Institute for Agriculture and Trade Policy

Import Food Safety in the Twilight of the Bush Administration

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The Institute for Agriculture and Trade Policy works locally and globally at the intersection of policy and practice to ensure fair and sustainable food, farm and trade systems.

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Introduction

The U.S. Food and Drug Administration (FDA) advisory in May 2007, for U.S. companies to recall pet food with contaminated ingredients imported from China, triggered Bush Administration and food industry plans to reorganize import food safety programs.[1] Publicity about the deaths or illness of an estimated 39,000 pets,[2] combined with dozens of news stories about contaminated and otherwise dangerous toy imports from China contracted for by U.S. companies,[3] led the Bush Administration to form an Interagency Working Group (IWG) on Import Safety. On July 18 President Bush gave the IWG, composed of representatives of 13 federal agencies, the mandate "within existing resources, to promote the safety of imported products."[4] The IWG published a preliminary report in September and a final report in November.

Our analysis primarily concerns two of the IWG entities, the FDA and the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS). Although the political impetus for the IWG report has partly to do with contaminated Chinese imports, the report's recommendations are intended to apply to exporters from all countries. Furthermore, though China is the fourth leading agricultural exporter to the U.S. ($2.8 billion in fiscal year 2007) it trails the European Union (about $15 billion), Canada ($14.7 billion) and Mexico ($9.9 billion) by quite a distance.[5] The intensive Congressional focus on product safety and quality issues on Chinese exports has lead to a larger investigation into the integrity of U.S. inspection and customs services.[6] As Chinese President Hu Jintao told President George Bush during the Asia-Pacific Economic Cooperation ministerial in September, food safety is not just a Chinese problem.[7]

In a subsequent report, IATP will parse the terms of the FDA agreement with China to facilitate food trade, and the capacity of governments to implement and enforce the agreements. In this paper, the focus is on import food safety in the IWG report and on the FDA's "Food Protection Plan,"[8] released the same week as the IWG report, which was chaired by Secretary of Health and Human Services (HHS) Michael Levitt, who oversees the FDA. The Grocery Manufacturer Association (GMA), which worked closely with the Bush Administration on the IWG report, released its own food safety management proposal just after the IWG interim report in September. The GMA report too merits brief comment, if only because of the industry's pervasive influence over food safety regulation and the IWG report in particular.

FSIS and FDA are under Congressional pressure to fundamentally reform their food safety management practices, as oversight and appropriations committees are not satisfied that the agencies are using Congressional funding for their Congressionally mandated purpose.[9] At least one Member of Congress asked to be included in the IWG deliberations but was rebuffed,[10] although it is Congress that would have to appropriate money and amend existing legislation to implement the IWG recommendations. At Congressional hearings on food and product safety in October, witnesses deferred to the yet to be published IWG recommendations. A representative of the Office of the U.S. Trade Representative warned that tough import safety measures would incite retaliatory responses and charges of trade protectionism by World Trade Organization members.[11]

Overview: Export a flawed U.S. food safety system to increase U.S. food imports?

Nearly three decades of deregulatory pressure on U.S. agencies responsible for import food safety have left the United States increasingly vulnerable to substandard and unsafe products. Faced with U.S. industry demands to process rising volumes of imports from an increasing variety of suppliers as rapidly as possible, both FDA and FSIS are seeking to accommodate the trade objectives of the food industry, while offering consumers promises of a safer food supply. But many of the regulatory tools proposed by the IWG and FDA have exposed U.S. consumers to unsafe food when implemented domestically. The waves of U.S. meat product recalls in 2007 leading up to the February 17 recall of 143 million pounds of ground beef originated from plants employing regulatory models that the IWG and FDA plans would "export" to foreign firms supplying the U.S.[12]

Reports and testimony by the Government Accountability Office (GAO), the USDA's Office of the Inspector General (OIG),[13] former FDA officials, and non-governmental organizations on FSIS and FDA food safety controls provide a good baseline for determining the extent to which the IWG, FDA and GMA recommendations for import food safety are desirable and practicable. These agencies and individuals have been debating – indeed, battling – not only over how to make imported foods safe, but how to make U.S. production and distribution of food safe.

The public health costs of foodborne illness are very high. In a January 29 letter to GAO, Senator Edward Kennedy and Representative Henry Waxman noted, "FDA has estimated that illnesses from just 13 food-borne pathogens result in over 13 million [U.S.] illnesses and $57 billion in costs annually" (*sic*). That estimate, they note, is less than a fifth of total U.S. foodborne disease incidence and mitigation costs, according to a 1999 report, the last year the government estimated U.S. foodborne illness and prior to the import boom.[14]

GAO believes U.S. government food safety management controls are so flawed that it has included food safety among its series of "high risk" auditing reports. For example, USDA and FDA verification of voluntary industry food product recalls takes a month or more, often exceeding the shelf life of the recalled foods.[15] Audits and correspondence about the domestic situation are instructive, since the IWG is proposing to export U.S. food safety management practices to countries that wish to export to the United States.

> *"As we have repeatedly reported, our fragmented food safety system has resulted in inconsistent oversight, ineffective coordination and inefficient use of resources. With 15 agencies collectively administering at least 30 laws related to food safety, the patchwork nature of the federal food safety oversight system calls into question whether the federal government can more efficiently and effectively protect our nation's food supply." GAO testimony to the U.S. House of Representatives, April 24, 2007.*

It is tempting to dismiss the Bush Administration initiatives on import product and food safety as a belated action plan without the budget or personnel for U.S. implementation. Why not wait for a new Administration to show what it will do in food safety? Such complacency could prove dangerous. Much of the FSIS and FDA man-

agement, to say nothing of a myriad of food industry lobbyists, will remain in the next Administration to try to realize these initiatives. Food industry lobbyists pressed the IWG not to increase import inspection at U.S. ports of entry and the IWG duly outlines food safety controls that de-emphasize physical inspection and product testing.[16]

No company intends to import contaminated or otherwise hazardous products. But greater physical inspection and testing exposes importers further to U.S. liability law, while the off-shoring and outsourcing of product safety certification proposed by the IWG provides another layer of plausible deniability for corporate liability prevention. Now is the time to review what the IWG has proposed in the twilight of the Bush Administration and outline some alternatives to it in advance of a new Administration.

Managing a Projected Import Boom

The overall motive for the IWG report is the projected tripling of U.S. food imports in (fiscal year) 2006 from $2 trillion to $6 trillion by 2015.[17] Such projections, at least for food and agriculture, are sometimes based on unrealistic, but econometrically convenient assumptions. For example, the Organization for Economic Cooperation and Development/ UN Food and Agricultural Organization projections for the meat sector assume "an absence of animal disease outbreaks and no explicit accounting of animal disease restrictions on production, trade or consumption."[18] Economic modelers are well aware that such outbreaks can violently disrupt their projections, but since the costs of surveillance, detection and mitigation of animal diseases and/or food borne illness are difficult to estimate, they are left out of the forecasting equation.

Although we may take import forecast estimates with a grain of salt, the IWG agencies document a dramatic increase in U.S. imports, nearly doubling in value between 2003 and 2006. Canada, China, Mexico, Japan and Germany accounted for more than half the value of imports in FY 2006, with another 145 countries accounting for the remaining U.S. import value. A huge challenge for U.S. officials at the more than 300 ports of entry is the infrequency of shipments per importer. About 45 percent of importers took delivery of one shipment and only about a fifth of all importers took delivery on more than 11 product shipments in 2006.[19] Infrequency of product shipments to the more than 825,000 importers makes it difficult to gather exporter specific data for the risk-based screening, inspection and testing system that the IWG would establish. Risk profiles for exporting countries and for certain products (e.g. meat, dairy, seafood) can be estimated and used in inspection and testing. But how will IWG agencies ensure the cooperation and compliance of so many infrequent importers with product safety rules pertaining to the anticipated increase in imports?

Neither the preliminary nor final IWG reports to President Bush disaggregate food import data from that of other kinds of imports. However, according to a former FDA administrator, of 18 million FDA regulated import transactions ("commercial lines of entry"[20]) in 2007, about 60 percent were food imports. FDA regulated food imports include about 60 percent of U.S. fruit and vegetable consumption and 75 percent of seafood consumption. The number of import transactions doubled between 2002 and 2007.[21] The FDA has authority over about 80 percent of the U.S. food supply, including domestic production worth $417 billion and imports worth $49 billion in 2007.[22] Given its generic approach to import safety, the IWG illustrates import system problems with food product examples. For example, the lack of USDA's inspection data integration with the customs data system used to allow imports into the United

States—a failing that has been the object of Congressional ire at least since the late 1980s—is described as potentially exposing consumers to contaminated food. Avoidance of U.S. food safety requirements by transshipping food from a federally unapproved exporter through an approved exporter is another example.[23]

The final IWG report presents 14 broad recommendations and 50 action steps, each with lead agency or agencies units and a short (less than a year), or long-term time frame.[24] Since there is no budget to implement the recommendations, we may assume that the time frame is notional. Most of the actions steps that would apply to food products concern the FDA.[25] Given the volume of imports over which FDA has authority, some IWG agency activities, though much needed, are markedly belated. As the FDA reports, "For example, FDA has begun an active-information sharing campaign with many of its foreign counterparts to obtain information about product approval, inspection, testing and safety for FDA-regulated food, medical products and cosmetics."[26] This is clearly a step in the right direction although shockingly late in relation to the huge increase in U.S. imported products since 2000.

Applying HAACP Principles To Reduce Inspection and Testing

The IWG "strategic framework" for ensuring the safety of the expected tripling of imports is based on a "paradigm shift" from a "snapshot" of inspection and enforcement at the port of entry to a "real time 'video' across the product's import 'life cycle'[27] at the most appropriate points of production and distribution."[28] The model for how this "paradigm shift" is supposed to operate in real time is by applying Hazard Analysis and Critical Control Point (HACCP) principles, first developed with the food industry, to all import products. The principles are supposed to identify points of production and distribution risk, and prevent those risks before they are detected in inspection and before industry would be subject to government sanctions for unsafe products. Examples of food manufacture Critical Control Points include time and temperature requirements for cooking or for maintaining a cold chain during the transportation and storage of food. "Inspection" of HACCP documentation, and not "snapshot" product inspection and testing, is to provide the "real time video" of food safety.

The IWG would extrapolate HACCP, a voluntary food quality assurance plan that USDA began to apply as a mandatory food safety program in 1999 in U.S. slaughter houses,[29] to cover all import products. From the moment that FSIS management implemented HACCP, first as a pilot program, it was controversial. In June 2000, the U.S. Court of Appeals found that the pilot project violated the U.S. meat and poultry product inspection acts because it did not allow federal inspectors to inspect products, only the paperwork of the plant inspectors who carried out inspection under HAACP. The acts require federal inspectors to perform continuous inspection alongside plant inspectors.[30] Nevertheless, USDA's further implementation of HAACP has been in the direction of reducing federal inspection and testing requirements. For example, the USDA proposed in 2001 to stop testing for salmonella in meat used in school lunch programs, a rule that was hurriedly withdrawn under massive public protest. The "risk-based" inspection program that USDA had proposed to implement in 2007 is HAACP applied to inspection.[32]

> *"Under the pre-HACCP system, the production of meat and poultry products was monitored at every stage by Government employees, rather than by in-plant managers. The HACCP program reversed this arrangement by allowing a plant to monitor itself. It gave industry, not Government, the primary responsibility for ensuring the safety of meat and poultry systems." USDA Inspector General's report on HACCP, June 2000.*

Verifying USDA and industry claims of pathogen reduction under HACCP in food safety management is very difficult because industry selects which Critical Control

Points (CCPs) it will enforce and retains test results of sampled meat as confidential business information, even when those results test positive for a contaminant.[33] Indeed, when the OIG tried to audit selected plant HAACP plans in 2000, the auditors were not allowed access to the plans, as plant managers cited the HACCP plans themselves as confidential business information.[34] A survey of federal meat inspectors and salmonella test results in HACCP implementation suggests that the federal government retains so little control over meat hygiene programs that any pathogen testing results it reports must be regarded as suspect.[35]

Furthermore, industry may simply fail to enforce the CCPs it may or may not have chosen. For example, in July 2007, FSIS banned "downer cattle" from being processed into food because inability to walk may signal the presence of BSE (Mad Cow disease).[36] But veterinary inspection evidently was not a CCP at the Hallmark/Westland slaughterhouse and meat processing plant. On January 30 the Human Society of the United States announced the results of its investigation at the plant, including graphic video clips of animal abuse to force downer cattle to walk again. FSIS advised Westland on February 17 to recall 143 million pounds of ground beef, 37 million of which had been shipped to school lunch programs all over the country.[37] Though the USDA believed the meat posed no threat to public health, the largest meat recall in U.S. history was apparently triggered by a HACCP implementation failure. FSIS stated there was no reason to increase inspection since Hallmark/Westland was "an isolated incident of egregious violations."[38] The American Meat Institute (AMI) responded, "Claims that we are not regulated heavily enough or that inspection oversight is lacking are simply outrageous." The statement was followed by a list of AMI activities, including free training in HACCP for AMI members.[39]

> *"USDA's testimony today proves gaps in the food safety system exist because there is a shortage of federal meat inspectors. We cannot rely on slaughter and meatpacking establishments to summon a USDA veterinarian if an animal goes down prior to the slaughter line. This shortsighted policy is nothing more than the fox guarding the henhouse. . . .We must provide additional resources so that USDA can boost the number of inspectors currently in the field." Senator Tom Harkin. Press release. February 28, 2008.*

Not withstanding the controversies over whether HACCP has been an effective USDA food safety management program,[40] the IWG proposes to extend the use of HACCP principles to "all entities involved in the import life cycle – foreign growers and manufacturers, foreign governments, foreign exporters, U.S. importers, manufacturers and retailers, testing and certification bodies, and regulatory authorities at the federal, state and local levels" for all imported products.[41] Adherence to HACCP principles would be the framework for extending U.S. food safety management practice to all products in all countries that export to the United States.

Such an extrapolation, if feasible and desirable, would require at the very least a great increase in personnel and financial resources over present levels. In terms of the IWG generic approach to product safety, consider the resource implications of Consumer Product Safety Commission testimony to Congress: "[the] Commission currently has *no* [emphasis in the original] full-time presence at any port and little or no presence at several of the major ports. We currently inspect less than 1% of the products under our jurisdiction that come into this country."[42] According to Randall Gooden, a liability prevention expert at the American Society for Quality, an industry association, lack of product inspection is no problem: "The Consumer Product Safety

Commission is doing exactly what they were supposed to do. They were meant to be a reporting agency, not an inspection agency. If you're going to import products from third world countries, then you better have your own people there to assure the product is to [the importer's] spec[ification]." From this viewpoint, industry personnel at the production site offer the "best protection against harmful products."[43] Government agencies should not exercise regulatory authority, but only report on what industry is doing to safeguard products.

FDA's import food inspection rate, to judge by a Food and Water Watch study of seafood imports, is no greater than that of the Consumer Product Safety Commission, and its product testing for contamination and other hazards is even less. By comparison, the European Union physically inspects about 20-50 percent of seafood imports and Japan 12-20 percent, depending on the type of seafood.[44] But for the IWG, and indeed, for the food industry, a dearth of inspection personnel and testing laboratories is no great problem. Inspection and testing at the port of entry belong to the old "snapshot" paradigm to be replaced by the "video" model of the IWG Strategic Framework. In the words of GMA President and former U.S. House Representative Cal Dooley, "we cannot simply inspect our way to a safer food supply," a sentiment echoed by USDA and FDA officials.[45] Just a couple of the IWG action steps would enhance inspection, an indispensable way of verifying that other safety programs are working as designed. For example, action step 9.3 calls for "rapid test methods for pathogens and other contaminants" that would enable inspectors and other port authorities to decide whether to allow imports into commerce. Generally speaking, the IWG hopes to protect consumers by working with industry to prevent product safety problems before inspection and testing expose them.

Third-Party Certification

Some of the IWG recommendations are presented as safety measures that would lessen the need for inspection and testing. Consider the certification recommendation: "As a benefit to inspecting officials, the process of checking for a certificate is not burdensome and does not require any additional government testing or evaluation."[46] Certification of products as safe by government agencies or private organizations accredited by the U.S. government may be voluntary, for products judged by the safety certifiers to be low risk, or mandatory for higher risk products (action steps 2.1 and 2.2).

Legislation would have to be approved to allow FDA to delegate its authority to accredit private organizations or foreign governments to determine whether foreign exporters had complied with FDA requirements. The delegation of FDA authority and oversight would include recognition of "an entity that accredits third parties." A third-party food safety certifier is neither a government agency with statutory responsibility for U.S. food safety nor the exporter, but a separate entity, such as a private certifying company. Under the IWG proposed delegated authority, FDA would not always be directly responsible for determining whether a third-party certifier was qualified to judge whether exporters complied with FDA requirements. (action step 2.3) Third-party certification companies often depend on the exporters they are certifying for their income, creating a potential but acute conflict of public/private interest.

The logic of employing third-party certification concerns both bureaucratic expedience and insulation from liability. The FDA is planning to extend its authority by

putting a handful of inspectors in major exporting countries to the U.S., such as China and India.[47] Such a small number will have almost entirely reporting rather than inspection duties, given the thousands of certified export food establishments in each country, and the unwillingness of governments to reduce their number to allow for effective oversight and onsite inspections. Third-party certification enables trade while insulating both the exporter and the government from legal liability if certified products cause harm to consumers. If the third-party food safety certifier fails to detect harmful products and loses either its government authorization or its company contracts, the certifier simply could go out of business. The burden of its failure would be borne by consumers. Since there is doubt within the U.S. government about the efficacy of third-party safety certification for domestic food production, it is not hard to imagine that the doubt will grow as the lines of delegated authority become longer and indirect.

As is revealed in a remarkable February 11th letter from FSIS administrators to FDA administrators, the FSIS review of FDA's Food Protection Action Plan does not express confidence in an FDA proposal to allow third-party food safety management audits of 17,000 domestic food processing facilities that FDA has identified as producing high risk products. Instead FSIS proposes discussing the possibility of having FSIS "help provide coverage as an effective governmental presence in the riskiest FDA plants," rather than relying on "an auditor paid by the plant."[48] If FSIS does not think that FDA can effectively inspect high-risk products in the U.S., it is unlikely that FSIS would support delegation of FDA authority over high-risk products produced in other countries. FSIS' offer of "help" comes after a harsh review of FDA's "Food Protection Plan" by the Government Accountability Office in February and following a no less harsh OIG review of the FSIS plan for risk-based inspection in December 2007.

The FDA and GMA plans for import food safety through "risk-based" management

The IWG report states that the FDA "Food Protection Plan" is integrated with its own "Import Safety Strategic Framework and Action Plan."[49] The FDA plan covers domestic food safety controls as well as the "approximately 189,000 registered foreign facilities [that] manufacture, process, pack, or hold food consumed by Americans."[50] Nevertheless, as the FDA frankly admits, "FDA often has very limited information regarding conditions under which most food is produced in foreign countries."[51] To compensate for this limited information and to comply with President Bush's "within existing resources" mandate, the FDA plan will "promote increased corporate responsibility to prevent foodborne illnesses" through "the adoption of voluntary preventive controls."[52] The reliance on voluntary industry compliance is extensive in the FDA plan. Even the proposal to at long last request Congress to provide FDA with authority to order product recalls of unsafe or potentially unsafe food may be delayed while FDA decides whether a private firm has "unduly delayed" a product recall when advised to do so by FDA officials.[53]

The GAO testimony to Congress on January 29 about the FDA protection plan is remarkable for what GAO could not determine. GAO reported, "FDA officials told us that they have internal plans for implementing the Food Protection Plan that detail timelines, staff actions, and specific deliverables. While the FDA officials told us they do not intend to make these plans public, they do plan to keep the public informed of their progress."[54] Lacking access to FDA operational strategies and FDA's proposed-

budget for implementing the plan, the GAO could not fulfill its duty to inform Congress about the likelihood of the plan's success. GAO, Congress and the public will have to take it on faith that the plan is progressing. FDA Assistant Commission for Food Protection David Acheson said that the Food Protection Plan would be applied only "to a very narrow spectrum of products" that FDA designates as high risk.[55]

In light of what little GAO could determine about the FDA "Food Protection Plan," the IWG proposal to have FDA personnel in foreign food processing plants does not augur a great improvement in food safety controls. An earlier GAO review of FDA data concluded that FDA's on-site audits of about 190,000 foreign food plants exporting to the United States had "decreased from 211 in fiscal year 2001 to fewer than a hundred in fiscal year 2007."[56] According to a former FDA official, few audits are annual and they take only 2-3 days (compared to 2-3 week for a domestic plant audit) in order to visit as many plants as possible to save money on a foreign trip. The agency uses the quantity of audits, rather than the quality to qualify its foreign surveillance program as a success.[57] The FDA Plan assumes that third-party safety certifiers would be able to inspect more facilities at less cost than if on-site audits were conducted by FDA officials.

> *"For years FDA has allocated less than 200 inspectors (on average less than 1 per port) to conduct entry reviews, collect samples and conduct physical examinations and investigations of all imported products, including food and drugs . . . Do the math. The current FDA organization, IT [information technology] systems and regulatory paradigm have not, and can not effectively manage the foreign industries or mitigate the related risks. More money alone may not be enough." Benjamin England, former FDA official. Testimony to the U.S. House of Representatives. November 1, 2007.*

Despite the unwillingness of the FDA to share the details of its "Food Protection Plan" with the public, the agency and its supporters in Congress and the food industry, particularly the Grocery Manufacturers Association (GMA), have called for a great increase in its food safety budget.[58] This budget increase would be used to foster the "adoption of voluntary preventative controls" by industry, in concert with GMA's own plan for the future of import food safety.

The GMA characterizes its own proposals as "renewing the public-private partnership on product safety." Exporting companies ("suppliers") would be required to have a quality assurance program that would incorporate food safety measures. FDA would be authorized by Congress to assess the performance of the exporters' food safety programs in complying with the program design dictated not by the FDA, but by the importing companies. FDA qualified importers, on the other hand, "could voluntarily elect [emphasis in the original] to participate in a program designed to permit FDA to identify confidently their products as being in compliance [with FDA requirements], thus entitling the importer to priority treatment at US borders."[59] According to the GMA, implementation of its "Voluntary Qualified Food Importer Safety Program" would reduce port congestion, reduce inspection for qualified importers and enable FDA to focus its inspection resources on higher-risk products of unqualified importers.

Another "pillar" of the GMA plan is for FDA to do capacity building, particularly in developing countries, to enable foreign governments to build their food safety pro-

grams and infrastructure. Like other parts of the GMA proposal, there is no budget estimate, but this part of the program would probably be the most expensive. Many of the proposed measures presume the existence of infrastructure (e.g. testing laboratories, refrigerated warehouses) that may not exist in some of the 150 countries from which food is exported to the U.S. Other measures, such as those contained in FDA bilateral food safety Memoranda of Understanding (MoU), would require, among other things, "access to raw data and results of product testing,"[60] which presumably foreign governments could receive from the U.S. under the terms of the MoU. Foreign governments would thus have access to data denied to U.S. citizens as Confidential Business Information.

Finally, GMA reiterates a laundry list of needs for increased resources to rebuild FDA capacity for food safety regulation and to ensure compliance with regulations. Yet it is not at all clear how these needs will be funded, much less foreign capacity building. Industry opposes paying the kind of inspection and testing fees that FDA already collects for drug imports. Food industry lobbyists say that the industry already spends substantially on food safety and should not pay an additional fee for the benefits of safe food enjoyed by consumers. Consumer organizations have opposed "user fees" that would make the agency budget too dependent on the regulated industry. Republican Senators have doubted the existence of a crisis at FDA and have advocated more private sector efforts combined with consumer education on the cooking of food.[61]

What should not be done: export de facto industry control over import food safety

The IWG and FDA proposals to substitute increased port entry product inspection and testing with third-party food safety certification at the point of export merely offshore and outsource the high risk regulatory management problems of U.S. food processing plants well documented by GAO and OIG. On the basis of these audits of the U.S. food safety system, we should ask, "Are the IWG proposals to institute a 'risk based' food safety management system in countries that wish to export to the United States based on a tested and proven system for food produced and consumed in the United States?" (A "risk-based" system would circumvent the "continuous inspection" requirement of the U.S. meat and poultry inspection acts by removing federal inspectors from plants FSIS management deems low risk and assigning them to higher risk plants.)

Questions to ask, could include, for example: Since in December 2007 the OIG judged FSIS plans to institute risk-based inspection in the U.S. to be hasty and unjustified by data,[62] what amount and quality of pathogen data and food safety assessments of foreign exporters will be required to make the IWG proposed risk-based inspection an effective import food safety management program? Congress has denied funding and forbidden FSIS to implement its plan for risk-based inspection, until the OIG reports that FSIS has sufficient verified data to stipulate specific risks and measures to deal with those risks in U.S. slaughterhouses and meat-packing plants.[63] Before trying to impose a flawed risk-based system on foreign exporters, wouldn't the first political and policy priority be to fix the broken U.S. food safety system over which Congress has statutory authority?

Without the political will to take back and assert federal control over public health matters affecting food, the scores of technically sound and cost effective proposals to fix FSIS and the FDA, such as the FDA Science Board proposals,[64] will be sacrificed

to fear of loss of trade. But U.S. trading partners, astonished at the increasing size of U.S. product recalls and the apparent inability of FSIS and FDA to enforce rules on the industries they regulate, are already reluctant to trust U.S. assurances that U.S. food exports, particularly meat exports, are safe for their consumers. Billions of dollars in potential annual food export sales are lost due to an ineffective, industry-controlled food safety system. Since FSIS does not let U.S. consumers know the names of retail outlets to which contaminated or potentially contaminated product have been sent, why should foreign officials assume that the U.S. will assist them in tracing the origins of contaminated or otherwise hazardous U.S. food exports?[65]

The Bush Administration assumes that greater imported food dependency is inevitable and that U.S. food safety controls should accommodate industry demands to increase imports by letting industry continue to exert primary control over food safety. However, the continuation of business as usual in food safety is by no means inevitable in a new Administration, if that Administration has the political will to reassert public control over food safety as a public health program and finds the financial means to pay for that assertion.

The Bush Administration assertion of political will would assure U.S. import safety by shifting the burden of import safety from U.S. agencies and importers to foreign exporters. Both HHS Secretary Michael Levitt and Representative Joe Barton, ranking member on the Committee on Commerce and Energy responsible for FDA oversight, favor amending the Food, Drug and Cosmetic Act to establish U.S. extraterritorial jurisdiction to enable prosecution of foreign exporters for violations of FDA rules.[66] Such an amendment could enable criminal prosecutions of foreign exporters, e.g. for drug counterfeiting, as well as civil contaminations, e.g. for shipping unintentionally contaminated food to the United States. However, the diplomatic backlash to the notification of such legislation to the World Trade Organization would very likely include reciprocal demands for legislation to enable prosecution of U.S. exporters.

Conclusion: What should be done: reassert government control over importers

Rather than legislate to create a trade diplomacy stand-off with no public health benefits, a new Administration should more tightly regulate the importing companies over which the U.S. government has jurisdiction, since they specify the product contracts that exporters are to fulfill. Although importers would presumably stop doing business with exporters who could not fulfill contract requirements, federal agencies must be able to discipline those importers whose exporters meet contract requirements but not federal requirements for import. (Reasserting regulatory authority over importers does not preclude exercising authority to decertify exporters who fail to meet U.S. import requirements. But such export decertification, in the absence of regulation of importers, will not by itself lead to enhanced import product safety.)

Given the infrequency of annual shipments per importer noted earlier in this paper, one way to increase infrequent importer compliance with federal requirements would be to require, as part of an import license, a pooled performance bond to which infrequent importers would contribute. Deductions from an annual performance bond would be taken in the amount needed to pay for government investigations of import food safety failure beyond the normal costs of import re-inspection, testing and quarantine. Frequent importers, such as WalMart, would pay annual individual performance bonds. Importers with a clean performance record would be reimbursed the amount of the bond with interest following the close of the federal fiscal year.

Importer performance bonds could both incentivize compliance with food safety and other import requirements and provide the government a dedicated financial reserve to deal with the public health consequences of food safety management performance failure. Since the budgetary legacy of the Bush Administration will be massive debt, sometimes hidden off the federal budget,[67] other financial means, such as importer performance bonds, will have to be found to exercise regulatory authority.

Allocation of assets to budgets is largely a function of policy priorities, and not simply of fighting over a perennial scarcity of resources for a government that is supposed to sit back and let the free market work, except when it needs another taxpayer rescue. The public health costs of food safety management failure are too high to subject FDA and FSIS to further budgetary austerity. The Bush Administration recommended a $51 million increase in 2009 to FDA's approximately $1.5 billion base budget for fiscal year 2008 for all FDA activities. The FDA Science Board's Subcommittee on Science and Technology called for a $129 million increase in 2009 for FDA's "food supply" regulation alone, rising to $755 million by 2013, $350 million of which would be dedicated to imported food safety.[68] The budget chasm between what the FDA's Science Board estimates is needed financially for the FDA to do its job and what the Bush Administration is willing to commit will be difficult to bridge in a new Administration, absent a corporate tax increase.

A new Administration should reform the import food safety system to include only products that the government can demonstrate are traded safely, according to full and transparent documentation of certification, inspection and testing data. An Administration emboldened to reassert federal authority over import food safety should have at a minimum:

- A corps of food safety inspectors adequate in number, equipped with cutting -edge inspection technology, specially trained in import food product re-in spection, and fairly remunerated at every U.S. port of entry;
- Legislative authority to allow regulators the discretion to reduce the number of ports of entry for high-risk products when import food safety controls prove inadequate to ensuring safe trade;
- Legislative authority to allow regulators to suspend import licenses or put importers on conditional probation for failure of their suppliers to comply with U.S. federal import requirements, including food safety requirements.
- Food safety budgets adequate not only to pay the costs of regulation, inspection, testing and other programs, but also with dedicated funds for re search into emerging pathogens and other hazards, and for mitigating public health harms resulting from food safety management failures.
- Legislative authority for federal agencies to cooperate with the food industry on equipping developing country food safety authorities with training and infrastructure to verify that their government-certified export establishments comply with U.S. import requirements, including food safety requirements.

Resources:

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