



## Global Food Safety Monitor February 26, 2009

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### Introduction

"The world needs an international food safety agency," said retired World Health Organization (WHO) scientist Gerald Moy to the annual Toxicology Forum in late January in Washington, DC. Not surprisingly, Dr. Moy proposed that the agency be located within WHO, which has a small food safety program but nothing like the staffing level and multi-disciplinary scientific capacity of the agency that Moy envisions. But it is difficult to imagine that such an agency will be created in the near future, if only because of resistance to investment in public health programs, of which food safety is one, particularly as the financial services industry drives the global economy over a cliff.

As the stories below indicate, scientific data often are buried or ignored in the regulatory process. Bureaucratic delays and euphemisms, the economic sophistry of cost-benefit analysis, and judiciary coddling of corporate malfeasance all impede the realization of science-based policy, to say nothing of a safer food supply. Nobody wants us to eat unsafe and unwholesome food, but few in power have announced their willingness to pay more taxes for safer food or bear the liability costs of illness caused by unsafe food.

Much of the resistance to stringent international food safety regulation and enforcement begins in the United States, whose companies and government have sought to globalize their largely self-regulatory system. Lobbyists for the Grocery Manufacturers Association (GMA) and nine other food industry associations wrote on January 22 to the U.S. House of Representatives committee that oversees the Food and Drug Administration (FDA) food safety program, "Americans continue to enjoy the safest food supplies in the world but rising food imports and changing consumer preferences pose new challenges that require Congress and the Administration to modernize our food safety net." What does "modernization" entail? (We reviewed the GMA "modernization" proposal for expediting its member companies' food imports by reducing inspection and testing at ports of entry through the "science" of "risk-based inspection." [Import Food Safety in the Twilight of the Bush Administration.](#))

Stories in this issue concerning salmonella and *E. coli* contamination show that to improve inspection and prevent contamination, the FDA and USDA must have data for a risk profile. Both agencies must be authorized to do their own testing and inspection to obtain and verify such data. Furthermore, they must have complete and prompt access to company testing data. But more than a decade after companies began

to self-regulate food safety through the Hazard Analysis Critical Control Point (HACCP) philosophy, GMA is still mulling over whether Congress should require that FDA and USDA have mandatory access to company food testing data. Since the FDA and USDA officials spread U.S. regulatory practice around the world, both through Codex and bilateral technical assistance programs, this decision on government access to company food testing data could be replicated globally.

--Steve Suppan, Editor

Source: Stephen Clapp, "Former WHO official urges takeover of Codex," *Food Chemical News*, February 2, 2009.

## **Salmonella in Peanut Butter: Business As Usual?**

How could U.S. authorities allow the Peanut Corporation of America (PCA) to sell peanut paste contaminated with salmonella until voluntary product recalls began on January 10, given that private laboratories had informed PCA that the paste from one of its plants had tested positive for the pathogen 12 times in 2007-2008?

The media coverage of the massive contamination outbreak, sickening 642 as of February 16 (about half of them children under 16) and contributing to the deaths of at least nine people, may suggest a singular case of regulatory failure, with criminal undertones. Does the spectacle of PCA president Stewart Parnell refusing to answer questions at a U.S. House of Representatives hearing on February 11, by availing himself of the constitutional protection against self-incrimination, point merely to an outbreak caused by a rogue company that took advantage of de-regulatory loopholes?

Senators Patrick Leahy and Amy Klobuchar have called for a criminal prosecution of PCA, which declared bankruptcy on February 12, thus reducing its exposure to civil law suits. Such a prosecution might bring a measure of justice for the families of the salmonella victims. But the regulatory environment that allowed the contamination to fester and spread to 44 states and Canada, resulting in the recall of more than 2,200 products with peanut paste and a 22 percent drop in peanut butter sales, will be much harder to prosecute. The U.S. federal court's doctrine of deference to regulatory authorities implies that regulatory negligence, even regulatory cooperation with industry to elude effective regulation, is no crime.

As the FDA's Stephen Sundlof explained to Senator Klobuchar at an Agriculture Committee hearing, neither Georgia's state inspectors with delegated FDA authority nor private testing labs are obliged to report contamination incidents or testing results to the FDA. Reports about contamination and the contaminated products themselves are company property under the FDA (and USDA) definition of "adulteration." Sundlof told reporters that the FDA had accessed PCA testing results only by invoking the authority of the Bioterrorism Act! Deibel, one of the PCA's private testing labs, opposes even today turning over testing results to federal authorities, alleging that reporting of adulteration would discourage companies from using third party testing services.

The difficulty of changing the regulatory environment was signaled by the response of Scott Faber, vice president for federal affairs of the Grocery Manufacturers of America (GMA), the largest trade association for food processors and retailers, to a reporter from *Food Chemical News*. More than two years after the massive contamination of peanut butter in a ConAgra plant and more than a month after the public was made aware of PCA's contamination, Faber was asked whether federal regulators should receive the results of tests for contamination. He responded, "We're thinking about it. No comment on that issue."

Notwithstanding GMA's reticence on the advisability of reporting third party and company testing information affecting public health promptly and fully to public officials, GMA has advocated that the U.S.

system of relying on third party audits of food facilities be internationalized through the standards of the Codex Alimentarius Commission. GMA, in a "wish list" on Codex submitted to the Obama administration, signaled its opposition to a European Union proposal for a Codex health certificate for exports. Such a certificate would make clear that "competent authority," i.e., governments, and not industry, would control food safety management to certify the safety and wholesomeness of their exported foods. Testing for a health certificate might have prevented the export of contaminated product and triggered an investigation and product recall.

(The Associated Press reported that a Canadian importer rejected contaminated PCA peanuts in mid-September. The FDA recorded the rejection but did not test the product, nor did it follow up with PCA to prevent further shipments from the PCA plant, alert the public, test other PCA plants and initiate product recalls that might have prevented some of the illness and death from salmonella poisoning.)

Perhaps even more alarming than GMA's resistance to government control over food safety management, is the acknowledgement by the FDA's Associate Commissioner for Food Safety, David Acheson, that the traditional distinction between high and low risk foods is disappearing. Speaking to high level government and industry scientists at the annual Toxicology Forum, Acheson said, "Products you think you can get away with [from regulation], you can't. . . . Ten years ago we would have never linked an outbreak [of salmonella] to peanuts." Since the FDA's, USDA's and food industry's advocacy of de facto industry control over "risk-based inspection" is based on the presumption that some foods inherently pose greater food safety risks than others, Acheson's acknowledgement likely discomfited more than a few toxicologists and regulators.

Acheson didn't venture comments on what had changed in food production so that salmonella and other pathogens are contaminating peanuts and vegetables. Since salmonella is a pathogen that originates in animal agriculture, e.g., egg or poultry production (currently under USDA authority), for the FDA to regulate effectively to prevent an outbreak, either the Food Drug and Cosmetic Act has to be changed or Congress has to create a new agency with new legal authority to implement and enforce farm to fork food safety. Such an agency could, for example, prohibit the location of Confined Animal Feed Operations (CAFO) within the watershed of a horticultural operation or require that CAFO manure not be spread on fields growing crops for human consumption. The U.S. congressional battle has produced at least half a dozen different legislative proposals. But whether a new food safety agency is located within the FDA or USDA, or is an independent agency, will be less important than whether the government is willing to ensure that it, and not the regulated industry, controls food safety management.

Sources: Joan Murphy, "Peanut product recall prompts call for more testing, disclosure of internal results," *Food Chemical News*, February 2, 2009; Michael Moss, "Safety Net Missed Problems at Peanut Plant," *The New York Times*, February 9, 2009; Caroline Scott Thomas, "Internal emails revealed as PCA president refuses to testify," February 12, 2009, [www.foodnavigator-usa.com](http://www.foodnavigator-usa.com); Jason Huffman and Joan Murphy, "Bankruptcy filings delay lawsuits filed against PCA," *Food Chemical News*, February 23, 2009; Cynthia Dizikes, "Salmonella outbreaks: Why was FDA in the dark?" [www.minnpost.com](http://www.minnpost.com), February 5, 2009; Joan Murphy, "DeLauro food safety bill 'back for the first time,'" *Food Chemical News*, February 9, 2009; David Shaffer, "Klobuchar: Prosecute peanut case," [www.StarTribune.com](http://www.StarTribune.com), February 16, 2009; Sharon Theimer, "Contaminated Peanuts From Troubled Firm Rejected at Canadian Border Weeks Ago," Associated Press, January 30, 2009; Stephen Clapp, "GMA submits wish list for Codex to Obama team," *Food Chemical News*, January 26, 2009; Letter from the Grocery Manufacturers Association et al. to the U.S. House of Representatives Committee on Energy and Commerce, January 22, 2009; Stephen Clapp, "FDA's Acheson: Line is blurring between high- and low-risk foods," February 2, 2009; "New FDA Bills On Back Burner Despite Salmonella Outbreak," *Inside U.S.Trade*, February 6, 2009.

## **Detecting Salmonella and Other Pathogens with Nano-sensors**

In mid-December, the USDA's Agricultural Research Service (ARS) announced that, in cooperation with the University of Georgia and a South Korean research institute, it had developed a technology to detect salmonella pathogens within 10 minutes. Nano-sensors, measuring millionths of a meter, incorporate a dye that lights up when it encounters the salmonella bacteria on a food or food preparation surface. Salmonella, which causes vomiting, severe diarrhea and occasionally death, results in 1.4 million intestinal infections annually in the United States alone. The ARS researchers said that the nano-sensor technology could be adapted to detect other pathogens. No timeline for pilot project testing prior to possible commercialization of the technology was announced.

The USDA has no regulations concerning nanotechnology products and processes, nor is there a dedicated budget to develop environmental, health and safety data from which to develop regulations: On February 18, the FDA told participants in a Food and Drug Law Institute nanotechnology conference that it did not believe that nanotechnology products, including "devices," required any new regulation. Apparently, the nano-sensors, developed with taxpayer money, could be ingested by taxpayers without regulation or perhaps even their knowledge.

Sources: Sharon Durham, "Nanotechnology May Be Used for Food Safety," Agricultural Research Service, December 15, 2008, <http://www.ars.usda.gov/is/pr/2008/081215.htm>; Jane Byrne, "Nano sensors offer rapid detection of salmonella, claims ARS," Foodnavigator-usea.com, January 6, 2009; Junsue Fu, et al., "Au/Si Hetero-Nanorod-based Biosensor for salmonella Detection," USDA Agricultural Research Service, March 11, 2008. [http://www.ars.usda.gov/research/publications/publications.htm?seq\\_no\\_115=230890&pf=1](http://www.ars.usda.gov/research/publications/publications.htm?seq_no_115=230890&pf=1) and research project description at [http://www.ars.usda.gov/research/projects/projects.htm?ACCN\\_NO=414429](http://www.ars.usda.gov/research/projects/projects.htm?ACCN_NO=414429). Joan Murphy, "FDA to tweak guidelines but no new regulations planned for Nanotechnology," *Food Chemical News*, February 23, 2009.

### **"USDA Passed and Inspected": "Buyer Beware."**

The U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) issued a notice on January 7 to advise beef processing plants that they "cannot conclude that *E. coli* O157:H7 is not reasonably likely to occur in its production process because the product it [the processing plant] receives bears the mark of inspection." Parsing the tortured language of the notice, FSIS warned the beef processors that the FSIS seal, "USDA Passed and Inspected," on cattle carcasses didn't mean that the raw materials of their products were safe and wholesome to eat. Instead the FSIS seal of approval meant only that company documents submitted to FSIS claimed that the slaughterhouses had followed their self-defined Hazard Analysis Critical Control Point (HACCP) programs.

Bill Marler, a lawyer representing victims of *E. coli* poisoning, was gratified that FSIS was admitting that HACCP had not reduced the incidence of *E. coli* in processed meat to acceptable levels. Marler's *E. coli* blog noted that even though the amount of recalled beef products decreased from a record 29 million pounds in 2007 to 7 million pounds in 2008 according to FSIS records, the data was hardly reassuring, especially to *E. coli* victims and their families.

John Munsell, former owner of a small meatpacking company, wrote that the FSIS notice was shocking for omitting any mention of a self-evident remedy to *E. coli* contamination in processing plants: focus regulatory resources to prevent contamination in the slaughterhouses. He quoted a USDA inspector general's report on the 2002 massive outbreak at a ConAgra slaughter house where "*E. coli* was becoming a continuous problem." According to Munsell, since 1998, FSIS has let large companies self-regulate under HACCP, a "science fiction red herring," and continues to focus resources on detecting *E. coli* and other pathogens after the slaughterhouses have shipped the contaminated, but USDA-approved, carcasses

to meatpacking plants. Munsell challenged new USDA Secretary Tom Vilsack to order FSIS to focus prevention measures on the slaughterhouses.

(On February 6, the union representing Canadian Food Inspection Agency veterinarians appealed to a federal appeals court to stop CFIA management from introducing FSIS-type HACCP rules in poultry production. Despite this and other criticisms of HACCP, Senator Tom Harkin, chair of the Senate Committee on Agriculture, said that his committee might introduce a bill that would require the FDA to adopt USDA's HACCP program that is applied to meat and poultry production.)

Notwithstanding the FSIS warning to beef processors about the misleading meaning of "USDA Passed and Inspected," the U.S. Meat Export Federation said it saw "little justification" for a Mexican food safety inspection rule, implemented on January 30, which would allow "combos" of beef or pork weighing up to 2000 pounds into Mexico only if the meat were fresh and chilled. A U.S. industry source estimated that U.S. pork sales to Mexico would drop by 80 percent under the new requirement. SENESICA, Mexico's equivalent of FSIS, said that the rule was necessary because U.S. exports of frozen meat were impossible to inspect and test for pathogens, except for the exposed surface of the "combos." Mexican meat importers, in tandem with the USDA and U.S. meat exporters, hope to reverse the frozen combo ban. Since the Mexican testing requirement is to achieve the legitimate public policy objective of protecting public health, as long as the requirement is applied equally to Mexican meat production for domestic consumption, a U.S. challenge to overturn the requirement would be unlikely to prosper in the WTO dispute settlement process. Hence, the very credible threat of unauthorized U.S. trade retaliation against Mexico is the likely tool of choice for reversing the ban.

Sources: Amber Healy, "Inspection seal does not mean food is *E. coli* free, FSIS warns," *Food Chemical News*, January 19, 2009; Bill Marler, "E. coli recalls slowed some in 2008; but we are still talking about MILLIONS OF POUNDS," January 2, 2009, <http://www.ecoliblog.com>; John Munsell, "Notice 05-09: HACCPgate Exposed," Foundation for Accountability in Regulatory Enforcement, February 2009; Alex Binkley, "Union seeks legal halt to CFIA poultry inspection changes," *Food Chemical News*, February 16, 2009; Sally Schuff, "Peanut recall fuels calls for HACCP," *Feedstuffs*, February 9, 2009; "U.S. Exporters Fear Result of Mexican Meat Measure; Meeting Postponed," *Inside U.S. Trade*, January 9, 2009; "Reforzamiento y Muestreo de Inspección de Productos Cárnicos de Importación a México," SENESICA, February 11, 2009, <http://148.243.71.63/default.asp?idnot=365>; "Mexican meat combo bin ban in doubt," *Food Chemical News*, February 2, 2009.

### **Private Standards on the March!**

Private food standards initiatives by transnational corporate food processors and retailers have begun to join forces to prevent duplication and contradiction. Despite the concerns of delegates to the World Trade Organization and the Codex Alimentarius Commission that private standards are conflicting with and replacing public standards negotiated by government officials (see *Monitor*, No. 2), private groups are harmonizing standards to reduce certification costs and increase use of the standards along the food supply chain.

In early February, the Safe Quality Food (SQF) Institute based in Washington, DC, announced that it would adjust its SQF 1000 standard for produce growers to that of GLOBALGAP, based in Germany. In its "How-to Guide for Primary Producers," SQF states that it is "the only primary production certification recognized by the Global Food Safety Initiative that links to food manufacturing, distribution and agent/broker management certification." The certification process requires adoption of a HACCP program for "higher risk" foods and both document and on-site auditing by a third party certifier. There are guidance documents for horticulture, aquaculture, grain and intensive animal agriculture production, and optional protocols for responsible environmental and social management practices. Sector specific guidance is proprietary, for purchase and available only to program participants.

In the United States, standards for growers of leafy greens for Fresh Express, a large packer and distributor, include such requirements as removal of all wildlife from growing fields. Faced with loss of contracts, California growers have thus far cleansed 30,000 acres for the sake of Fresh Express' effort to avoid another cycle of contamination of California produce by *E. coli* O157:H7. Since non-agricultural vegetation traps the great majority of pathogens that are carried by field water, this private requirement for growers appears to be another instance of an ad hoc attempt to control a food safety problem with a measure not based in science, nor even common sense.

In mid-January, the USDA failed in an effort to stop development of a national sustainable agricultural practices standard for adoption by the American National Standards Institute (ANSI). The USDA's Agricultural Marketing Service charged that the standards development process "contains provisions that are unfair to materially affected entities, i.e., major agricultural interests." ANSI, the oldest U.S. standards body, rejected the charges, but cautioned the Standards Committee against "dominance" by a California-based certification body that used its organic agricultural standard as the basis for a draft ANSI standard.

As if to rebut the development of a sustainable agricultural standard, those "major agricultural interests" formed the Keystone Alliance for Sustainable Agriculture, which on January 12 released a report, *Field to Market*, on the practices of "production agriculture." Alliance members sought to develop benchmarks of sustainable agriculture that could be applied voluntarily. CropLife International, which represents agricultural biotechnology and pesticide companies, praised the report for showing how industrialized agriculture "continued improvement for the benefit of the environment."

Given the weight of the USDA and the Keystone Alliance against developing a sustainable agricultural practices standard, it may not be possible for ANSI to adopt such a standard, no matter how transparent, science-based and inclusive the process. However, it will be a tragedy for U.S. agriculture, and for agriculture around the world, if a private standards process for "sustainable agriculture" excludes not only public interest groups but sustainable land management and other good agricultural practices.

Sources: Stephen Clapp, "GLOBALGAP and FMI to partner on produce safety standards," *Food Chemical News*, February 9, 2009; "Implementing the SFQ 1000 System: A How-to Guide for Primary Producers," Food Marketing Institute, 2008, [http://www.sqfi.com/SQF\\_1000\\_Guide.pdf](http://www.sqfi.com/SQF_1000_Guide.pdf); "Can Wildlife Be Allowed to Co-exist with Nature?" Metro Farm Forum, October 30, 2008, <http://www.metrofarm.com/forum/viewtopic.php?f=2&t=113&sid=e43fe33986d808875ae507b4f376226c>; Elanor Starmer, "All sterilized up: Produce guidelines throw sustainability out; keep toxic bathwater," February 23, 2009, <http://www.ethicurean.com/2009/02/23/produce-safety-part-ii/>; Stephen Clapp, "USDA fails to derail ANSI sustainable agriculture standard" and "Keystone Alliance releases model for measuring sustainable agriculture," *Food Chemical News*, January 26, 2009.

## Resources

**John Applegate, et al, "Reinvigorating Protection of Health, Safety and the Environment: The Choices Facing Cass Sunstein," Center for Progressive Reform, White Paper #901, January 2009, <http://www.progressivereform.org/SunsteinOIRA.cfm>.**

Because U.S. industry and government officials claim that U.S. rules are "science-based" with no political interference, it is important to understand the work of the Office of Information and Regulatory Affairs (OIRA) of the presidential Office of Management and Budget (OMB). All regulations, including food safety, are analyzed, and approved for implementation or not, in terms of OIRA's cost-benefit grid. Following the Bush administration's relentless promotion of industry self-regulation, there was hope that President Barack Obama would nominate an OIRA director who would regulate in the public interest.

However, according to the authors of this paper, the nomination of Cass Sunstein, a former colleague of President Obama's at the University of Chicago Law School, to head OIRA, represents "more of the same." The authors assume that the Senate will confirm Sunstein and summarize eight major issues that require him to abandon his and OIRA's reliance on cost-benefit analysis, a profoundly deficient decision-making framework. (Two of the authors have elsewhere published an alternative analytic framework for OIRA use.

For example, the authors comment on how cost-benefit analysis discounts regulatory benefits 3-7 percent annually, so that future benefits, e.g., a world without climate change, are incalculable, and tough rules to reduce greenhouse gas emissions unjustifiable in cost benefit terms. The authors dissect Sunstein's rationale that because the elderly are on average less economically productive, the benefits of a rule, e.g., against arsenic residue in water (or food), may not be justified by the cost imposed on industry of eliminating arsenic from water (or food). The policy presumptions of cost-benefit analysis can lead to quantum differences in the estimates that OIRA uses to determine whether a rule's benefits outweigh its costs. For example, Sunstein's own analysis of two cost-benefit studies of the same rule shows that benefits could be as little as \$13 million or as much as \$3.4 billion, providing the decision-maker with no reliable guidance about the rule's likely effects. The authors conclude that cost-benefit analysis should be abandoned, as its policy presumptions and data have been easily manipulated by those for whom regulation is a cost to be transferred to consumers, workers and the environment.

**"Food Safety, Plant and Animal Health: Human Health and Sustainability Dimensions,"  
Issues in Brief, International Assessment of Agricultural Knowledge, Science and  
Technology for Development, January 2009, <http://www.agassessment.org>.**

This issue brief is one of seven whose texts incorporate the findings of the International Assessment on Agricultural Knowledge, Science and Technology for Development (IAASTD), which was sponsored by five United Nations agencies, the World Bank and the Global Environment Facility. Fifty-eight governments approved the project's "Summary for Decision-Makers" after a weeklong line-by-line review in April 2008 in Nairobi, Kenya. More than 400 authors from a wide range of disciplines assessed thousands of documents to produce a global report, five regional reports and a synthesis report. (IATP worked on the policy options chapter and reviewed the investment chapter of the global report.) This issue brief outlines major challenges to improving surveillance of food-borne diseases and to intervening effectively when outbreaks occur, and then summarizes policy options for meeting these challenges. One sample policy option: "Establish regional or national food safety trust funds to ensure continuous funding mechanisms for national or regional surveillance systems. The trust funds could be financed from targeted Overseas Development Assistance and/or an increase in agrifood corporate taxes."

