevate Codex standards to a new role as the world’s presumptively trade-legal standards and as a point of reference in any WTO dispute regarding food safety, a Codex equivalency policy could have a significant impact on any domestic food equivalency policy developed by U.S. agencies which regulate food. Exporting nations denied food equivalency decisions by importing nations could use the Codex policy as ammunition in a WTO dispute, making a nation’s *process* for determining equivalency itself a WTO adjudicable issue, over and above whatever other conflicting sanitary measures may be the cause of the trade friction. For more information on this complex topic and the Codex policy, please see Appendix A of this report.

U.S. agencies are struggling to implement these equivalency and harmonization mandates. Agencies are developing differing procedures for making equivalency decisions and widely differing processes for including the public in this decisionmaking.

The agencies with the primary responsibility for food safety in the U.S. are the USDA’s FSIS, which regulates meat, poultry and processed eggs, and the FDA, which regulates all other food, shell eggs

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and contaminants in animal feed and drugs and drug residues in animals for human consumption.<sup>65</sup> In addition, both FDA and the Environmental Protection Agency have a role in regulating pesticides and genetically engineered foods.<sup>66</sup> USDA's Animal and Plant Health Inspection Service (APHIS) regulates animal welfare, animal imports and has responsibility for protecting against agricultural pests and diseases.<sup>67</sup> The new National Organic Program (NOP), which went into effect in October 2002, is also regulated by USDA.<sup>68</sup>

Each of these agencies is currently considering or negotiating equivalence determinations on an array of issues. With regard to equivalency decisionmaking, each agency has differing legal requirements, policies, procedures and plans for incorporating public comment.

More information is available about agency performance in involving the public in equivalency decisionmaking in Appendix B of this report. To summarize briefly:

- C FDA is required by the Uruguay Round Agreements Act to pursue formal notice and comment rulemaking when engaged in equivalency decisionmaking in the food safety area. Yet, in 1999, FDA and other U.S. agencies signed onto a Veterinary Equivalency Agreement with Europe covering over 40 product areas without giving prior public notice of the agency's plans to participate in the agreement. Additionally, FDA issued a proposed rule containing a draft equivalency policy in 1997 but has never finalized this policy as a formal, binding rule. Instead it has actively pursued the development of the internationally harmonized equivalency rules at the Codex and intends to rely on that international policy in an undefined manner.
- C In 1999, USDA issued an equivalency policy after a public comment period, but never issued the policy as a formal binding rule. In a public meeting on the policy, USDA explained that it would give formal notice in the Federal Register of "initial" determinations of equivalency (tracking its long-standing practice of listing countries eligible to export to the U.S. in the Code of Federal Regulations). However, the agency stated it would not give notice of "continuing" equivalency determinations unless there was a major new development in an exporting nation's program. Thus, in December 1999 USDA approved 32 nations as having equivalent Hazard Analysis and Critical Control Point Programs for controlling microbial contamination, but never publicly noticed these complex negotiations in advance.
- C USDA also runs the National Organic Program (NOP) which contains provisions allowing for equivalency determinations between nations. This is particularly ironic with regard to the NOP program as it was developed to eliminate the "patchwork" of differing regulations between U.S. states. Having eliminated one patchwork of varying procedures and standards, the regulation's equivalency terms facilitate the creation of new, international patchwork of differing standards which can be declared "equivalent" and still receive the same U.S. "organic" label. The National Organics Standards Board has stated its intention of giving public notice of equivalency prior to making any equivalence decision in a non-binding policy document.
- C APHIS was a leader in the development of the 1999 U.S.-EU Veterinary Equivalency

Agreement, yet apparently has no formal or informal publicly available policy on equivalency. APHIS is also engaged in judging foreign food irradiation facilities equivalent and therefore eligible to irradiate food destined for the U.S. market to eradicate insects and pests.

It is worth mentioning for comparison purposes that the National Highway Transportation and Safety Administration (NHTSA), which is engaged in determining the equivalence of individual foreign car safety standards to U.S. standards under the WTO's TBT agreement (which governs trade in non-food products), has developed a formal process contained in a binding rule on how it will engage in harmonization and equivalence determinations involving a single standard (such as a windshield wiper standard), while other U.S. regulatory agencies are operating with informal, non-binding equivalence policies involving multiple standards, and some agencies have no policy at all. The diversity of procedures and processes being followed by agencies in this area is itself a problem, providing consumers and the public with little assurance that equivalency decision are being made in a comprehensive, uniform, predictable and publicly-accessible fashion.

### **III. FSIS ACCEPTS FOREIGN REGULATORY SYSTEMS AS EQUIVALENT**

“FSIS’ process for evaluating the equivalency of foreign meat and poultry food regulatory systems is both path breaking and precedent-setting. No other food regulatory system in the world, to our knowledge, is actively engaged in applying the concepts of equivalence to the degree and extent as is FSIS. The matter of exactly how an importing country judges, and determines equivalence is controversial. The world is watching how FSIS carries out its equivalency process.”<sup>69</sup> *Food Safety and Inspection Service*

“Equivalency is a method by which nations can create exemptions to each other’s food safety laws to advance trade.”<sup>70</sup> *Center for Science in the Public Interest*

FSIS’ “precedent-setting” experiment with the concept of equivalence in the area of meat inspection is particularly instructive, both because of the scale on which it has been implemented and because of the gravity of the potential harm to the public if proper safety standards are not followed.

#### **A. THE U.S. LEGAL FRAMEWORK FOR MEAT SAFETY**

The current U.S. meat inspection system dates back to 1906 and retains the basic elements that were adopted then in response to the public’s demand for reform following publication of Upton Sinclair’s famous exposé of conditions in slaughterhouses, *The Jungle*. The 1906 Federal Meat Inspection Act instituted sanitary standards for slaughter and processing plants, mandated antemortem and post-mortem USDA inspection of every carcass, and required continuous USDA inspection of slaughter and processing plants.<sup>71</sup> The 1957 Poultry Products Inspection Act added similar requirements for poultry into U.S. law. In 1967 the enforcement authority of USDA was strengthened by the Wholesome Meat Act, which added prohibitions against adulteration and misbranding.<sup>72</sup>

FSIS regulations prohibit contamination with fecal material, ingesta (stomach contents), urine, bile, hair, dirt or other foreign matter and the agency enforces a “zero tolerance” policy for these contaminants.<sup>73</sup> In 1994, following the outbreak of *E. Coli* 0157:H7 that killed four people and sickened hundreds who had eaten contaminated meat at Jack-in-the-Box restaurants, USDA classified *E. Coli* 0157:H7 as an adulterant and instituted a sampling program to test for the deadly pathogen.<sup>74</sup>

Enforcement of FSIS’ legal authority to keep unsafe meat off the market begins with the filing of “Noncompliance Report” (NRs) by government inspectors working in slaughter and processing establishments.<sup>75</sup> If violations reported in these forms are not corrected, FSIS has the authority to implement a progressively more intensive range of sanctions, from issuance of a Notice of Intended Enforcement Action (NOIE), to suspension or withdrawal of its inspectors, which prevents sale of meat

from the affected plants, to civil seizure of meat and imposition of criminal penalties.<sup>76</sup> From October 1, 2002 to December 31, 2002 there were 31, 718 NRs; 17 NOIEs were issued to large plants; 50 NOIEs to small plants; 57 NOIEs to very small plants; five suspensions of inspection in large plants; 35 suspensions in small plants and 48 suspensions in very small plants.<sup>77</sup> FSIS does not have the power to order recalls, though it may recommend them and monitors and announces those that the industry institutes voluntarily.<sup>78</sup>

In 1996, USDA added regulatory provisions requiring slaughter and processing plants to develop and implement Sanitation Standard Operating Procedures (SSOPs) and process controls known as Hazard Analysis and Critical Control Points (HACCP) plans.<sup>79</sup> At the same time, a microbial testing system was established under which slaughter plants are required to test for generic *E. coli* at set sampling and testing frequencies in order to demonstrate compliance with the FSIS “zero tolerance” standard for fecal contamination.<sup>80</sup> As an additional safeguard, FSIS itself tests for *Salmonella* in slaughter facilities and in plants that produce raw ground meat.<sup>81</sup>

The HACCP program has proven to be extremely controversial. In the U.S., meat inspectors have charged that in many plants it has been treated as a substitute for, instead of an addition to, direct inspection requirements, with the result that food safety has been compromised.<sup>82</sup> There have been a mounting number of recalls in the years since HACCP was instituted. Between 1994 and 2001, FSIS announced food recalls have risen by more than fivefold, from about 5 million pounds in 1994 to 315 million pounds in 2001.<sup>83</sup> Meat and poultry recalls are so common that they are increasingly ignored by consumers. In 2000, a pilot project initiated by USDA that explicitly attempted to “privatize” inspection in slaughter plants by reducing the role of government inspectors was unambiguously rejected by the U.S. Federal Court of Appeals in the case of *American Federation of Government Employees v. Glickman*, which held that “[d]elegating the task of inspecting carcasses to plant employees violates the clear mandates of the FMIA [Federal Meat Inspection Act] and PPIA [Poultry Products Inspection Act].”<sup>84</sup>

The core requirements of U.S. law remain unchanged and include:

- C Mandatory sanitary standards for slaughter and meat processing;
- C Inspection of slaughter and processing plants performed by meat inspectors whose impartiality is ensured by their status as government employees;
- C Continuous inspection of operations, meaning the presence of federal inspectors in plants during all hours of operation;
- C Visual inspection by inspectors of each carcass;
- C Sampling and microbial testing;
- C Legal authority to keep potentially unsafe meat off the market; and,<sup>85</sup>
- C U.S. law requires whistle blower protections for federal meat inspectors.

Prior to adoption of the 1994 Uruguay Round Agreements Act, FSIS had detailed procedures in place governing eligibility to export meat to the U.S. Foreign meat inspection systems were required to have laws and regulations, and sanitary and quality standards, identical to those of the U.S., including those requiring government meat inspectors.<sup>86</sup> In addition, all foreign inspection systems were required to conduct “supervisory” visits to each establishment certified as eligible to export meat to the U.S., no less

frequently than once a month as a backup check to ensure that the regulatory requirements were being met.<sup>87</sup> To ensure compliance with U.S. standards, FSIS itself conducted the actual audits of foreign slaughter and processing establishments certifying them as eligible to export to the U.S.,<sup>88</sup> and FSIS staff was frequently stationed in the other countries.<sup>89</sup>

## **B. FSIS ADOPTS WTO EQUIVALENCE RULES**

However, shortly after the passage of the Uruguay Round Agreements Act, in 1995 FSIS amended its meat and poultry import regulations stating that “[u]nder this new law, drafted to comply with GATT, the United States can no longer require foreign countries wishing to export meat and poultry products to have meat and poultry inspection systems that are ‘at least equal’ to those in the United States ...”<sup>90</sup> All other provisions of the U.S. regulations remained the same. Thirty-seven countries that had previously been found to meet the “equal to” standard were grandfathered in and immediately declared “equivalent.”<sup>91</sup> When the HACCP and pathogen reduction regulations were adopted in 1996, FSIS became responsible for determining these 37 countries’ “equivalent” with regard to the new HACCP program.

In order to be classified as “equivalent,” a country must be found by USDA to have a regulatory program administered by its national government that implements standards equivalent to those of the U.S. meat inspection system in the following areas: uniform enforcement; ultimate control by the national government; competent, qualified inspectors; authority to certify or refuse to certify meat intended for export; adequate technical and administrative support; and inspection, sanitation, quality, species verification, and residue standards.<sup>92</sup> The country’s legal authority must impose equivalent requirements for antemortem and post-mortem inspection; official control of establishments; direct and continuous official supervision of slaughtering and preparation of product; separation of certified establishments from uncertified ones; sanitation requirements; control over condemned product; and HACCP system.<sup>93</sup> According to the regulatory requirements, maintenance of eligibility is dependent on the results of periodic reviews conducted by FSIS.<sup>94</sup> In order to ensure that its requirements are being met, the regulations require that foreign regulatory system must conduct supervisory inspection visits to establishments eligible to export least once a month (these are the so-called “monthly supervisory reviews”) and write up the results and must perform random sampling in accordance with sampling and analytical techniques approved by FSIS.<sup>95</sup> Moreover, once a country’s system is declared equivalent, that nation’s government becomes responsible for approving plants interested in exporting to the U.S., not U.S. auditors. U.S. auditors will then annual inspect only a small sample of these plants as part of the systems audit they are supposed to conduct on an annual basis.

In March 1999, FSIS publicly announced a policy and a process for determining equivalence and invited comment in the Federal Register.<sup>96</sup> The three parts of the equivalency process include document analysis, on-site system audit and port-of-entry reinspection.<sup>97</sup> FSIS officials stated at a public meeting that it would use this process for both initial equivalency determinations and continuing eligibility determinations, which are “generally” made on an annual basis,<sup>98</sup> and that it would use two “generic criteria” to evaluate all alternative sanitary measures: (1) Does the alternative measure “comport with” USDA requirements for the import of meat and poultry products to the U.S.; and (2) Does the alternative

measure afford U.S. consumers the same level of public health protection as is provided by USDA domestic measures?<sup>99</sup>

*Pathogen Reduction/HACCP Equivalence:* At a public meeting on December 14, 1999, with no prior public notice of its intentions to declare nations equivalent, FSIS announced that 32 of the 37 countries already approved for shipping meat products to the U.S. had been determined to have “equivalent” pathogen reduction and HACCP systems in place.<sup>100</sup> Paraguay was at that time suspended (for unsanitary establishment conditions and for failing to implement *E. coli* requirements), and four countries, Guatemala, Honduras, Slovenia and the Dominican Republic, voluntarily delisted all their certified export establishments.<sup>101</sup> FSIS announced that 36 countries had adopted FSIS’ Sanitation Standard Operating Procedure (SSOP) requirements; that 32 had adopted FSIS’ HACCP requirements; that 18 had adopted FSIS’ *E. coli* testing requirements, with 13 adopting different testing requirements, which FSIS had found to be equivalent;<sup>102</sup> and that of the 27 countries to which the *Salmonella* testing regulations were applicable, eight had adopted FSIS’ requirements, with 19 adopting different measures which FSIS had found to be equivalent.<sup>103</sup> In addition, it is notable that one country, the Netherlands, decided to use an altogether different microbiological indicator of contamination, testing for enterobacteriaceae not *Salmonella*. This departure from U.S. regulation was also defined as “equivalent” by FSIS staff.<sup>104</sup>

Although the federal regulations require that FSIS employees conduct *Salmonella* testing and send the test samples to government labs, FSIS revealed at the meeting that other countries’ export establishments could use private laboratories for this purpose if the laboratories met certain criteria.<sup>105</sup> This departure from U.S. federal regulatory requirements did not go through notice and comment rulemaking prior to its adoption by the agency. Ten countries allow their meat processing establishments to take samples, 12 countries’ systems use private laboratories.<sup>106</sup> FSIS explained at the meeting, “We don’t, or we are not in a position to, dictate that you must [use a government laboratory]. That is the way we operated before 1994. If we had these requirements prior to then, it would have been rather simply put, it’s got to be government labs, its got to be government people selecting the samples.”<sup>107</sup>

The December 14, 1999 meeting was notable for two other reasons. First, because FSIS staff felt confident in undertaking such a massive comparison of nations for pathogen reduction and HACCP with no public notice or opportunity for public comment. Yet, as noted above, FSIS’ own policy is to give public notice regarding renewals of countries declared equivalent when nations make significant changes to their system. It is difficult to imagine a more significant change that required for each nation to develop a fully functioning HACCP system. Secondly, FSIS also revealed that rather than requiring the exporting country to provide documents in English, the agency spent over \$550,000 on translation costs.<sup>108</sup> Other federal agencies, such as the FDA in the context of similar multinational agreement (the U.S.-EU Mutual Recognition Agreement for pharmaceuticals and medical devices), have insisted that nations requesting equivalency bear the burden of translation costs.

*On-Site Audits:* Instead of directly inspecting foreign establishments as it did before the 1995 adoption of the “equivalence” mandate, FSIS now relies on “system audits” to determine whether an exporting country’s regulatory system can be declared “equivalent” to that of the U.S. Six FSIS auditors,

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who are veterinarians, are responsible for conducting all foreign country audits. Each audit can take from two to six weeks.<sup>109</sup> Although since the September 11, 2001 attack, USDA has received new funds to ensure the security of the food supply, it is unclear how much of that money has gone to import inspection and auditing. Despite an ever-increasing volume of meat and poultry imports as of March 2003, the number of auditors remains the same as in 1996 – six.<sup>110</sup>

In conducting annual “system audits,” FSIS auditors translate and analyze documents and data, meet with exporting country inspection officials, and accompany the foreign country officials on-site as they inspect usually a small sample of the plants that are approved by foreign governments as eligible to export to the U.S.<sup>111</sup> Once a system has been declared “equivalent,” FSIS relies on the other country’s regulatory officials to conduct the ongoing inspection and monitoring of the establishments in which animals are slaughtered and meat is prepared for export to the U.S. The number of eligible plants that are actually visited by an FSIS auditor as part of the annual system audit varies widely and can be as few as nine out of 513 certified establishments, which is the case in Canada.<sup>112</sup> As explained by Sally Stratmoen, Acting Director, Equivalence Division, FSIS’ Office of International Affairs: “We used to approve plants. Now we approve governments.”<sup>113</sup>

*Port-of-Entry Reinspections:* Port-of-entry reinspections consist of visual inspection of all imports for transportation damage, proper packaging, labeling, certification, general condition and accurate count.<sup>114</sup> and more in-depth testing of a subset based on a frequency determined by FSIS’ automated system.<sup>115</sup> The frequency of reinspection used to be based on plant performance. In other words, plants with a history of violations were targeted for more in-depth border scrutiny. However, in a 2002 news release, FSIS announced that it was switching to a “new statistically-based sampling program based on the annual volume of shipments.”<sup>116</sup> Under the new sampling program, product and percentages were slated to vary dramatically according to export volume, with nations exporting a smaller amount to the U.S. receiving more scrutiny and nations exporting larger amounts receiving less.<sup>117</sup>

New data from the last quarter of 2002 indicates for the first time how this system is working. The data shows a precipitous drop both in the rate of inspection and the number of pounds of beef rejected at the border. When the new system kicked in during the fourth quarter of 2002, it resulted in a 65% drop in the rate of meat and poultry inspected from the previous quarter.<sup>118</sup> Up until that point, FSIS regularly inspected approximately 200 million pounds of meat at the border each quarter and rejected 2 to 3 million pounds per quarter, maintaining an average inspection rate of 18%.<sup>119</sup> In the last quarter of 2002, FSIS only inspected 61 million pounds and rejected a mere 713,000 pounds.<sup>120</sup> The inspection rate dropped to 6%. Under this inspection system meat that may have been previously rejected at the border, may now make it onto supermarket shelves. In addition, *zero* eggs were rejected in the last quarter of 2002, as compared to 73,000 pounds of rejected eggs in the previous quarter.<sup>121</sup>

The new system is described in the FSIS news release as the system that has been in effect for Canada.<sup>122</sup> The “streamlined” Canadian system, which was put in place in 1989 with the passage of the Canadian-U.S. Free Trade Agreement, has been criticized for not providing sufficient protection by the owner of one of the 150 private import inspection establishments in which FSIS reinspection takes place. Mike Tisdale, owner of U.S. Import Meat Inspection, in Sweetgrass, Montana, testified at a 2001 USDA

hearing that: "...[T]he current Canadian system is in need of some change before being applied for the rest of the world importing meat to the U.S. For example at my facility we received shipments totally [sic] roughly 400 million pounds of meat last year, yet, our FSIS inspector was only instructed to examine approximately 100,000 pounds or two hundredths of one percent. We feel this level of inspection is far too low to provide a clear picture of a foreign country's inspection program. Even with this low level of inspection two and a half million pounds of Canadian meat was refused entry into the U.S. last year." Mr. Tisdale reports that during one week in January 2003, U.S. inspectors were instructed by the automated computer system which designates lots for sampling only to take samples for testing from seven of 248 tractor trailer loads from Canada that came through his import establishment.<sup>123</sup>

### FSIS MEAT AND POULTRY BORDER INSPECTIONS

<u>Quarter</u>	<u>Imported (Pounds)</u>	<u>Inspected (Pounds)</u>	<u>Rejected (Pounds)</u>
Oct-Dec 2001	945,349,541	173,433,150 18% inspection rate	2,157,568
Jan-March 2002	923,756,633	166,930,958 18% inspection rate	2,701,236
April-June 2002 <sup>1</sup>	2,098,192,964	228,858,614 21% inspection rate	3,025,087
July-Sept 2002	1,053,344,944	191,767,489 18% inspection rate	2,141,695
Oct-Dec 2002 <sup>2</sup>	968,700,383	61,093,061 6% inspection rate	712,744

Unless a shipment is selected for in-depth examination by the automated system, routine visual inspection of a container holding 700-1000 cartons of imported meat can take as little as 15-20 minutes.<sup>124</sup> Routine visual inspection consists simply of an examination of transportation damage, general condition of shipment, labeling compliance and proper certification.<sup>125</sup> For countries other than Canada, the product is taken off the truck and "staged" so that the inspector can walk around each pallet.<sup>126</sup> Canadian meat is not taken off the truck for inspection, but instead is given a cursory inspection at the back of the truck.<sup>127</sup> In addition, carcasses examined at the back of the truck are pre-selected by Canadian inspectors who are motivated to put the place the best product in the back of the truck.

Once imported meat from Canada or any other country is allowed entry, it can be added to and mixed with domestic or other foreign meat and meat products.<sup>128</sup> In the second quarter of 2002 alone,

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<sup>2</sup> New AIIS system takes effect.

1,098,192,964 pounds of meat were presented for import.<sup>129</sup> Approximately 79% was given no more than the visual form of reinspection. Yet, three million out of the more than 1 billion pounds presented were refused entry.<sup>130</sup> “We could be inspecting more product at no additional cost to the government or the consumer. My employees and the FSIS inspector have already been paid and spend much time waiting for the one in 20 shipments that are selected for inspection. We should be fully utilizing these already paid for man-hours to inspect more meat,” says Tisdale.<sup>131</sup>

*Crucial Missing Elements:* Moreover, two components of the U.S. meat inspection process underpin the integrity of the entire system; neither are required from foreign inspection systems which are deemed “equivalent.” First, in U.S. establishments, FSIS inspectors “have access at all times, by day or night, ... to every part” of slaughtering and processing establishments.<sup>132</sup> By contrast, before FSIS sets foot in a foreign establishment, it has informed the exporting country “who will be visiting, what they wish to see, where they wish to go, and when they wish to do so.”<sup>133</sup> Second, a U.S. inspector’s ability to carry out the duty to ensure that food is safe is backed up in the U.S. by a whistleblower law, which has benefitted the American public greatly over the years as countless numbers of whistleblowers have protected the public from unsafe meat, drugs, and other dangerous products, as well as government and corporate fraud, waste and criminal behavior. However, foreign meat inspection systems are not required to provide this protection.<sup>134</sup>

### **C. FSIS’ PERFORMANCE IMPLEMENTING EQUIVALENCE**

Since 1995, FSIS has implemented “equivalence” in ill-considered haste on a vast scale. The results were predictable and devastating. The first report on the extent of the problems was produced by the USDA’s own Office of the Inspector General in 2000. The unusually harsh report described a meat and poultry inspection system in chaos. The report noted that:

- C FSIS granted equivalency status to six countries for their HACCP program without conducting onsite reviews;<sup>135</sup>
- C Seven foreign establishments that had lost their eligibility to export to the U.S. were found to have shipped 4,625,363 pounds of meat and poultry into the U.S.;<sup>136</sup>
- C Nineteen plants that had not been re-certified as meeting U.S. standards were allowed to continue to export meat to the U.S.;<sup>137</sup>
- C Procedures for determining equivalency were not detailed enough to ensure that all aspects of a country’s regulatory system were reviewed in accordance with applicable regulation and equivalency determinations were based on insufficient documented analysis and support;<sup>138</sup>
- C Regulatory requirements that countries provide annual certifications of plants and residue test plans were not enforced;<sup>139</sup>
- C FSIS had no clear procedures for determining if another country’s alternative testing methods were equivalent;<sup>140</sup>
- C FSIS was underutilizing technical experts of the Technical Services Center and over utilizing program analysts of the Equivalency and Planning Branch. In astonishingly severe language, the Inspector General wrote “We question whether the Equivalence and Planning Branch, collectively, has the technical expertise to make equivalency determinations;”<sup>141</sup> and

C Violations by certain countries were tolerated, while the same violations by other countries were not tolerated. The fact that FSIS had no written procedures for terminating eligibility raised the specter of arbitrary decisionmaking.<sup>142</sup>

The USDA Inspector General followed up with a 2003 report. Eighteen of the recommendations in the June 2000 Inspector General's Report concerned port-of-entry reinspection. Yet, amazingly, in a report released in February 2003, the Inspector General found that FSIS had taken "adequate action" on only four of these 18 recommendations.<sup>143</sup> Although the need for increased management oversight had been one of the major findings of the June 2000 report, the Inspector General found in 2003 that "inaction occurred because no one was held accountable for implementing these recommendations and no mechanism was established to alert top FSIS management officials that this work was not being done."<sup>144</sup> The report revealed that between January 1999 and March 2001, over seven million pounds of meat which had entered the U.S. market came from 37 foreign establishments whose eligibility in the computerized information system was contradicted by other documents.<sup>145</sup> Because of FSIS' laxity and failure to take corrective action after the June 2000 report, the Inspector General concluded that it was not possible for the agency to ensure that all meat entering the U.S. market was produced in plants that were eligible to export to the U.S.

In a January 2003 interview with Public Citizen, one FSIS employee confirmed the confusion and lack of good processes in the equivalency division of FSIS, by describing incomplete files, lengthy delays in responding to a request for an equivalency determination, and pressure from supervisors to declare a file complete even though many documents had not yet been translated into English.<sup>146</sup>

In 2002, 43 countries had been granted equivalency status by FSIS for exports to the U.S. of meat and meat products from cattle, sheep, swine and goats.<sup>147</sup> Argentina, Australia, Austria, Belgium, Belize, Brazil, Canada, Costa Rica, Czech Republic, Denmark, Dominican Republic, El Salvador, England and Wales, Finland, France, Germany, Guatemala, Honduras, Hungary, Iceland, Ireland, Italy, Japan, Mexico, Netherlands, New Zealand, Nicaragua, Northern Ireland, Norway, Paraguay, Poland, Republic of China, (Taiwan), Republic of Croatia, Republic of Slovenia, Romania, Scotland, Spain, Sweden, Switzerland, Uruguay, Venezuela, and Yugoslavia. Five have been granted equivalency status for poultry exports: Canada, France, Great Britain, Hong Kong, Israel and Mexico.<sup>148</sup> Canada and Australia together account for approximately 70% of all meat and poultry imports.<sup>149</sup>

Starting in 2000, Public Citizen began filing requests under the Freedom of Information Act (FOIA).<sup>150</sup> for the documentation underlying meat inspection equivalency determinations for a number of countries. In response, FSIS produced audit reports for 12 countries, allowed Public Citizen to review several files, but then claimed that other information was so widely dispersed that its production would be burdensome and time-consuming and demanded that Public Citizen make advance payment of prohibitive sums before providing further access. More recent requests for the documentation underlying such equivalency decisions still have not been responded to by FSIS. In 2001, FSIS began posting the most recent audit reports and some of the ensuing correspondence on its website.<sup>151</sup> Although 43 countries are listed in the Code of Federal Regulations as eligible to export to the U.S., there are audits for only 33 countries on the website.

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Public Citizen's review of the FSIS audits of five of countries, Argentina, Australia, Brazil, Canada, Mexico, and Argentina, reveal a significant degree of confusion about the application of "equivalence" in practice and an alarming gap between decisions made at the policy level and information used for equivalency determinations acquired in the slaughterhouses and processing plants:

- C Systems with sanitary measures that differ from FSIS policy, and in some cases, actually violate the express language of U.S. laws and regulations, have been declared "equivalent;"<sup>152</sup>
- C Improper and/or unapproved testing procedures and sanitation violations have been re-identified by FSIS year after year and are not remedied, but the countries have retained their eligibility status to export to the U.S.;<sup>153</sup>
- C After their regulatory systems have been designated "equivalent," countries have altered their methods and procedures or adopted new ones that have never been evaluated by FSIS, which FSIS has only discovered when later conducting an on-site audit;<sup>154</sup>
- C Regulatory systems have been rated equivalent even though sufficient personnel and monetary resources are not available to carry out all required functions;<sup>155</sup>
- C Countries continue to use their own methods and procedures while awaiting a response from FSIS to a request for an equivalency determination, but are treated as equivalent while they wait for a response;<sup>156</sup> and,
- C FSIS auditors and foreign food safety officials disagree about whether or not particular measures have already been found to be "equivalent" by FSIS.

According to Sally Stratmoen, Acting Director of FSIS' Equivalence Division, FSIS has tightened its approach and now requires countries to demonstrate remedial enforcement efforts when deficiencies are found.<sup>157</sup> However, the efficacy of this approach remains to be demonstrated, as evidenced by a November 2002 letter from Stratmoen to her Mexican counterparts pointing out that FSIS had received no notification from Mexico about corrective actions following identification of deficiencies six months earlier, although FSIS "expected the Mexican government to issue these letters and following 30 days from issuance verify that the establishment made all necessary corrections."<sup>158</sup> In order to determine the equivalence of foreign inspections systems' enforcement powers and capacity, FSIS sent a questionnaire to be completed by the exporting countries' regulatory officials.<sup>159</sup> No country met FSIS' initial FY 2002 time line for submission of the information.<sup>160</sup> In fact, many countries had such difficulty responding to the detailed questionnaire that what was to have been a major initiative focusing on enforcement is more than a year behind.<sup>161</sup>

All the while, meat continues to come into the U.S. from these countries, stamped with a USDA grade and placed on grocery shelves. Although a law authorizing a country-of-origin labeling system in the U.S. was approved by Congress in 2001 and was slated to come into effect in 2004, industry is actively seeking a repeal of this measure, apparently with the support of the USDA.<sup>162</sup> USDA has been dragging its heels with regard to issuing the required regulations, and in late June 2003, the House of Representatives Appropriations Committee voted to eliminate funding for implementation of this program. Thus, the fate of this program has yet to be decided. Without country-of-origin labeling, consumers have no way to make informed purchasing decisions in light of concerns about international disease outbreaks or food safety lapses.

### **Case 1: Argentina - Is Twice a Year Equivalent to Daily?**

In 2002, Argentina exported 85 million pounds of beef and veal to the U.S., even though some exports were prohibited due to the outbreak of foot and mouth disease in that nation.<sup>163</sup>

A review of Argentina's audit reports over the years reveal a variety of problems. In June and July of 1997, FSIS audited Argentina's national laboratory and all of the 20 Argentinean establishments that were then certified as eligible to export meat and meat products to the United States.<sup>164</sup> Thirteen of the establishments were rated as "acceptable" and seven were rated as provisionally acceptable but requiring re-review. Yet, Argentina's schedule for conducting the "re-reviews" is not specified in the report. The auditor noted that:

Incidents of cross-contamination were observed in twelve [sic] establishments, and contamination with oil, hair, and feces in four while carcasses contacting the floor were found in six plants. Plant system controls to assure sanitary [sic] plant operations and effective preventive maintenance of plant facilities were not in place in the following cases: in four location, [sic] condensate, flanking [sic] paint, contamination of product-contact areas, and in three locations, maintenance and cleaning of product-contact equipment was not adequate. Product-contact equipment was not maintained or adequately cleaned in three establishments. Also, sanitizers were not maintained at 180F in slaughter and processing operations, in four cases.<sup>165</sup>

There is no information in the 1997 audit report about Argentina's demonstration of an effective compliance and enforcement system. Yet, overall, Argentina's meat inspection system was determined by FSIS to have sufficiently effective controls in place to be eligible to export meat and meat products to the United States.

Documents obtained by Public Citizen in response to the FOIA request raise serious questions about FSIS' equivalency determination concerning Argentina. The information provided to FSIS by Argentina did not establish that Argentina was meeting U.S. requirements in the areas of mandatory HACCP plans or continuous inspection and explicitly stated that monthly supervisory visits were not a part of the Argentinean regulatory system. For example, the 1996 Procedures Manual of the Argentinean regulatory agency describes its hazard management program as a "new volunteer program" based on HACCP that is to "be voluntarily put in effect by the industries."<sup>166</sup> The manual describes a multi-tiered system of regulatory inspection in which the frequency of inspection is determined by the number of defects noted in the prior inspection. Establishments at the first tier of this system are to be inspected no more frequently than every six months and second tier establishments, every three months.<sup>167</sup> Inspection plans are to include "[t]he place and date of where the inspection will be conducted."<sup>168</sup> The U.S. regulations, by contrast, require the *continuous* presences of federal inspectors in slaughter plants at all hours of operation and *monthly* supervisory visits to each establishment that produces meat for export to the U.S.<sup>169</sup>

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The FOIA documents include minutes of meetings held within FSIS to review the information submitted by Argentina in support of its request for a continuing equivalency determination. At a meeting in 1998, FSIS officials noted that Argentina's hazard management system was voluntary, that Argentina intended to implement a less than continuous inspection system for establishments that implement hazard management, and that Argentina had not provided any information on how it would implement *Salmonella* standards and testing. The officials speculated among themselves that "[p]resumably an establishment would have to have implemented HACCP in order to export to the U.S."<sup>170</sup> The FSIS officials recorded that "clarification" was needed in three areas: continuous inspections, mandatory HACCP and an explanation as to whether Argentina had an effective enforcement component.<sup>171</sup> A year later, FSIS officials reviewing the equivalency determination for Argentina were still recording that information and noted that clarifications were needed as to the existence of an effective regulatory enforcement component and that Argentina's *Salmonella* testing program could not be reviewed until additional information was provided.<sup>172</sup>

Thus, years after having rated Argentina's system to be "equivalent," FSIS officials were still unsure of Argentina's adherence to key safety provisions of the U.S. regulatory system.

Argentina was audited again in March and April of 2001.<sup>173</sup> At that time, Argentina was eligible to export only cooked and canned meat due to an outbreak of foot and mouth disease.<sup>174</sup> Approximately one-fifth, or eight of the then 35, certified establishments were audited and all were found generally acceptable. Argentina was found to be using both government and private laboratories to perform *Salmonella* testing. Monthly supervisory reviews were being conducted at that time. However, Argentina has since experienced a major economic crisis during which payment of government workers was suspended for months at a time over the past two years, endangering Argentina's ability to reach and maintain the necessary level of direct regulatory involvement.

The most recent audit of Argentina available on the FSIS website was conducted in May and June 2002.<sup>175</sup> The FSIS auditor visited 11, or 1/3, of the 34 then-certified establishments. Of the 11, three were delisted during the audit because of problems that "impacted on food safety and public health" and a fourth was delisted because of metal contamination that had been found at an import station.<sup>176</sup> An additional plant was delisted on the basis of a record review that showed no evidence of monthly supervisory reviews for eight months.<sup>177</sup> HACCP implementation, an area of deficiency in the 2001 audit, was again deficient in 90% of the plants visited. The auditor concludes by stating that Argentina's inspection system "was found to have ineffective controls to ensure that product destined for export to the United States was produced under conditions equivalent to those ... FSIS requires ..."<sup>178</sup> Nevertheless, Argentina retains its eligibility to export cooked and canned meat to the U.S.

FSIS rated Argentina "equivalent" despite the fact that Argentina's official policy violated the requirement of monthly supervisory reviews and despite Argentina's failure to produce information sufficient to enable FSIS to determine whether continuous inspection was being performed or whether an effective enforcement system was in place. FSIS has continued to classify Argentina as "equivalent" even though four out of 11 plants visited by the FSIS auditor in 2002 had to be removed from the eligibility list because they were not meeting U.S., or equivalent, standards. What would the auditor have found if

he or she had visited the remaining 23 plants?

### **Case 2: Australia - Is One Inspector Equivalent to Four?**

Australia and Canada are the top two exporters of red meat into the U.S. In 2002, Australia exported 1.1 billion pound of beef and veal into the U.S.<sup>179</sup> In the mid-1990's, Australia partially privatized its domestic meat inspection program and by the end of June 1997, 430 government meat inspectors had been eliminated.<sup>180</sup> Between 1998 and 2000, government funding for meat inspection dropped from \$20.3 million to \$6.4 million.<sup>181</sup>

In the late 1990s, Australia proposed to take its domestic, largely privatized meat inspection system international and asked the U.S., the EU and other trading partners to approve its domestic system for export. Its new export plan was called the Meat Safety Enhancement Program (MSEP). MSEP tracked the domestic program by greatly reducing the role of federal inspectors and putting company employees in charge of inspection duties.

In 1999, European safety officials evaluated the MSEP program and rejected its use on meat for export to Europe, concluding after an on-site assessment: "In many instances, the Australian quality assurance systems permit establishment employees to act as if they were officers of the competent authority. This is in breach of the requirement that inspectors should enjoy a status which guarantees their impartiality. The level of official supervision and control is reduced to a level below that required by the European legislation and must therefore be considered inadequate."<sup>182</sup>

However, MSEP received a warmer welcome in the U.S. After soliciting public comment on the new Australian program, FSIS found MSEP to be equivalent to the U.S. system in June 1999.<sup>183</sup> The U.S. approved MSEP even though the program reduced the role of independent governmental inspection to a single inspector at the end of the line to examine carcasses. This one inspector would stand in for an average of four inspectors who traditionally work the length of the processing line, examining each carcass and all other operations of the plant.<sup>184</sup>

Although the U.S. has approved MSEP as equivalent, no meat is currently being shipped to the U.S. Because MSEP was rejected by the EU, and because the plants that export to the EU are also the plants that export to the U.S., Australia has refrained from switching over those plants to the MSEP system.<sup>185</sup> The privatized Australian system is used for meat produced for Australian domestic consumption. After the programs implementation, public health officials noticed dramatic changes in Australian *Salmonella* rates. Between 1993, when a pilot version was introduced, and 1999, reported cases of *Salmonella* in Australia increased by over 60%, from 4,520 to 7,436, and the numbers continue to climb.<sup>186</sup> In 2002, there were 7,747 reported cases of *Salmonella*.<sup>187</sup>

Australia refers to its domestic system as "co-regulation,"<sup>188</sup> but has been labeled "corporate self-inspection" by Tom Devine of the Government Accountability Project (GAP) who investigated its effects in Australia in November 1999.<sup>189</sup> Through document reviews<sup>190</sup> and interviews with 15 whistleblowers and others, GAP documented a serious deterioration in the Australian food safety

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system.<sup>191</sup> Though export facilities that have retained government inspectors were found to maintain higher standards than domestic plants, Australian export inspectors also identified numerous sanitation violations, including pools of bloody fecal soup on floors that workers track onto production lines and dressing tables; pigeon and swallow fecal droppings on equipment, workers and food; and urine flying out of carcasses, with no protection from cross contamination of equipment, food or workers showered by sprays.<sup>192</sup>

FSIS audited the Australian meat inspection system in 2000, actually visiting only nine of the 99 establishments then-certified as eligible to export meat to the U.S., a rate of inspection of 10%.<sup>193</sup> The auditor approved Australia's use of private laboratories for *Salmonella* testing as meeting FSIS requirements. Of the nine establishments audited, eight were found to be acceptable; one was not. The overall system continued to be rated as "equivalent." The report documents the following problems that were raised with Australian officials:

- C Feces on product in three of the nine establishments and no effective procedure for detection and removal of urine spillage on sheep carcasses in four of the nine;<sup>194</sup>
- C No post-mortem inspection of the heads of small stock;<sup>195</sup>
- C Different rate of sampling for generic *E. coli* testing for sheep;<sup>196</sup> and
- C Failure to incise lymph nodes of beef heads on routine post-mortem examinations.<sup>197</sup>

As to the first issue, Australian officials responded that they would "form a managerial group to solve this problem [fecal and urine contamination] immediately."<sup>198</sup> Regarding the other three problems, Australian officials responded that they had "submitted to International Policy Staff, FSIS, [for equivalency determination] and they were awaiting a response."<sup>199</sup>

In August and September 2001, FSIS returned to conduct another audit. At that time, there were 103 establishments certified to export meat to the United States.<sup>200</sup> FSIS visited 11 of the 103 establishments, a rate of inspection of 10%, reviewed the records of another 18 and also visited three ratiite (ostrich and emu type birds) establishments newly proposed for certification. Twelve of the 14 plants that were audited were found to have effective system controls in place and two were recommended for re-review because their HACCP programs were found not to meet FSIS regulatory requirements. One establishment was suspended from eligibility to export to the U.S. ("delisted") because it had no HACCP program. The FSIS auditor noted that Australia had not adopted FSIS' regulatory requirements for *E. coli* testing in sheep.<sup>201</sup>

Again, as in the previous year, the auditor raised problems regarding the U.S. zero tolerance for feces, ingesta, milk and urine and again Australian officials responded that they "will form a managerial group to solve this problem immediately."<sup>202</sup>

Once again, the U.S. auditor raised the issues of incomplete post-mortem inspection of the heads of small stock and different rate of sampling for generic *E. coli* testing for sheep. Again, as they had the previous year, Australian officials responded that the issues "had been submitted to International Policy Staff, FSIS, and they were awaiting a response."<sup>203</sup>

FSIS' most recent reported audit of Australia was performed in February and March 2002. Thirteen of the 101 then certified establishments were audited and all were found to have effective system controls in place.<sup>204</sup> FSIS found improvement in the area of urine spillage, but noted failures to prevent cross-contamination in seven of the 13 audited plants.<sup>205</sup> In a review of Australia's enforcement activities, the report states that 31 meat-related incidents resulted in discussions with management, including security breaches, obstruction of authorized officers, entry of ineligible product into the export chain, and incorrect trade descriptions and regulations relating to official marks.<sup>206</sup> As before in 2000 and 2001, the auditor noted that Australia had not adopted FSIS' regulatory requirements for *E. coli* testing in sheep and has requested an equivalency determination on this issue. As before in 2000, the auditor pointed out that lymph glands of beef heads are not being incised in post-mortem examinations.<sup>207</sup> In October 2002, FSIS requested that their Australian counterparts "immediately commence with the incision and examination of the ... lymph nodes of the heads of all cattle slaughtered from which meat is obtained for export to the U.S." pending FSIS' review of Australia's equivalence proposal on this issue.<sup>208</sup>

The likelihood that a U.S. consumer will encounter Australian beef increased in April 2002, when the McDonald's chain announced that it was going to start using imported Australian beef in U.S. restaurants.<sup>209</sup>

FSIS rated Australia "equivalent" despite the fact that its privatized inspection system violates the fundamental U.S. requirement of impartial government inspectors; despite the fact that it repeatedly failed to remedy violations of U.S. sanitation standards; despite the fact that it uses a method of testing for *E. coli* that has not been found to be equivalent by FSIS; and despite the fact that it has not required plants to perform post-mortem inspections as mandated by U.S. law.

### ***Case 3: Brazil - Company-Paid Meat Inspectors Equal to Government Inspectors?***

Brazil is eligible to export only cooked beef products to the U.S. due to the presence of hog cholera, swine vesicular disease and foot-and-mouth disease.<sup>210</sup> In 2002, Brazil exported 201 million pounds of cooked meat to the U.S.<sup>211</sup>

In January 1998, 26 Brazilian establishments were certified to export meat to the U.S. When FSIS announced that an audit was to take place, Brazil removed six of them from eligibility, stating that the plants voluntarily withdrew "for economic reasons."<sup>212</sup> FSIS audited 16 of the remaining establishments and found that one or more inspection employees were company-paid in 15 of the 16, for a total of 55 inspection employees who were compensated directly by the establishments they inspected.<sup>213</sup> Brazilian officials explained that funding problems had led to the use of company-paid inspectors, but that emergency funding was being sought through a Presidential Decree.<sup>214</sup> They further stated that company employees would stop inspecting meat to be exported to the U.S.<sup>215</sup> All 16 establishments audited by FSIS were rated acceptable, but the auditors recommended an on-site follow-up audit "to verify compliance of [sic] U.S. requirements" before the end of 1998.<sup>216</sup> The report does not refer to any enforcement activities.

The next audit of the Brazilian meat inspection system was not conducted until March and April

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1999.<sup>217</sup> At that time, 21 establishments were certified to export meat to the U.S. FSIS audited 14, two-thirds of the total, and found that in two there were “neither inspection system controls nor establishment system controls... in place to prevent, detect, control and correct contamination and adulteration of meat products.”<sup>218</sup> Yet of the 14 establishments audited by FSIS, nine were rated acceptable; five were rated “acceptable/re-review.” The report does not mention any enforcement activities, nor does it make mention of company-paid inspectors.

When FSIS audited Brazil in 2000, nine, or 36%, of the 25 then-certified establishments were visited.<sup>219</sup> Of the nine, one was rated unacceptable. Significant problems were found at the one laboratory audited, including lack of chemicals required for pesticide testing. At the exit meeting, Brazilian officials stated that funds for chemicals at the laboratory would be “available immediately.” Enforcement activities are mentioned only as a subject discussed with Brazilian officials.<sup>220</sup>

In July and August 2001, FSIS audited nine of the 28 then-certified establishments and found that “[i]n-depth knowledge of HACCP is lacking in most” of them.<sup>221</sup> Examples of the cross-contamination that was found to be occurring include:

- C In two establishments, over-spray above the carcass wash was falling from the contaminated rail onto a clean rail of carcasses;
- C The moving viscera (internal organs) table was coming up with residues from the previous use in three establishments;
- C The employee, who was cutting across the anus, continued the cut into other tissues without sanitizing the knife in two establishments, spreading fecal contamination; and,
- C The buccal cavity was opened before the mouth cavity was washed resulting in possible contamination of exposed product with ingesta in [one] establishment.<sup>222</sup>

An import station in the U.S. has found *Salmonella* in samples of cooked frozen meat from a Brazilian plant “on more than one occasion.”<sup>223</sup> Investigation of the plant revealed that hydraulic oil that was contaminated with *Salmonella* was dripping from a product press onto exposed meat. Monthly supervisory reviews were not being conducted in any establishments and the auditor noted that the requirement was “made clear” during the audit.<sup>224</sup> Although the auditor reports that Brazil found 155 violations and issued 62 warnings and 79 penalties, he also notes that he did not receive the documentation of enforcement activities that he had requested.<sup>225</sup>

The most recent reported audit of Brazil’s regulatory system was conducted in January and February 2002. Thirteen plants, 45%, of the 29 then-certified establishments, were audited. Seven were selected “because of their implication in misbranding of canned corned beef.”<sup>226</sup> Of the 13 plants, two were delisted by Brazilian officials after the auditor found serious sanitation problems. The auditor notes that serious problems were found in the remaining 11 establishments as well, but they were “allowed to continue to operate and within 30 days be verified for full compliance by” the Brazilian regulatory authority.<sup>227</sup>

Deficiencies that were identified in the prior audit that had not been corrected included failure to

perform pre-shipment reviews in all plants, HACCP plans with critical limits that were not measurable, actual and potential product contamination, failure to perform monthly supervisory reviews in all plants, and deficiencies in quality assurance in the private laboratories that performed microbiological testing.<sup>228</sup> Additional deficiencies identified during the audit included inadequate hazard analysis in 10 of the 13 plants' HACCP plans,<sup>229</sup> inadequate pest control prevention in 12 of the 13, and, in 10 of the 13, reconditioning of dropped product performed by the inspectors instead of by establishment personnel.<sup>230</sup> Under "Enforcement Activities" in the audit report, it was noted that in six establishments "inspection devices (brands) were not adequately kept under inspectional control."<sup>231</sup> Brazil uses plant employees to take *Salmonella* samples and private laboratories to test those samples.<sup>232</sup> These measures are rated equivalent even though they contradict U.S. regulatory policy.

In an April 10, 2002 response to the 2001 audit report, the Brazilian regulatory agency stated that Brazil would be submitting a request to have its quarterly inspection system declared equivalent to the U.S. requirement of monthly supervisory reviews.<sup>233</sup>

FSIS rated Brazil "equivalent" despite the fact that its use of company-paid inspectors violated the fundamental U.S. requirement of impartial government inspectors; despite the fact that it failed to carry out required testing in a timely fashion due to continued funding problems; despite fecal contamination and serious sanitation problems; despite its failure to demonstrate an effective enforcement system; despite its repeated failure to ensure that plants developed adequate hazard control plans; despite its use of company employees and private labs for *Salmonella* testing; and despite its repeated failure to conduct the monthly supervisory reviews required by U.S. law.

#### **Case 4: Canada - Myth vs. Reality**

In 2002, Canada exported 1.1 billion pound of beef and veal to the U.S.<sup>234</sup> Under "streamlined" inspection procedures put into place under the 1989 Canada-U.S. Free Trade Agreements, Canadian products have been treated differently than all similar products entering the U.S. and Canadian officials are authorized to conduct certain of the required testing procedures.<sup>235</sup> For example, depending on the level of inspection assigned by FSIS' computerized sampling system, a Canadian shipment may be given only a cursory check at the rear of the vehicle by the U.S. import inspector.<sup>236</sup> In contrast, shipments from other countries are off-loaded and subjected to a complete visual inspection for transportation damage, labeling, proper certification, general condition and accurate count. When a sample from a shipment of ground beef from a country other than Canada tests positive for *E. coli* 0157:H7, the U.S. import inspector will collect samples from the next 15 consecutive shipments from the same establishment. However, if the shipment is from Canada, the establishment may request that Canadian food inspectors perform the sampling and certify the results.<sup>237</sup>

Canada's inspection system operates differently from the U.S. system in a number of areas. Yet, two departures from U.S. regulatory requirements in the area of *Salmonella* testing have been classified as "equivalent" by FSIS: (1) The establishment takes the samples instead of government employees,<sup>238</sup>

and (2) private laboratories are used instead of government laboratories.<sup>239</sup> However, no equivalency determinations have been made as to other features of the current Canadian system, including failure to conduct the monthly supervisory reviews that are mandated by the U.S. regulations,<sup>240</sup> use of a different sampling system for generic *E. coli*,<sup>241</sup> and use of a different analytical method to test for *E. coli* 0157:H7.<sup>242</sup> In a letter dated October 15, 2002, U.S. officials promise to “expedite review” of Canada’s request for equivalency determinations.<sup>243</sup> In the meantime, Canada continues to operate by its different rules, and until the very recent discovery of a case of mad cow disease in Canada, Canadian meat continued to enter the U.S. under the streamlined border inspection system.

Differences of opinion in the area of microbial testing are far from academic matters. FSIS has been conducting a sampling program since *E. coli* 0157:H7 was classified as an adulterant in ground beef in 1994.<sup>244</sup> In February 2000, USDA’s Agricultural Research Service found that the prevalence of the potentially lethal pathogen was higher than previously reported, reaching levels of 28% in animals presented for slaughter and 43% of carcasses.<sup>245</sup> In September 2002, FSIS declared “war on *E. coli*” and began requiring all establishments that produce raw beef products to reassess their HACCP plans based on recent evidence that *E. coli* 0157:H7 “is a hazard reasonably likely to occur at all stages of handling raw beef products.”<sup>246</sup>

The Canadian Food Inspection Agency (CFIA), on the other hand, considered it necessary in September 2000 to publish a fact sheet entitled “*E. coli* 0157:H7 Myths v. Reality,” defending itself against “[r]ecent articles [that] have suggested Canada’s inspection system is not tough enough on *E. coli* in ground beef.”<sup>247</sup> The fact sheet contains the following passage:

MYTH: It is possible to effectively test meat for the presence of *E. coli* 0157:H7.

FACT: Health Canada does not recommend routine sample testing as a public health measure because the rate of occurrence of *E. coli* 0157:H7 in ground beef products is very low.

The deadly effects of *E. coli* 0157:H7 were demonstrated in Canada in May 2000, when seven people died in Walkerton, Ontario, after manure run-off from a farm contaminated the town’s drinking water.<sup>248</sup> In July 2001, the *Calgary Sun* reported that local cases of *E. coli* had doubled in the past two years and that CFIA had increased its monitoring of meat producers in Alberta following a recall of ground beef from Lakeside Packers for possible *E. coli* 0157:H7 contamination.<sup>249</sup> During this same time period, FSIS twice announced voluntary recalls of ground beef products produced by Lakeside Packers and distributed in the U.S. In June 2000, 46,000 pounds were recalled after the problem was discovered by laboratory tests performed by a customer and<sup>250</sup> in April 2001, 204,000 pounds were recalled after a sample of ground beef was tested by CFIA.<sup>251</sup> It is worth noting that when USDA discovered *E. coli* 0157:H7 in a shipment of ground beef from Lakeside Packers in 1997, Canadian officials reportedly called it an “isolated incident” and warned against overreacting.<sup>252</sup>

The most recent FSIS audit of Canada’s meat inspection system, for which a report is available on the FSIS website, was conducted in June and July 2001.<sup>253</sup> At that time, 513 establishments were certified to export meat and poultry to the U.S.<sup>254</sup> Of these, nine were audited, an inspection rate of less

than 2%. Six of the nine were rated as acceptable and three were recommended for re-review. Several problems that had been identified in the prior audit had not been remedied, among them deficiencies in dressing and sanitizing procedures, which “still need more improvement”<sup>255</sup> and reduced supervisory reviews, which were occurring only quarterly in Alberta and only one to three times per year in Quebec.<sup>256</sup> The auditor reported that “[t]he method for testing for *E. coli* 0157:H7 used by FSIS has not been approved by Health Canada, so it has not been used by CFIA.”<sup>257</sup> Zero tolerance for fecal contamination was not adhered to in all establishments and pre-shipment reviews were performed in only two, with the remaining establishments stating that they were not aware of the requirement.<sup>258</sup> Improper testing and evaluation of generic *E. coli* was found at two establishments, one of which was Lakeside Packers.<sup>259</sup>

When the auditor discussed U.S. requirements with Canadian officials, the officials responded by saying that they would confer with International Policy Staff regarding clarification of the equivalence of the sampling procedures. Despite the outright differences between Canadian and U.S. sanitary measures, and the unresolved issues awaiting equivalency determination, the U.S. auditor concluded that Canadian meat products were produced under conditions equivalent to those which FSIS requires in domestic establishments.

In a May 2002 letter responding to the 2001 audit, Canada contended that its failure to perform pre-shipment reviews is a feature of its hazard management plan, which was previously found by FSIS to be “equivalent” to the U.S. HACCP rule, and is therefore permissible under the concept of equivalence.<sup>260</sup> The director of Canada’s food inspection agency describes the U.S. auditor’s concern about monthly supervisory reviews – a mandatory provision of U.S. law – to be “an unfortunate misunderstanding.”<sup>261</sup> Citing FSIS’ knowledge that Canada has conducted quarterly, instead of monthly reviews “for years,” the director of the exporting country’s regulatory system takes over the role of the importing country and declares: “... [W]e considered this activity as ‘Equivalent’.”<sup>262</sup>

FSIS rated Canada “equivalent” despite its use of microbial sampling and analytical procedures that differ from FSIS requirements and have never been determined to be equivalent by FSIS; despite its use of company employees and private labs for *Salmonella* testing; despite plants not adhering to a zero tolerance policy for fecal contamination; and despite its repeated failure to conduct the monthly supervisory reviews that are required by U.S. law.

#### ***Case 5: Mexico - Equivalent, Except as Otherwise Noted***

Mexico is currently eligible to export raw and cooked beef products to the U.S.<sup>263</sup> In 2002, Mexico exported 16 million pounds of beef to the U.S.<sup>264</sup> In the spring of 1999, FSIS conducted an audit of Mexico’s meat inspection system and concluded that there were “serious concerns regarding the equivalence of the Mexican inspection system to the U.S. inspection system.”<sup>265</sup> At that time, there were 37 establishments certified as eligible to export meat to the U.S. The auditors found that company-paid inspectors conducted and/or controlled inspection in 17 of the 37 certified establishments, an inspection rate of 27%.<sup>266</sup> Ten establishments were audited; two were found to be acceptable; three were rated

marginally acceptable and had their eligibility to export suspended pending corrective action; five were found to be unacceptable and were decertified.<sup>267</sup> There is no reference to enforcement activities in the report.

In addition to the lack of government inspectors, the following major deficiencies were identified in the 1999 audit report:

- C Required monthly supervisory inspections were not being conducted;<sup>268</sup>
- C There were serious sanitation deficiencies, such as ingesta, fecal and hair contamination ( many deficiencies having been previously noted by the establishment or inspectors and not corrected);<sup>269</sup>
- C In four of five slaughter and ground beef operations reviewed, *E. coli* sampling was not conducted randomly;
- C *Salmonella* testing was not similar to FSIS and did not meet U.S. requirements;<sup>270</sup>
- C Government inspectors said they had no training in pathogen reduction implementation;<sup>271</sup>
- C There appeared to be no national monitoring program for *Listeria*;<sup>272</sup>
- C Laboratory results were not provided on a timely basis unless fees were paid by the establishments;<sup>273</sup>
- C One establishment was using labels approved by FSIS for a sister establishment in California;<sup>274</sup>
- C Required residue testing was not being done due to lack of resources;<sup>275</sup> and
- C Continuous inspection was not being provided in plants that operated two shifts due to staffing shortages.<sup>276</sup>

Finding that “[t]he information ... suggests that conditions of serious public health concern exist in Mexico,”<sup>277</sup> the auditors recommended that FSIS conduct a team “systems audit” of all establishments certified to export to the U.S. However, no review of all establishments was ever conducted and one of the plants that lost its certification during the audit, after a diseased carcass was found ready for boning, had its export license restored under a new name by Mexican officials.<sup>278</sup>

In November 1999, FSIS visited 20 plants of the 37 then-certified establishments. Of these, 12 were found to be acceptable; five were rated marginally acceptable; and three were found to be unacceptable.<sup>279</sup>

In November and December 2000, FSIS again audited Mexico’s meat inspection system.<sup>280</sup> Eleven, barely one-third, of the 34 then-certified establishments were audited and seven laboratories were visited. Seven of the establishments were found to be acceptable; three were acceptable but recommended for re-review; one was unacceptable. One establishment was still using a company-paid inspector, although the auditor noted that Mexico had been told during two prior audits that the requirement of government inspectors was “non-negotiable”.<sup>281</sup>

In the December 2000 report, the auditor documented that there was inadequate government oversight to ensure compliance with the *Salmonella* testing procedures and that laboratories were not using a procedure that would detect *E. coli* 0157:H7 in ground beef samples or performing reliably

compliant sampling for generic *E. coli*.<sup>282</sup> Most laboratories that were performing generic *E. coli* testing were doing it incorrectly and<sup>283</sup>“alternate testing methods” were being used for *Salmonella* and *E. coli* 0157:H7 that had not been submitted to FSIS for equivalence determination.<sup>284</sup> Six weeks or more could elapse before an establishment was delisted by Mexico after being found not to meet U.S. requirements.<sup>285</sup> When the Mexican supervisor who was performing the inspections during the audit tried to delist an establishment based on findings made on-site, her decision was countermanded by her superiors.<sup>286</sup>

Nonetheless, the auditor concluded that “except as otherwise noted,”<sup>287</sup> the inspection system of Mexico had effective controls in 10 of the 11 establishments audited to ensure that product destined for export to the U.S. was produced under conditions equivalent to those that FSIS requires in domestic establishments.

When FSIS performed another audit in November 2001, three of the 29 then-certified establishments were still found to have company-paid employees conducting inspections. These three plants were delisted. Eleven of the 29 certified establishments were audited and four of the seven approved private labs were visited. Effective controls were found to be in place for all of the establishments, but two were recommended for re-review.<sup>288</sup> Materials needed for *Salmonella* and *Listeria* testing were not readily available in some laboratories.<sup>289</sup> Some samples were not reaching the laboratory in a timely manner.<sup>290</sup> Two laboratories were using a sample size much smaller than FSIS requires and certain aspects of the testing methodology still needed to be submitted to the U.S. for equivalency determination.<sup>291</sup>

Yet again, the auditor concluded that “except as noted”<sup>292</sup> Mexico’s inspection system had effective controls to ensure that product destined for export to the U.S. was produced under conditions equivalent to those which FSIS requires in domestic establishments. Following the 2001 audit, USDA reportedly ordered reinspection of all Mexican meat at the U.S. border for several months.<sup>293</sup>

In the most recent reported audit of Mexico’s meat regulatory system, performed in April and May 2002, 12 of the 30 then-certified establishments were audited, an inspection rate of 40%.<sup>294</sup> The auditor noted in the section on enforcement activities that there had been no investigations or prosecutions in the previous year.<sup>295</sup> Of the four major concerns identified in the prior audit, two had been resolved and two had improved. “Thirty-day letters” requiring corrective actions were issued to three of the 12 establishments for deficiencies, such as incomplete HACCP plans, lack of an *E. coli* testing plan, and inadequate clean-up of splitting saws.<sup>296</sup> Six months after the audit was conducted, FSIS was still awaiting confirmation from Mexico that corrective actions had been taken in response to the “thirty-day letters.”<sup>297</sup> Although government inspectors collect *Salmonella* samples, the laboratory testing is done in both at government and private labs.<sup>298</sup>

FSIS rated Mexico “equivalent” despite the fact that its repeated use of company-paid inspectors violates the fundamental U.S. requirement of impartial government inspectors; despite its failure to adhere to the core U.S. requirement of continuous inspection; despite its failure to perform microbial testing adequately, or at all; despite its use of non-government labs for *Salmonella* testing; despite problems with

fecal contamination; despite its failure to comply with the requirement of monthly supervisory reviews; despite its failure to demonstrate an effective enforcement system; despite its failure to correct contamination problems; and despite its use of testing methodologies that have never been found to be equivalent by FSIS.

Reviewing just these five of the over 40 countries whose regulatory systems have been declared equivalent to that of the United States, U.S. officials documented significant violations of all of the core protections of the U.S. meat safety laws. Sanitary standards have not been met; required testing has not been performed or has been performed improperly; continuous inspection and required supervisory oversight have not been provided; and the key safeguard of direct inspection by impartial publicly-paid inspectors has been disregarded. And yet, FSIS continues to rate these country's meat inspection standards as "equivalent" and U.S. consumers continue, unknowingly, to purchase and eat meat that has not been produced in compliance with their democratically enacted laws.

#### IV. CONCLUSION AND RECOMMENDATIONS

Even without exposing the public to such flagrant violations of U.S. food safety policy through equivalence, the domestic food safety system has plenty of problems. Massive recalls like the 2002 Conagra recall of millions of pounds of contaminated ground beef, which caused one death and sickened 47 people in 23 states, continue to occur and continue to be mishandled by USDA officials who are reluctant to crack down on huge slaughter and processing operations.<sup>299</sup> Public Citizen has reported extensively on problems related to the HACCP system in the U.S. and the problems with implementing U.S. microbial testing standards, (*See*, Public Citizen and Government Accountability Project reports, *Jungle 2000: Is America's Meat Safe to Eat?* and *Hamburger Hell: The Flip Side of USDA Salmonella Testing Program*). In addition, Public Citizen has extensively studied the machinations of the food irradiation industry, which is selling this untested and unsafe technology to the American public as a silver bullet for microbial contamination and is in the process of expanding operations overseas in order to irradiate more and more produce headed for U.S. markets.

Consumers and health and safety advocates need to monitor food safety issues here at home and continue to press the U.S. government for higher standards and for better enforcement. However, given the increasing volume of meat imports, U.S. consumers also need to be vigilant about imported meat. The staff of 75 U.S. border inspectors is a thin blue line charged with ensuring the safety, wholesomeness and proper packaging and labeling of the 4 billion pounds of meat and poultry products entering the U.S.

The concepts of equivalence and harmonization were born in the context of the European Common Market, which is now a borderless grouping of countries where goods and products are granted unfettered entry across national boundaries. Notably, these issues still remain controversial in Europe and generate frequent lawsuits between nations. This is true even though the Common Market countries also provided a significant amount of financial and technical assistance to nations which needed to elevate their standards to achieve a comparable level of protection to other EU nations. This is particularly striking considering the relatively small gaps between the European countries compared to the differences between U.S. standards and those of many of the nations from which it imports meat.

Given the vast discrepancy in resources and infrastructure between the 145 member nations of the WTO and the discrepancies even within the three NAFTA nations, it is becoming abundantly clear that the concept of equivalence is not easy to translate to other multi-lateral groupings. The U.S. food safety budget is close to a billion dollars.<sup>300</sup> By contrast, in 1992, Mexico's spending on food safety inspection was \$25 million. Three years later, with food exports soaring under NAFTA, but with Mexico reeling from the peso crash and obligated by new loan agreements to implement further "structural adjustment," Mexico's food inspection funding was slashed to \$5 million.<sup>301</sup> By 2001,

Mexico's total food safety and animal and plant health budget had returned to the \$25 million level – half a percent of Mexico's agriculture ministry budget and less than one dollar per Mexican citizen.<sup>302</sup> Yet, over the past nine years since NAFTA went into effect, Mexican fresh meat exports to the U.S. have risen 300%.<sup>303</sup>

Developing countries are demanding, and they deserve, significant levels of technical support and financial assistance to lift their food safety standards, first to protect their own citizens from foodborne illnesses and second, to facilitate trade. Such assistance is one of developing nations' primary demands in the WTO negotiations. Many countries, with few funds to implement food safety programs, have difficulty in even achieving minimal standards promulgated by international standard-setting organizations, like the Codex Alimentarius Commission and thus view equivalency as a possible way out of this conundrum.

Developed nations are not delivering the aid needed to help these countries adopt, implement and enforce either Codex standards or importing country standards. According to a survey of Codex member countries used in a recently released Food and Agriculture Organization/World Health Organization evaluation of Codex, legislators in many developing countries are reluctant to adopt standards since there is no money to enforce and implement them domestically.<sup>304</sup> The evaluation report revealed a "stark contrast" between the technical assistance and capacity building requested by developing countries to equip governments to implement standards and the modest educational trainings on food safety offered by developed nations and international agencies.<sup>305</sup> Discussions on how to assist developing countries with their "SPS" problems are taking place in the WTO, the Codex, the World Bank and other international institutions. However, for the most part, these discussions focus on raising funds to help officials from developing nations participate in the meetings of the institutions themselves, not on a coordinated effort to raise global food safety by investing in domestic food safety operations.

This report documents that the increasing level of imports due to WTO-required equivalency determinations, combined with different foreign standards, the inadequate auditing of foreign plants and minimalist border checks has resulted in a broad abrogation of U.S. food safety standards. Compounded with a shrinking level of international aid for capacity building and vast discrepancies in the food safety infrastructure of nations, this is a recipe for disaster. Just at a time when all governments must be more vigilant about increased risk of food contamination due to higher levels of trade, and even the possibility of terrorist biocontamination, regulation and government action is constrained by legally-binding trade promotion rules that elevate the fast and unfettered importation of products over all other concerns.

To address these problems and concerns, Public Citizen makes the following recommendations:

**EQUIVALENCY IS NO SUBSTITUTE FOR COMPLIANCE:** Congress must intervene to change the underlying law and regulations so that USDA once again establishes that trading partners maintain the same standards as the U.S. to be eligible to export food products into the U.S. The only deviation from U.S. standards that should be allowed are more stringent standards geared toward preventing specific food safety hazards posed by unique geographical conditions. FDA must be given similar authority to approve countries as compliant with U.S. standards for food production purposes and ban product from countries that are not compliant.

**SUBSTANTIALLY INCREASE BORDER INSPECTION ACTIVITIES:** After the September 11, 2001 attacks, FDA received funds to put 300 new consumer safety officers at U.S. ports of entry.<sup>306</sup> However, it is projected that in 2003 FDA will only be able to increase its inspection rate from .6% to 1.3% of imports.<sup>307</sup> In addition to other funds, USDA received funds for 20 new mobile “Import Surveillance Liaison Inspection Officers” to enhance border inspection operations.<sup>308</sup> Until very recently, USDA’s 75 border inspectors attempted to inspect an estimated 18% of meat imports and randomly sample a small subset of this percentage for microbial contamination, illegal drug residues and species verification.<sup>309</sup> This situation was already a cause for concern prior to the recent changes in the computerized Automated Import Information System, but the changes to the AIIS border inspection system which kicked in during the last quarter of 2002 bring new cause for alarm. As previously noted, the changes resulted in a 65% drop in the rate of meat imports inspected, from 18% to 6%. In addition to securing more funds to substantially increase border inspection activities, immediate Congressional scrutiny is needed to examine this new system and the cause and effect of this tremendous drop-off in border inspection.

**ADEQUATE STAFF AND PERSONNEL FOR OVERSEAS AUDITS:** Both USDA and FDA must be given more money for conducting rigorous overseas audits and the follow up that is necessary to instruct foreign regulators on U.S. food safety policies and procedures. FSIS’s six auditors appear to be a woefully inadequate number of staff to annually confirm the equivalency status of 43 nations for fresh meat and five for poultry. It is hard to believe they will have the resources to perform rigorous audits of the more than 25-plus additional nations demanding equivalency.<sup>310</sup> Some audit teams visit only a small fraction of the plants eligible to export. U.S. audit teams should not only examine the laws, regulatory structure and enforcement record and capacity of each nation, but they should resume the practice of inspecting and certifying every foreign plant shipping product to the U.S. on an annual basis. FDA should also be granted funds to implement certification of each plant eligible to export to the U.S. Currently FDA is only able to inspect a small portion of plants that export food to the U.S.

**DEVELOP CLEAR POLICIES FOR PUBLIC INVOLVEMENT IN AGENCY INTERNATIONAL ACTIVITIES:** The implementation of WTO-mandated harmonization and equivalency mechanisms fundamentally undermines domestic, democratic decisionmaking regarding food safety policy. Consumers have little idea that important regulatory decisions involving the safety of the food on their plates are being made in imprecise, bilateral equivalency negotiations or unaccountable multilateral trading institutions like the Codex and the WTO. All federal agencies engaged in international activities, must develop clear and consistent rules for public engagement in these activities to give U.S. consumers a voice through a participatory public process during multi-year negotiations and certainly before agreements are finalized.

A model administrative procedure for equivalency and harmonization activities is attached to this briefing memo as Appendix C. It is entirely unacceptable that the U.S.-EU Veterinary Equivalency Agreement was negotiated for six years without public notice. Similarly it is inappropriate for FSIS to recertify year after year that certain trading partners are “equivalent” without giving the public an opportunity to review FSIS data, evidence of problems and other information. Closed-door decisionmaking has no place in federal agencies charged with consumer protection.

**TRADE SHOULD NO LONGER TRUMP PUBLIC HEALTH:** There is a growing international call for a paring back of the key WTO agreements like the WTO TBT and WTO SPS agreements that inappropriately delve into regulatory issues via such trade promotion mechanisms as harmonization and equivalency. Not only do the provisions in these agreements make it easier for nations to attack each other’s public health, consumer protection, and food safety regulations at barriers to trade, but they inappropriately elevate trade promotion over all other public policy concerns, including that of ensuring a safe and wholesome food supply. If the same domestic regulatory standard is applied to both domestic and imported food, the level of protection or enforcement is something those living with the results must decide. There is no trade issue if there is no discrimination.

**FUNDS FOR CAPACITY BUILDING:** The U.N. projects that by 2030, two thirds of the meat produced in the world will come from developing nations.<sup>311</sup> In addition to compliance and verification, developed nations must live up to their responsibility to assist developing nations with the financial and technical assistance needed to secure the safety of their own domestic food supply as well as exports. This assistance must go well beyond educational trainings and demonstrate a substantial commitment to ensuring global food safety as a public health priority. The woeful inadequacy of current efforts poses needless health threats for consumers around the world.

**COUNTRY-OF-ORIGIN LABELING SHOULD BE IMPLEMENTED BY USDA:** The 2002 Farm Bill included a country-of-origin (COOL) labeling provision for beef, lamb, pork, farm-raised fish, fruits and vegetables that is slated to be implemented by 2004. The Bush administration objected to the country-of-origin labeling requirements, but ultimately accepted them in the context of the overall legislative package it felt compelled to support. Since passage, the COOL requirements have been under attack by industry and U.S. trading partners alike.<sup>312</sup> Canada, Australia and New Zealand have all complained that COOL violates NAFTA and WTO rules.<sup>313</sup> Recently, USDA Secretary Ann Veneman has made statements suggesting that the law could be repealed by Congress.<sup>314</sup> On June 25, 2003, the House Appropriations Committee approved the 2004 Agriculture and FDA Appropriations Bill which defunds the COOL program. Rather than back-tracking on the COOL program, Congress and the USDA should promptly implement rules for COOL which are overwhelmingly supported by consumers who want more information about the food on their plates, not less.<sup>315</sup> The complexity of applying COOL to ground beef, which can contain meat from a multitude of nations, should prompt USDA to develop new rules for processors placing limits on co-mingling of meat, in order to facilitate rapid trace-back systems if contamination is discovered.

**EXAMINATION OF AGRICULTURAL CONCENTRATION:** In recent years, a small number of large firms have come to dominate the meat and grain industry in the U.S. through a complex cluster of

alliances, joint ventures, partnerships and mergers. The U.S. government has encouraged this consolidation by failing to enforce the 1921 Packers and Stockyards Act, a strong anti-trust policy for the livestock and meat industry.<sup>316</sup> Much of the meat produced in the developing world now and in the future will be produced by these companies, which are increasingly moving off-shore to take advantage of lower wages, low production costs and tax rates, as well as poor environmental and food safety standards. Congress should investigate the effects of this concentration on independent meat and grain producers, food workers, consumers and the environment. Congress should also instruct the General Accounting Office to investigate the extent to which U.S. agencies such as the USDA and the Office of the U.S. Trade Representative are using tax dollars to encourage or subsidize the relocation of this industry overseas. Rigorous enforcement of the Packers and Stockyards Act by the USDA and the U.S. Department of Justice is a first step to addressing this issue in the U.S. and the potential for international anti-trust policies should also be explored under the auspices of the United Nations.

## APPENDIX A: CODEX PRODUCES WTO-APPROVED EQUIVALENCY RULES

The Codex Alimentarius Commission (Codex) in Rome is poised to approve international guidelines to promote trade in food products to facilitate the equivalency mandate of the World Trade Organization's Sanitary and Phytosanitary (SPS) Agreement. The Codex was established as an international food standard-setting body in 1962 by the World Health Organization and the U.N. Food and Agriculture Organization. The WTO SPS Agreement sets criteria that WTO nations must follow regarding policies designed to protect human, animal or plant life and designates Codex standards as the world's presumptively trade-legal standards and the point of reference in any WTO dispute.

*Codex Guidelines on the Judgement of Equivalence of Sanitary Measures Associated with Food Inspection and Certification Systems*, are slated for final approval and adoption at the June 30-July 7, 2003 Codex Alimentarius Commission meeting.<sup>317</sup> If passed as anticipated by the Codex General Assembly, these *Guidelines* could serve to undermine differing domestic policies on equivalency around the world.

Once in place, Codex equivalency *Guidelines* are sure to generate more problems than they solve. Nations denied food equivalency decisions will use the Codex *Guidelines* as ammunition in their WTO disputes, and a nation's *process* for determining equivalency could itself become a WTO adjudicable issue over and above whatever other sanitary measures may be causing trade friction.

***The Harmonization Rules of NAFTA and the WTO:*** In addition to equivalency, there is another NAFTA and WTO-required trade facilitation mechanism that significantly affects domestic regulatory standards. NAFTA and the WTO both oblige member governments to base their domestic standard-setting on specified international standards and on international standard-setting techniques. For example, the WTO SPS Agreement requires that countries "base their sanitary and phytosanitary measures [food standards] on international standards, guidelines or recommendations."<sup>318</sup> This process is called "harmonization" by its proponents, and is especially relevant to this briefing paper because of a current proposal to create international standards for determining food equivalency. This effort has been sanctioned by the WTO and is aimed at encouraging nations to develop the exact same procedure for determining equivalency and discouraging the diversity of procedures that a democratic, participatory process in different countries might create.

The potential problems related to the establishment of such internationally harmonized rules in the food safety area or any other area of public health or environmental protection are multi-fold. Theoretically, international harmonization could occur at the lowest or highest levels of public health or environmental protection or somewhere in between. Unfortunately, the actual provisions in NAFTA and the WTO requiring harmonization, or providing incentives for harmonization, are likely to result in the lowering of the best existing domestic public health, social, economic justice, natural resource conservation and environmental standards around the world.

This is the case because, under NAFTA and the WTO, international standards serve as a ceiling which countries cannot exceed rather than as a floor that all countries must meet. The agreements provide for the challenge of any domestic standards that go *beyond* international standards in providing greater citizen safeguards, but contain no provisions for challenging standards that fall below the named international standard. Thus, the provisions in NAFTA and the WTO promoting harmonization are likely to serve only as a one-way downward ratchet on domestic standards. Challenges of domestic standards that exceed international standards are resolved in the binding dispute resolution system built into these agreements, which is closed to public participation or observation. This is the “race to the bottom” that is built into WTO and NAFTA rules.

U.S. agency officials are currently engaged in innumerable harmonization negotiations around the world in an ever-increasing number of venues, some governmental and some private. NAFTA and the WTO name specific international standards, such as those established by the International Organization for Standardization (ISO) in Geneva and the Codex in Rome as presumptively complying with trade rules. Both the ISO and Codex are dominated by industry. Citizen input into these organizations is essentially non-existent and significant participation by health or consumer groups is extremely limited. For instance, one individual at Consumers International currently attempts to cover five of the ISO’s 2850 working groups, and only three U.S. consumer groups lobby within the Codex, which has 24 committees meeting all over the world on a regular basis. The result of the WTO and NAFTA harmonization mandates is nothing less than a profound shift of regulatory activities away from a fairly open and accountable process under the U.S. Administrative Procedures Act and other open government laws to international organizations operating under extremely different rules regarding membership, governance, and transparency with few provisions for public involvement.

***Codex Guidelines for Equivalency:*** An internationally harmonized standard for determining the equivalence of food regulations is being considered for final action at the Codex in July 2003. Given that NAFTA and the WTO grant Codex standards a new role, as the world’s presumptively trade-legal standards, a Codex equivalency rule could have a significant impact on any domestic food equivalency rules developed by U.S. agencies which regulate food.

The development of internationally-harmonized equivalency rules in the Codex was accelerated at the behest of the WTO. The promise of the establishment of these rules is being used by developed nations as an inducement to get developing nations to go along with their demands in the wider, multilateral negotiations now underway at the WTO.<sup>319</sup> Currently, developed nations are pushing for a major new WTO expansion, including the launch of negotiations of four new binding agreements covering the so-called “Singapore issues” of procurement, competition, investment and trade facilitation. In contrast, developing nations mainly oppose any expansion of WTO rules and seek full implementation of the benefits they were promised in previous WTO agreements. At the 2001 WTO Ministerial Meeting in Doha, Qatar, equivalency was officially listed as an implementation issue that would further existing WTO commitments for more and speedier market access by developing countries, deserving the focused attention of all WTO members.<sup>320</sup> While developed WTO member countries were willing to commit to deregulation in this context, potentially undermining public health and safety, they rejected market access concessions, such as steep cuts in the subsidies currently paid to agribusiness which effectively shut many

poor countries of food trade and undermine domestic food security in poor countries.

Later that year, the WTO's SPS Committee issued an official communique to the Codex Alimentarius demanding that it expedite international equivalency rules it had been working on for many years.<sup>321</sup> The WTO's involvement in the process clearly illustrates that the primary rationale for equivalency is one of trade facilitation. Ensuring a safe and wholesome food supply for the protection of consumers around the world is a lesser concern.

The Codex *Guidelines on the Judgement of Equivalence* were developed by the Codex Committee on Food Import/Export Inspection and Certification Systems (CCFICS) and approved at its December 2002 meeting in Adelaide, Australia,<sup>322</sup> and forwarded the document for final action to the July meeting of the full Codex.

Codex defines equivalency as "the capability of different inspection and certification systems to meet the same objectives."<sup>323</sup> Equivalency agreements "may result in reducing the importing country's rate of physical checks or sampling to test against standards or to avoid additional certification in the country of origin."<sup>324</sup> The Codex *Guidelines* establish a multi-step process for determining equivalence. However, the *Guidelines* are solely process-oriented and fail to cover key issues such as the types of information that must be taken into account when determining equivalency. After multiple meetings, the countries participating in CCFICS were unable to agree on the types of information to be taken into account when judging equivalence and thus postponed this politically hot topic suggesting that such a list could be developed later as an annex to the agreement.<sup>325</sup> Such a list should not only cover the specific aspects of meat slaughter and inspection standards to be compared, but also other aspects of law, regulation and practice such as the adequacy of a nation's SPS budget and a nation's track record of enforcement and product recalls. Without including this full range of comparisons, meat produced under widely differing systems could be judged to be "equivalent" for trading purposes, undermining consumer protection across the globe.

During its development, a number of U.S. and international consumer groups commented on the significant shortcomings of the Codex proposal. In October 2002, Consumers International pressed unsuccessfully for the development of at least three annexes to the agreement: the first would specify the kinds of information requested by importing countries that would be used to make and maintain a judgment of equivalence; the second would outline the terms for onsite visits by importing country authorities to verify if and how the exporting countries' application of SPS measures meets importing country requirements; the third would specify the kinds of technical assistance to be provided by importing countries to assist exporting countries in satisfying importing country requirements.<sup>326</sup> No such annexes were included in the final proposal.

Worse, the proposed Codex equivalency policy inappropriately creates a new limit on the criteria and information that can be supplied and should be requested for the determination of equivalence "to that which is necessary for this purpose."<sup>327</sup> This clause inserts a new "necessity test" limiting the criteria that importing countries may want to utilize in a determination of equivalence, and practically encourages trade challenges against criteria deemed by an exporting nation to be more than strictly "necessary." In the

context of WTO or NAFTA complaint, this language is likely to expose the judgement by a country's food safety experts about what is necessary, to second-guessing by trade officials operating in a closed trade tribunal.<sup>328</sup>

Consumer groups also recommended that the Codex policy explicitly note that nations are free to introduce and maintain domestic standards with a higher level of protection. In other words, countries are not locked into Codex standards. In contrast, the Codex *Guidelines* state that "to facilitate a judgement of equivalence between countries and promote harmonization of food safety standards, Codex member nations should base their sanitary measures on Codex standards and related texts."<sup>329</sup> The ability of countries to maintain different standards under constraining WTO rules is only referenced in a footnote to this text. Given that Codex sanitary standards regarding meat inspection contain significant deviations from U.S. law, (Codex meat inspection standards, for instance, allow company self-inspection of meat),<sup>330</sup> a requirement to rely on international standards raises the specter of the U.S. being required to determine equivalency with countries that do not have the budget to pay for government meat inspectors, and therefore rely on the food industry to police itself or face WTO or NAFTA trade challenges for failing to do so.

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

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

An international harmonized policy on equivalency will serve no purpose except to undermine domestic, democratically-achieved equivalency policies. Rather than promoting such a weak policy in the Codex, the U.S. Codex delegation should have postponed action on an international equivalency policy until a domestic policy was agreed upon after formal rulemaking.

## **APPENDIX B: U.S. AGENCIES STRUGGLE WITH EQUIVALENCY**

The following examples illustrate the problems with how the concept of equivalence is being implemented in U.S. law and regulation, particularly with regard to the maintenance of the domestic system for accountability and public participation in agency decisionmaking provided for in the Administrative Procedures Act and other open-government laws. U.S. federal agencies are failing to develop consistent procedures for notifying the public and incorporating public comment in equivalency decisionmaking.

***FSIS Equivalence:*** As noted above, the passage of the Uruguay Round Agreement Act in 1994 resulted in changes to U.S. import regulations when the words “equal to” were replaced with the word “equivalent.” All other criteria for the importation of meat laid out in the regulations remained the same. Shortly thereafter, FSIS decided that all 37 countries that had previously been certified by FSIS as eligible to export meat to the U.S. under a standard requiring importing governments to adopt identical meat inspection standards were at least “equivalent” to U.S. standards.<sup>331</sup> In other words, these countries were automatically judged to be equivalent and grandfathered in without further analysis. It was not until four years later, in 1999, that FSIS published draft criteria for making equivalency determinations.<sup>332</sup> USDA responded to public comments on this policy in December 1999, but never promulgated the policy as a formal binding rule.<sup>333</sup> Moreover, the FSIS policy does not specify on what basis FSIS will determine alternative sanitary measures equivalent, does not create a policy for terminating equivalency, and leaves an unacceptable amount of room for judgment calls by USDA officials.

In a public meeting on April 14, 1999, USDA officials explained that the agency had decided that formal international agreements were not needed to engage in equivalency.<sup>334</sup> Instead the agency would announce that it would make “determinations” pursuant to the importation criteria laid out in 9 CFR §327.2 and formalize those decisions via notice and comment rulemaking in the Federal Register. The agency also conducts formal rulemaking on an “initial” determination of equivalence, because it has been agency practice to list nations certified to export and now “equivalent” nations in the Code of Federal Regulations. So for example, in 2001, the agency initiated formal rulemaking on a draft equivalency proposal for the newly constituted nation of Slovakia, but no final action has been taken on that determination due to the detection of bovine spongiform encephalopathy in that region.<sup>335</sup>

However, the agency has decided not to provide public notice of “continuing” equivalency decisions with trading partners once determined eligible to export even though these nations may undergo changes in their regulatory structures, and their eligibility for equivalency is supposed to be assessed annually.<sup>336</sup> This means that the USDA does not consult the public on its decisions regarding whether a nation’s equivalency status should be extended and the agency fails to notify the public when problems are found with trading partners violating U.S. law or utilizing standards different than those required by U.S. law.

The agency also announced that it would provide public notice (but not necessarily formal

rulemaking) when a nation determined equivalent made a significant change in its regulatory system.<sup>337</sup> For instance, the agency published a “notice” in the Federal Register seeking comment when Australia (which had previously been found eligible to export to the U.S.) sought equivalency for a new pilot project for meat inspection that replaced federal meat inspectors with company employees.<sup>338</sup> Some months later, USDA posted a “notice of equivalency” stating that the Australian program had been deemed to be equivalent with modifications.<sup>339</sup> In 1999, the agency posted notice that it was evaluating a new Canadian program covering chicken, turkey and other fowl that greatly reduced the role of government inspection.<sup>340</sup> However, perhaps due to a U.S. court ruling highly critical of a similar privatization scheme here, no further action was taken on Canadian proposal.

When the USDA initiated its Hazard Analysis and Critical Control Point (HACCP) program aimed at countering microbial contamination of meat in 1996, it notified trading partners that they needed to implement a similar program for exports to maintain eligibility to export into the U.S. In December 1999, USDA analyzed the HACCP systems of 37 nations and without first giving public notice in the Federal Register, approved 32 as having equivalent implementation of their HACCP systems.<sup>341</sup> Although HACCP, which implicates hundreds of individual sanitary standards, surely constituted a “significant” change meriting prior public notice and consultation, FSIS did not provide the public with advance notice of these important negotiations, arguing that this was not necessary as the countries’ inspection systems already had been approved as equivalent. In 2000, the U.S. Office of the Inspector General issued a scathing critique of the manner in which FSIS handled these equivalency decisions, which is reviewed at greater length later in the body of this report.

***National Organic Program Equivalency:*** The 1990 Organic Foods Production Act authorized the development of a National Organic Program (NOP) which would outline the criteria for determining what products can be labeled and sold as “organic” foods in the U.S.<sup>342</sup> After years of discussion and debate, including an extensive notice and comment rulemaking in the Federal Register, the NOP went into effect in October 2002.

While the program was created with extensive public participation, a little-noticed provision in the regulation allowed for equivalency determinations regarding the organic programs of other countries. The regulation allows for food to enter the U.S. and be labeled organic if a foreign certifying agent approves the food as “organic” per the exporting country’s standards and if the foreign government authority that accredited the certifying agent “acted under an equivalency agreement with the United States.”<sup>343</sup> In other words, organic foods meeting exporting country requirements, but not necessarily U.S. organic standards can be sold in the U.S. and labeled “organic.”

Although USDA initially announced that it was weighing the benefits of a public meeting to determine how to carry out equivalence “in the true spirit of transparency,”<sup>344</sup> it has instead launched into negotiations with a number of countries including India, Japan, Australia and the European Union (EU), before developing an equivalence process regarding organic food standards informed by public participation.<sup>345</sup>

In the context of its ongoing negotiations with the EU, USDA’s National Organic Standards

Board (NOSB) published a set of proposed criteria to be used for determining equivalence in April 2002 including: 1) is the regulation consistent with U.S. objectives, as stated in the NOSB Principles of Organic Production and Handling?; 2) would recognition of the regulation as equivalent have any negative impacts on domestic producers or handlers?; 3) does the foreign regulation meet the expectations of domestic consumers?; and 4) are there environmental management requirements unique to the exporting country?<sup>346</sup>

Comparison of the U.S. and EU organic standards reveals a number of substantive differences, including differences regarding whether food produced using sewage sludge as fertilizer and antibiotics qualify as organic. These two issues among others prompted massive public outcry to the initial U.S. proposed rule which resulted in those measures being dropped from the final proposal. Yet, the measures are being reconsidered as part of the U.S.-EU equivalency negotiations. There are a number of differences between U.S. and EU organic standards:

**U.S. Organic Standard**

- Sewage sludge prohibited
- Lumber treated with arsenate prohibited
- Livestock feed must be 100 % organic
  
- Antibiotic use prohibited

**EU Organic Standard**

- Sewage sludge permitted
- Lumber treated with arsenate permitted
- Feed may be 60% “in-conversion” and 25% conventional
- Antibiotics allowed, with restrictions<sup>347</sup>

To date, USDA has not determined any country equivalent in the organic food category. The very notion of equivalency is particularly troubling in the context of the organic food rules given the very purpose of the NOP 1990 Organic Foods Production Act is to assure “consumers that organically produced products meet a consistent standard.”<sup>348</sup> The act was written to eliminate a perceived “patchwork” of organic standards that varied from state to state, and the USDA regulations consist of 150 pages of standards and requirements U.S. food producers in all states must meet before their products can be labeled “organic.” Yet, the U.S. regulations providing for equivalency determinations stand in sharp contrast to the notion of consistency, as differing standards can be arbitrarily designated “the same” for trade importation purposes. Having eliminated one patchwork of varying procedures and standards, the regulation’s equivalency terms facilitate the creation of new international patchwork of differing standards which can be declared “equivalent”– and receive the same U.S. “organic” label.

While the NOSB has stated in a draft document seeking public comment on the U.S.-EU organics equivalency discussions that the program will use notice and comment rulemaking before finalizing its equivalency determinations, in line with USDA’s practice for certifying countries to export to the U.S., this is hardly reassuring.<sup>349</sup> While public notice is always a desired minimum for public participation, in this instance, hundreds of thousands of producers and consumers participated in the creation of the National Organics Program. When the regulations were finalized they thought their job was done. In reality, very few of these small farmers and consumers have the ability to monitor the Federal Register and weigh-in on each international negotiation. As a consequence USDA may declare alternate standards, even on issues as hotly contested as sewage sludge, “equivalent” and thus establish an alternate regulatory system for organic imports.

***FDA Equivalence:*** FDA's statutes and regulatory structure with regard to imports differs greatly from USDA's. Until the 2002 Bioterrorism Act, most foods falling under FDA authority were simply shipped to the U.S. from plants all over the world, only a small fraction of which FDA officials were able to inspect. Now, per the requirements of the new law, by December 2003 foreign plants must pre-register and notify FDA of incoming shipments. Although following the September 11, 2001 terrorist attacks, FDA received new funds for border inspection, the agency will only be able to increase border inspection activities from .6% of imports in 2001 to a projected 1.3% of imports in 2003.<sup>350</sup>

It is worth noting at the outset that the FDA has a long history of entering into simple compliance agreements. FDA has negotiated more than 50 Memorandum of Understanding (MOU) with foreign governments that commit these governments to meeting U.S. standards before exporting food and other products under the agency's jurisdiction to the U.S.

Additionally, FDA has been involved in a protracted equivalency negotiation with Europe regarding good manufacturing practices for pharmaceuticals under the auspices of a 1998 U.S.-EU Mutual Recognition Agreement (MRA). Because this agreement deals with non-food product standards, it falls under WTO TBT Agreement rules. The pharmaceutical MRA is a significant cause of transatlantic friction and is years behind its implementation schedule primarily because FDA has found it labor-intensive and time consuming to approve other countries' regulatory systems as "equivalent." After five years, no country has yet been determined equivalent although a great deal of staff time and money has been spent attempting to implement the agreement. FDA's go-slow approach in product equivalency stands in sharp contrast to USDA's enthusiastic embrace of the concept.

FDA has engaged in food equivalency discussions, but has never developed a formal food equivalency policy. FDA issued a "notice" of a draft equivalency process in 1997, but never formalized the policy as a final rule.<sup>351</sup> To our knowledge, FDA has not used its draft procedure to determine any food inspection system equivalent to that of the United States.

Although it has not yet finalized and promulgated its own rule on equivalency, FDA was a leader in the effort to promulgate the international equivalency guidelines at the Codex Alimentarius discussed in Appendix A. FDA has said it would rely on the Codex *Guidelines* once finalized and approved, but has not specified in what manner, i.e. if the agency will adopt the Codex *Guidelines* as a guidance or a regulation or take no formal action at all.<sup>352</sup>

The proposed Codex policy is significantly less consumer protective than the draft equivalency policy published by FDA in 1997. In July 2002, the Washington-based consumer group Center for Science in the Public Interest (CSPI) sent a letter to the FDA, which leads the U.S. delegation for the Codex Committee in charge of developing the Codex *Guidelines*, pointing out the differences between the two proposals.<sup>353</sup> The 1997 FDA draft policy clearly stated that to assure that imported foods were as safe and wholesome as domestically-produced foods, U.S. standards "would not be relaxed to facilitate a finding of equivalence."<sup>354</sup> By contrast, the Codex *Guidelines* do not provide any assurances that domestic standards will not be relaxed. In addition, the FDA draft policy requires ongoing verification,

including import checks at the border, while the Codex *Guidelines* states that “importing parties may be able to reduce the frequency and extent of verification measures following a judgement of equivalence.”<sup>355</sup> The FDA draft policy states that the U.S. will conduct one or more on-site visits to verify that foreign regulatory systems, including plant inspection systems, are functioning as indicated in paper reviews. Rather than recommending that such site visits be a regular part of verification and monitoring, the Codex *Guidelines* merely suggest that exporting country provide access to enable its inspection systems to be examined by the importing party.<sup>356</sup>

Unlike other federal agencies, FDA is required by the 1994 Uruguay Round Agreements Act to conduct formal rulemaking before declaring countries SPS measures equivalent under FDA statutes.<sup>357</sup> The Act requires the FDA to publish a proposed regulation when it wants to declare a foreign food standard “equivalent,” disclosing the basis of the proposed determination, providing the public with an opportunity to comment on the proposal, and taking into account the comments received in making the final decision.<sup>358</sup> In contrast, Codex *Guidelines* merely suggest that governments consult with interested parties “to the extent practical and reasonable,”<sup>359</sup> providing no assurances that consumers or other interested parties will truly have a voice in the process. Unfortunately, FDA has announced that it does not feel obliged to engage in notice and comment rulemaking when equivalency decisions are reached under the WTO’s TBT agreement, although the public health implications of determining equivalency in the pharmaceutical products area are just as much of a concern as equivalency in the food products area.<sup>360</sup>

Many consumer advocates believe that FDA’s eagerness to assist in the development of an international policy before developing its own policy on food equivalence reveals the systematic prioritization of trade facilitation goals over public health goals. If the agency were interested in protecting the health of American consumers as its first priority, then it seems reasonable that it would develop a domestic policy aimed at achieving that goal first. If, however, the agency’s primary interest is promoting trade, the latter makes sense.

***APHIS Equivalency:*** USDA’s Animal and Plant Health Inspection Service has no publicly available equivalency policy or any policy for public involvement in equivalency decisionmaking, but is engaged in at least two equivalency negotiations nonetheless. On July 20, 1999 the U.S. and the European Commission signed a far-reaching agreement concerning trade in animals and animal products affecting over \$1.5 billion in U.S. exports annually.<sup>361</sup> Called a Veterinary Equivalency Agreement or VEA, major products covered include: live animals, meat and edible meat offal, fish and crustaceans, molluscs and other aquatic invertebrates, dairy produce, birds’ eggs, natural honey, margarine, a variety of animal fats and oils, pasta, soups and broths, ice cream, flours, meals and pellets, animal blood, glands and other animal organs, animal or vegetable fertilizers, casein, gelatins, peptones, enzymes, raw hides, skins and fur skins of animals, wool, and fine or coarse animal hair.<sup>362</sup> Considering the scope of products covered by the VEA, a number of U.S. regulatory agencies will play a role in its implementation, including USDA, FDA and the Fish and Wildlife Service.

The VEA outlines a four step process for determining the equivalence of U.S. and EU standards in over 40 product areas, although to date equivalency has not been achieved in any product area. Article

7 of the VEA requires that: 1) The parties identify the sanitary measure for which equivalence is sought; 2) the importing party explains the objective of the sanitary measure; 3) the exporting party demonstrates that its sanitary measure achieves the importing party's appropriate level of protection; and 4) the importing party analyzes the supplied information.<sup>363</sup> The type of information analyzed includes risks identified by the importing party, provisions within the exporting party's legislation regarding standards, procedures, policies, infrastructure, the resources and relative power of the exporting party to enforce these controls, and evidence from the exporting party as to the efficacy of its enforcement controls.<sup>364</sup>

An important aspect of the VEA, which resulted in changes to U.S. domestic regulatory policy, involves the issue of determining what regions are free of certain animal diseases and therefore eligible to export. Article 6 of the VEA requires that "the importing Party shall recognize for trade the health status of regions, as determined by the exporting Party."<sup>365</sup> This tracks the internationally-harmonized standards set by the International Office of Epizootics, the WTO-recognized veterinary standard-setting institution based in Paris, but represents a significant shift in pre-existing U.S. policy. Prior to the equivalency agreement, when there was an outbreak of an animal disease in a European country, the U.S. would commonly ban imports from the entire country. Now, under the regionalization rules of the VEA, European officials are supposed to determine the sub-national region which is diseased and from which products can be banned, and the U.S. is required to comply with that determination. On October 28, 1997, APHIS issued a final rule implementing the changes to U.S. regulations needed to fulfill the regionalization requirements of the VEA before it was even signed.<sup>366</sup>

There are significant problems associated with the regionalization approach. For instance, importing parties need assurance that federal and sub-federal veterinary authorities will honestly and promptly report potentially devastating diseases. Yet routine experience tells us that this does not always occur.

According to APHIS, the VEA was negotiated for six years before it was finalized,<sup>367</sup> yet in the U.S., there were no public meetings, nor a single congressional hearing on the matter and no agency involved solicited public comment on the negotiations in the Federal Register. It has yet to be seen whether or how agencies will notify the public when specific equivalency determinations are made in each of the 40-plus product areas covered by the agreement.

In addition to the veterinary equivalency agreement, APHIS is engaged in equivalency negotiations in another area although APHIS has no overall policy on equivalency, has not developed a list of criteria that will be used to judge equivalence and apparently has no plans to do so.<sup>368</sup> The agency is currently preparing to declare foreign irradiation facilities as technically equivalent to U.S. facilities under the WTO TBT Agreement to enable them to irradiate certain fruits and vegetables intended for export to the United States to eradicate pests.<sup>369</sup> It is not clear why this is classified solely as a technical or TBT issue dealing with the facilities themselves, when the irradiated fruits and vegetables are headed for the U.S. market and to the dinner tables of U.S. consumers.

***NHTSA Equivalency:*** The National Highway Transportation and Safety Administration is also engaged in equivalency under the WTO TBT Agreement. The agency regularly reviews petitions to

incorporate foreign standards as “equivalent” to U.S. vehicle safety standards, giving manufacturers in the U.S. the option of using either. While an examination of TBT equivalency is beyond the scope of this paper, the manner in which NHTSA is handling equivalency is worth mentioning because it has gone farther than any agency in attempting to promulgate a formal process for equivalency and to develop a separate policy for incorporating public comment into the process. NHTSA gave public notice and accepted public comment on both policies in the Federal Register.

NHTSA is the only federal agency to have performed formal rulemaking to establish its harmonization and equivalency procedure. After soliciting public comment and responding to it on the record, it issued a final rule in May 1998 which incorporates a number of helpful elements.<sup>370</sup> First, the NHTSA policy clearly states that its practice will be to identify and adopt those foreign vehicle safety standards that “clearly reflect best practices i.e., that require significantly *higher* levels of safety performance.”<sup>371</sup> Second, “if resource limitations make it necessary to choose between competing petitions [for amendment of standards], the agency will give priority to granting a petition asking the agency to *upgrade* one of its standards to the level of a superior foreign standard over granting another petition simply asking the agency to add a compliance alternative.”<sup>372</sup> Third, every petition to amend a NHTSA vehicle safety standard must be accompanied by appropriate data and an analysis of the relative benefits of the NHTSA and foreign standards meaning that NHTSA places the burden of proof on the petitioner by requiring the petitioner to supply the data and analysis to support the petition.<sup>373</sup> Fourth, if the agency tentatively decides that a foreign standard is functionally equivalent or better than a NHTSA standard, the agency will issue a notice of proposed rulemaking and request public comment on the tentative determination and the proposed amendment.<sup>374</sup> Finally, the agency explicitly affirms that any final rule to amend a NHTSA standard will be made in accordance with the applicable law of the United States and “only after careful consideration and analysis of the public comments.”<sup>375</sup> Under this process, NHTSA has already turned down a number of equivalency petitions such as one for windshield wipers that they believe were an unacceptable abrogation of a U.S. standard.

It is notable that FSIS felt comfortable analyzing the hundreds of sanitary standards that go into a HACCP program and declaring these complicated programs “equivalent” without prior notice and comment rulemaking on the equivalency negotiations. Meanwhile, NHTSA regularly employs rulemaking simply when considering the equivalence of a single standard. At a minimum, all U.S. agencies should have formal policies promulgated as a binding rule regarding how they will undertake the process of equivalency decisionmaking and how they will incorporate the public in this process. A model Administrative Procedures Act policy for equivalency decisionmaking is attached as Appendix C of this report.

## **APPENDIX C: MODEL ADMINISTRATIVE RULEMAKING PROCEDURE FOR AGENCIES RE: INTERNATIONAL HARMONIZATION, EQUIVALENCE, AND MUTUAL RECOGNITION**

Prior to engaging in international harmonization activities, mutual recognition agreements, or equivalence determinations, each agency should follow existing rule-making procedures to promulgate a formal rule setting forth procedures to be followed to assure such public input and involvement as are reasonable and as required under the Administrative Procedure Act (APA), the Federal Advisory Committee Act (FACA), the Freedom of Information Act (FOIA), the Sunshine Act or other applicable law. The agency rule should incorporate the following procedures.

### **I. Harmonization**

Each agency involved in harmonization activities should invite and facilitate public participation concerning the proposals for the international harmonization of U.S. regulations and standards of other nations or those being developed by international standard-setting organizations by:

1. publishing once each year in the *Federal Register* the agency's plans for harmonization activities in the following year and providing an opportunity for interested parties to comment on the substance of the standards, the prioritization of agency resources used on such activities, and to submit particular proposals or ideas for agency consideration.
2. prior to the agency's engagement in a specific harmonization activity
  - a. publishing in the *Federal Register* any proposed harmonized standard, all subjects for negotiation, and any proposed U.S. position for such negotiations, including
    - (i) reference to the legal authority under which the activity is proceeding;
    - (ii) a description of the subjects and issues involved, the nations involved, a discussion of the potential U.S. public benefit of the harmonization activity, whether the proposed harmonization activity could result in a level of protection higher or lower than existing U.S. regulations or standards, and whether U.S. law encourages or authorizes harmonization in this instance; and,
    - (iii) the extent to which non-governmental parties will participate in the process and the applicability of FACA.
  - b. preparing an environmental assessment for any harmonization activity likely to affect the environment; and
  - c. inviting interested parties to comment on the proposed standard, and the U.S.

position on the standard and to attend a public hearing on the proposal within the comment period. The agency should respond to any comments on the record before engaging in international harmonization negotiations.

3. during the pendency of the harmonization activity
  - a. publishing in the Federal Register or on the agency's website on a periodic basis a description of the current status of all harmonization negotiations, draft documents (where appropriate), and the timetable for future harmonization activities;
  - b. ensuring that the public has prompt and meaningful access to all documents that are available under the Freedom of Information Act (FOIA) relating to the harmonization activity, including documents submitted by non-governmental entities and foreign governments; and
  - c. if industry representatives are involved in the activity, undertaking to obtain the participation of representatives of regulatory beneficiaries in any U.S. delegation, including providing financial support for such representatives if needed to facilitate their participation.
4. providing an additional notice and comment opportunity as provided in paragraph (2) if material alterations in the activity cause the agency to substantively depart from the terms or substance of the proposed regulation or standard or the previously stated U.S. position, as originally noticed. Any committees formed in the harmonization process should be treated as administrative committees for purposes of U.S. law.

## II. Equivalency Determinations

Agencies should invite and facilitate public participation concerning equivalency determinations by:

5. publishing in the *Federal Register*
  - a. notice of any petition or request for an equivalence determination from a foreign government;
  - b. early notice of U.S. agency intent regarding each requested or proposed equivalency agreement, including an explanation of: the agency's statutory authority to undertake equivalence; the criteria that will be used to determine equivalence; any risk assessments or applicable studies; an analysis of benefits for the U.S. public and risk posed by such an equivalency decision; an explanation of the findings that the measure provides the same or greater level of consumer protection as the counterpart domestic measure;

- c. early notice inviting interested persons to comment on a proposed equivalency determination and to attend a public hearing on the proposal within the comment period. Agencies should respond to any comments on the record before making a final equivalency determination;
  - d. if applicable, a draft of the agreement, before the agreement has been signed on behalf of the agency.
- 6. before entering into the equivalency decision, preparing an environmental impact statement for any determination likely to affect the environment.
  - 7. providing for an open docket to facilitate public comment during the implementation period.
  - 8. publishing a report on the functioning of any equivalency determination after two years of implementation and operation, and on a periodic basis thereafter.

### III. Mutual Recognition Agreements (MRAs)

Agencies should invite and facilitate public participation concerning MRAs by:

- 9. publishing in the *Federal Register*
  - a. notice of any petition or request that a U.S. agency negotiate or enter into an MRA;
  - b. notice of any decision by the agency to request a foreign government to negotiate or enter into an MRA;
  - c. early notice of U.S. agency intent regarding each requested or proposed MRA including an explanation of: the agency's statutory authority to undertake MRAs; any risk assessments or applicable studies; an analysis of benefits for the U.S. public and risk posed by such an agreement; an explanation of the findings that the MRA provides the same or greater level of consumer protection as the counterpart procedure formerly utilized by the agency;
  - d. early notice inviting interested persons to comment on a proposed or negotiated MRA and to attend a public hearing on the matter within the comment period. Agencies should respond on the record to any comments about the proposed MRA,;
  - e. a draft of the MRA, before the MRA has been signed on behalf of the agency.
- 10. before entering into an MRA, an environmental impact statement for any proposed MRA.likely to affect the environment.

11. providing for an open docket during the implementation period.
12. a report on the functioning of any MRA two years after implementation.

#### IV. Guiding Principles

Agencies should develop guiding principles for their harmonization activities and accept public comment with proceedings to formulate those principles. Agencies should decline to participate in international harmonization activities that are not governmental in nature, conducted without public notice of such activities and/or that do not permit public observers. Agencies should not recognize international standards that are developed with proceedings that do not allow for public notice and input. Agencies should view U.S. laws and regulations as a floor for negotiations and should not allow for the development of international standards lower than U.S. standards.

## ENDNOTES

1. The Transatlantic Consumer Dialogue is made up of the largest consumer organizations in the U.S. and Europe. It was formed in 1998 to give consensus recommendations on trade and consumer-related matters to the U.S. and European governments. Transatlantic Consumer Dialogue, *Principles of Harmonization*, Feb. 2000, at 2, available at <http://www.tacd.org>.
2. The Riksdag (Swedish Parliament), "EU Information: A Common Market, Fact Sheet Number 3," Aug. 29, 2001 at 3.
3. USDA, Animal Plant Health Inspection Service, "Overseas Investments by U.S. Meat Corporations: What's the Future for U.S. Exports?" *Changing Times in Animal Agriculture*, Jul. 2000, available at [www.aphis.usda.gov/vs/ceah/cei/chtimes0700.htm](http://www.aphis.usda.gov/vs/ceah/cei/chtimes0700.htm)
4. USDA, Animal Plant Health Inspection Service, "Overseas Investments by U.S. Meat Corporations: What's the Future for U.S. Exports?" *Changing Times in Animal Agriculture*, Jul. 2000, at 4.
5. USDA, Animal Plant Health Inspection Service, "Overseas Investments by U.S. Meat Corporations: What's the Future for U.S. Exports?" *Changing Times in Animal Agriculture*, Jul. 2000, at 3.
6. 21 U.S.C. §§601, 603-610; 620-621; 671-679.
7. GAO, "Issues USDA Should Address Before Ending Canadian Meat Inspections," Jul. 1990, GAO/RCED-90-176, at 1.
8. GAO, "Issues USDA Should Address Before Ending Canadian Meat Inspections," Jul. 1990, GAO/RCED-90-176, at 2. Also, U.S. GAO, "United States-Canada Open Border Proposal for Meat and Poultry Inspection System," Testimony by John Harman, Director GAO Food and Agriculture Issues before the Subcommittee on Agriculture Research and General Legislation, Senate Committee on Agriculture, Nutrition and Forestry, GAO/T-RCED-90-96, Jul. 12, 1990, at 10.
9. David Lapp, "Return to the Jungle," *Multinational Monitor*, May 1990.
10. *Id.*
11. See, for example GAO, "Issues USDA Should Address Before Ending Canadian Border Meat Inspection," GAO/RCED-90-176, Jul. 6, 1990. GAO Testimony: "United States-Canada Open Border Proposal for Meat and Poultry Inspection," Statement of John Harman, Food and Agriculture Issues, GAO, Before the Subcommittee on Agriculture Research and General Legislation, Senate Committee on Agriculture, Nutrition and Forestry, GAO/T-RCED-90-96, Jul. 12, 1990. "GAO, Food Safety and Quality: USDA Improves Inspection Program for Canadian Meat, but Some Concerns Remain," GAO/RCED-92-250, Aug. 1992.
12. 60 Fed. Reg. 38667, Jul. 28, 1995.
13. 9 CFR §327.2.
14. Dr. John Prucha, Assistant Deputy Administrator for International and Domestic Policy, USDA, Public Meeting: Equivalence Evaluation of Pathogen Reduction HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 15, on file with Public Citizen.
15. Mark Mannis, International Policy Development Division, USDA, Public Meeting: Equivalence Evaluation of Pathogen Reduction HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 170, on file with Public Citizen.
16. 9 CFR § 327.2.
17. USDA, FSIS Quarterly Enforcement Reports for 2002 available at . Noel C. Paul, "Where is the beef (from)?" *Christian Science Monitor*, Apr. 14, 2003.
18. Noel C. Paul, "Where is the beef (from)?" *Christian Science Monitor*, Apr. 14, 2003.
19. USDA, Public Meeting: FSIS Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Washington, D.C. Apr. 14, 1999, Transcript, at 100, on file with Public Citizen.
20. Winifred DePalma, Public Citizen telephone interview with Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, FSIS, Nov. 22, 2002.
21. USDA, Office of Inspector General, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III, at iii, available at <http://www.usda.gov/oig/webdocs/imported.pdf> and on file with Public Citizen.
22. GAO, "Procedures for Inspecting Canadian Meat Imports," GAO/T-RECD-97-121, Apr. 2, 1997 at 1.
23. The 1999 Belgian dioxin scare brought down the Belgian government when it was revealed that the government knew as early as mid-March 1999 that it had a problem with dioxin contaminated animal feed which spread to chicken and eggs, but failed to

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- notify the public until May 1999. (Corie Lok and Douglas Powell, "Belgian Dioxin Crisis of the Summer of 1999, a case study in crisis communication and management," Department of Food Science, University of Guelph, Ontario, May 2000.) In 2001, Argentina's neighbors blasted the government for not promptly notifying them of an outbreak of foot and mouth disease in that country. ("South Americans Call on Governments to Come Clean on Foot and Mouth," *Agence France Presse*, Mar. 14, 2001). News reports indicate that Chinese officials suppressed news and accurate statistics about the SARS epidemic for months. In April 2003, Chinese officials announced the country harbored 10 times the number of previously disclosed SARS infections. ("China Admits SARS Cover-Up," *Seattle Times*, Apr. 21, 2003.)
24. FSIS, Meat, Poultry and Egg Products Inspection: 1999 Report of the Secretary of Agriculture to the Congress, Mar. 2001 at 2.
  25. FSIS, Annual Report to Committee on Agriculture of the U.S. House of Representatives and to the Committee on Agriculture, Nutrition and Forestry of the U.S. Senate, Nov. 1999, at 38.
  26. FSIS, Public Meeting: Meat and Poultry Point -of-Entry Reinspection System, Transcript, Jun. 8, 2001, at 515-516.
  27. USDA, Public Meeting: In the Matter of FSIS Meat and Poultry Port-of-Entry Re-inspection System, Transcript, Jun. 8, 2001, at 563, available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/01-015N/Poe.pdf>.
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  30. Winifred DePalma, Public Citizen telephone interview with Don Smart, Director, Review Division, Technical Service Center, FSIS, Feb. 5, 2003.
  31. USDA, Public Meeting: FSIS Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Washington, D.C. Apr. 14, 1999, Transcript, at 153, on file with Public Citizen.
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  33. Public Citizen analysis of WTO 2002 report "WTO Overview of State of Play of WTO Disputes" WT/DSB/29/Add.1, Nov. 29, 2002, available at [www.wto.org](http://www.wto.org).
  34. For instance, in its 2000 report on equivalency, the USDA Office of Inspector General determined that 19 plants that had not been certified were allowed to ship meat to U.S. and that the U.S. had granted 6 countries equivalency status without first conducting on-site reviews. USDA, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III at ii-iii.
  35. Michael T. Osterholm, Ph.D., M.P.H., "Emerging Infections: Another Warning," *New England Journal of Medicine* editorial, Vol. 342, No. 17, Apr. 27, 2000.
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  46. FDA, "Protecting the Food Supply: FDA Actions on New Bioterrorism Legislation," Fact Sheet, Jan. 2003.
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55. World Trade Organization, Agreement on Application of Sanitary & Phytosanitary Measures, [WTO SPS Agreement], Articles 4.1, available at [www.wto.org/goods/spsagr.htm](http://www.wto.org/goods/spsagr.htm).
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61. 5 U.S.C. §552.
62. 5 U.S.C. §552b.
63. 5 U.S.C. Appx. §1.
64. WTO SPS Agreement, Art. 3.1.
65. FDA - 21 CFR §§100-190 (food for human consumption) and 21 CFR §§500-589 (animals feed and drugs); FSIS - 9 CFR §§300-590.
66. FDA - 21 CFR §§170-190; EPA - 40 CFR §180.
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75. USDA, FSIS Quarterly Enforcement Report, April 1, 2002 through June 30, 2002, available at <http://www.fsis.usda.gov/oa/haccp/QR3FY2002.pdf>.
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79. 9 CFR Part 416 (SSOPs) and Part 417 (HACCP). The SSOP regulations became effective on Jan. 27, 1997. The HACCP regulations became effective on Jan. 26, 1998 for plants with 500 or more employees; on Jan. 25, 1999 for plants with 10 or more but fewer than 500 employees; and on Jan. 25, 2000 for plants with fewer than 10 employees. 61 Fed. Reg. 38805 (Jul. 25, 1996).
80. 9 CFR §§310.25(a) and 381.94(a). The *E. coli* process control testing regulations became effective on Jan. 27, 1997. 61 Fed. Reg. 38805 (Jul. 25, 1996). Generic *E. coli* testing is in addition to the testing for the deadly pathogen *E. coli* 0157:H7 which FSIS has been conducting since the pathogen was declared to be an “adulterant” in 1994.
81. 9 CFR §§310.25(b) and 381.94(b). *Salmonella* performance standards and testing became effective on Jan. 26, 1998 for plants with 500 or more employees; on Jan. 25, 1999 for plants with 10 or more but fewer than 500 employees; and on Jan. 25, 2000 for plants with fewer than 10 employees. 61 Fed. Reg. 38805 (Jul. 25, 1996).
82. See, *Jungle 2000: Is America's Meat Safe to Eat, A Survey of USDA Meat Inspectors*, by Felicia Nestor, Government Accountability Project, and Wenonah Hauter, Public Citizen, September 2000, available at [www.citizen.org/cmep](http://www.citizen.org/cmep).
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85. 21 U.S.C. §§601, 603-610; 620-621; 671-679.
86. 9 CFR §327.2; 35 Fed. Reg. 15610 ( Oct. 3, 1970).
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90. 60 Fed. Reg. 38667, 38668 (Jul. 28, 1995).
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92. 9 CFR §327.2(a)(2)(i).
93. 9 CFR §327.2(a)(2)(ii).
94. 9 CFR §327.2(a)(2)(iii).
95. 9 CFR §327.2(a)(2)(iv).
96. 64 Fed. Reg. 12281 (Mar. 12, 1999).
97. FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Mar. 1999, at 9, on file with Public Citizen.
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99. 64 Fed. Reg. 70690, 70691 (Dec.17, 1999). Though FSIS announced in this document that it would post the “next version” of the FSIS Process on its webpage in the Spring of 2000, it does not appear to have done so.
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106. USDA, Public Meeting; Equivalence Evaluation of Pathogen Reduction/HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 95-96, on file with Public Citizen.
107. USDA, Public Meeting; Equivalence Evaluation of Pathogen Reduction/HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 112, on file with Public Citizen.
108. USDA, Public Meeting; Equivalence Evaluation of Pathogen Reduction/HACCP Requirements, Transcript, Washington, D.C. Dec. 14, 1999 at 63, on file with Public Citizen.
109. *Id.*
110. Email from Keith Payne, Office of Congressional and Public Affairs, FSIS, to Winifred DePalma, Public Citizen, Mar. 11, 2003, on file with Public Citizen.
111. FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Mar. 1999, at 9-10, on file with Public Citizen.
112. Audit Report for Canada, June 11 through July 6, 2001, USDA, available at [http://www.fsis.usda.gov/OFO/TSC/foreign\\_country\\_audit\\_reports.htm](http://www.fsis.usda.gov/OFO/TSC/foreign_country_audit_reports.htm). In approximately half of the countries that are eligible to export to the U.S., because comparatively few plants are certified, 100% are visited by FSIS. Dec. 5, 2002 Winifred DePalma, Public Citizen telephone interview with Don Smart, Director, Review Division, Technical Service Center, FSIS.
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123. Winifred DePalma, Public Citizen telephone interview with Mike Tisdale, owner of U.S. Import Meat Inspection, Jan. 24, 2003.
124. Winifred DePalma, Public Citizen interview with anonymous import inspector, Nov. 4, 2002.
125. Winifred DePalma, Public Citizen telephone interview with import inspector, Nov. 4, 2002.
126. USDA, Public Meeting; In the Matter of FSIS Meat and Poultry Port-of-Entry Re-inspection System, transcript, Jun. 8, 2001, at 522, available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/01-015N/Poe.pdf>.
127. USDA, Public Meeting; In the Matter of FSIS Meat and Poultry Port-of-Entry Re-inspection System, transcript, Jun. 8, 2001, at 529, available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/01-015N/Poe.pdf>.
128. 9 CFR §327.18. Starting in Sep. 2004, retailers of agricultural products including meat and fish will be required to notify purchasers of the product's country of origin under a provision of the Farm Security and Rural Investment Act of 2002, Bill, P.L. 107-171, 116 Stat. 134, §10816. USDA issued interim voluntary country of origin guidelines on Oct. 8, 2002. The Canadian Cattlemen's Association states that it is working with the Canadian government "to explore WTO and NAFTA challenges" to the new rules. Comments on the USDA-AMS Voluntary Guidelines for Country-of-Origin Labeling, prepared by Dennis

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130. *Id.*
131. USDA, Public Meeting: In the Matter of FSIS Meat and Poultry Port-of-Entry Re-inspection System, transcript, Jun. 8, 2001, at 563, available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/01-015N/Poe.pdf>.
132. 21 U.S.C. §606.
133. FSIS Process for Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Mar. 1999, at 10.
134. Statement by Dr. John Prucha, Deputy Administrator for Domestic and International Policy, FSIS, Apr. 14, 1999 Public Meeting, attended by Public Citizen.
135. USDA, Office of Inspector General, *Food Safety and Inspection Service, Imported Meat and Poultry Inspection Process, Phase I*, Report No. 24099-3-Hy, June 2000, Section III, at iii, available at <http://www.usda.gov/oig/webdocs/imported.pdf>.
136. *Id.*, at Section III, at 37.
137. *Id.*, at Section III, at ii.
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143. USDA, OIG, Food Safety and Inspection Service, Imported Meat and Poultry Reinspection Process, Phase II, February 2003, Audit report No. 24099-04-Hy, at iii-v, available at [usda.gov/oig/webdocs/24099-04-Hy.pdf](http://usda.gov/oig/webdocs/24099-04-Hy.pdf).
144. *Id.*, at 6.
145. *Id.*, at ii.
146. Winifred DePalma, Public Citizen telephone interview with USDA employee, Linda Lewis, Jan. 14, 2003.
147. 9 CFR §327.2(b). Because of endemic disease conditions, some countries, including Brazil, are eligible to export only cooked and canned products. 9 CFR §94.1. An outbreak of disease can cause a country to lose its eligibility, as happened to Argentina at the beginning of 2001 when foot and mouth disease was brought in by animals from a bordering country. 66 Fed. Reg. 29897 (Jun. 4, 2001).
148. 9 CFR §381.196(b). Mexico is eligible to export only process poultry products from poultry that has been slaughtered in the U.S. or another country eligible to export to the U.S.
149. USDA, FSIS, *Evaluating the Equivalence of Foreign Meat and Poultry Food Regulatory Systems, Port of Entry Reinspection*, slideshow, available at <http://www.fsis.usda.gov/OFO/HRDS/INTERNAT/seminar/pdf/15%20poe.pdf>
150. 5 U.S.C. §552.
151. Audit Reports available at [http://www.fsis.usda.gov/OFO/TSC/foreign\\_country\\_audit\\_reports.htm](http://www.fsis.usda.gov/OFO/TSC/foreign_country_audit_reports.htm). However, for some countries there is no information available more recent than 2001. According to FSIS, if FSIS is taking some action following an on-site audit, it may take longer for the report to become public. Winifred DePalma, Public Citizen interview with Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, FSIS Nov. 22, 2002.
152. *See*, Argentina, Australia, Brazil, Canada and Mexico, below.
153. *See*, Australia, Brazil, Canada and Mexico, below.
154. *See*, Mexico, below.
155. *See*, Brazil and Mexico, below.
156. It is FSIS policy to continue to allow trade while an equivalency request is under review. FSIS claims that it will suspend eligibility if a country does not provide satisfactory documentary evidence of an equivalent sanitary measure. 64 Fed. Reg. 70690, 70692 (Dec. 17, 1999). However, as the case examples below demonstrate, this is not happening. *See, e.g.*, Argentina and Mexico, below.
157. Winifred DePalma, Public Citizen telephone interview with Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, FSIS, Nov. 22, 2002.

158. Letter from Sally Stratmoen, Acting Director, Equivalence Division, Office of International Affairs, FSIS to Dr. José Angel Del Valle Molina, Director General de Salud Animal, SAGARPA, Nov. 26, 2002, available at [http://www.fsis.usda.gov/OFO/TSC/foreign\\_country\\_audit\\_reports.htm](http://www.fsis.usda.gov/OFO/TSC/foreign_country_audit_reports.htm).
159. Winifred DePalma, Public Citizen telephone interview with Don Smart, Director Review Staff Program Evaluation, Enforcement & Review, FSIS, Feb. 5, 2002.
160. *Id.*
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220. *Id.*, at 9.
221. Audit Report for Brazil - July 11 through August 3, 2001, at 4, available at [http://www.fsis.usda.gov/OFO/TSC/foreign\\_country\\_audit\\_reports.htm](http://www.fsis.usda.gov/OFO/TSC/foreign_country_audit_reports.htm). Attachment D to the audit report, at 17, contains a chart listing the nine establishments audited with space for checking off whether they were in compliance with six *Salmonella* testing requirements. Next to one of the plants, the phrase "not enough time" has been written across the check-off boxes.
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223. *Id.*, at 9-10.

224. *Id.*, at 10.
225. *Id.*
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227. *Id.*, at 3.
228. *Id.*
229. The Data Collection Instrument for HACCP Programs form, attachment B to the audit, contains a chart listing each establishment and placing a check mark or the word "No" next to each of twelve HACCP criteria. At the bottom of the form is the following phrase: "No = Establishment met FSIS basic regulatory requirements of HACCP programs. The HACCP plan(s) did not address adequately the applicable regulatory requirements for implementation." For six of the 13 establishments, more than half the twelve criteria are marked "No". *Id.*, at 22.
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