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No hiatus for food safety

Contrary to what one might surmise about the cause of an extended absence, the reason the Global Food Safety Monitor has not been published is not the editor's complacency about the state of food safety. Rather, the daily flood of food safety news has become difficult to synthesize and summarize. Subscribe to a few daily online news services and you will be whipsawed by hope and despair.

For example, towards hope: on August 10, Rory Harrington reported on FoodProductionDaily.com that University of Minnesota researchers had accidentally discovered a benign bacterium that could be used as a natural food preservative and that would kill such pathogens as E. coli and Salmonella. But, towards fear: Would this preservative kill the pathogens that have been discovered by Purdue University researchers to reside in plant tissues and that cannot be washed away, according to an August 17 story by Harrington? Such pathogens as a new strain of E. coli 104:114 on sprouts instigated the biggest food safety story of 2011, if you measure "biggest" by the number of consumers killed and hospitalized due to an outbreak of foodborne illness. (We refer to the well-reported outbreak in May in Germany that killed 46 people and sickened at least 3900,)

Instead of reporting headline news stories, we review three issues that are, metaphorically speaking, slow-boiling, and can be best synthesized over time; 1) the first steps towards agri-nanotechnology regulation; 2) the revision of U.S. agricultural biotechnology rules, and 3) challenges of getting regulatory agencies to cooperate to prevent foodborne illness if possible, and when not, to detect and prevent the spread of foodborne illness.

The resource note for this issue addresses the problem of interagency cooperation to detect the intentional contamination of food. However, the problem of regulatory cooperation among agencies should not require a public or environmental health emergency to overcome jurisdictional and budgetary fiefdoms towards cooperating to arrive at a solution.

This issue is dominated by U.S. regulatory agency news, and although U.S. food safety regulation and enforcement practices have long ceased to be the "gold standard" for food safety, they are still globally influential, particularly for countries that send their officials to

visit U.S. agencies or study in the United States. Even when U.S. agencies send their officials abroad to certify the safety of food exporting facilities, the food import safety issue is less "global" than a U.S. regulator and food industry story. The globalization of parts of the food supply chain, however, means that even though outbreaks of foodborne illness seldom travel globally, food safety measures to prevent and combat foodborne illness are shared globally.

Agri-nanotechnology in U.S regulatory agencies and at the Codex Alimentarius Commission

August 17 was the deadline for comment on voluntary draft guidance to pesticide manufacturers for reporting the use of nanomaterials in new and existing pesticide products to the U.S. Environment Protection Agency (EPA). EPA will use the 136 public comments received plus other information gathered by the agency to issue a final guidance document, possibly in 2012.

Civil society advocacy played a role in generating the request for comments. A May 2008 petition filed by the International Center for Technology Assessment called on EPA to regulate nanosilver in pesticide products. The Institute for Agriculture and Trade Policy (IATP) was one of 14 co-petitioners. At a January 26 meeting with the presidential Office of Management and Budget (OMB), co-petitioners had suggested that they might sue OMB for "undue delay" in releasing the draft EPA guidance for comment.

According to the draft guidance, "the use of nanoscale materials in pesticide products and treated articles may allow for more effective targeting of pests, use of smaller quantities of a pesticide, and minimizing the frequency of spray-applied surface disinfection." The production and commercial use of nanomaterials, atomic to molecular sized configurations of such materials as silver, titanium dioxide and copper, is currently unregulated in the United States.

However, a June 9 White House memo to all heads of departments and agencies on how to regulate nanotechnology states, "Companies are already offering nanotechnology-enabled products with breakthrough capabilities in areas such as disease detection, lighter and stronger materials and next-generation batteries." In June, IATP published "Racing Ahead: U.S. Agri-nanotechnology in the Absence of Regulation," which evaluated some causes of nanotechnology regulatory paralysis prior to the White House memo and simultaneous announcement of requests for comment on draft guidance by the EPA and the Food and Drug Administration (FDA).

IATP's comment about the EPA draft guidance commended the agency for taking an important first step to gather comprehensive information to enable risk assessment and pre-market safety evaluation of pesticides with nanomaterials. But we emphasized, "The exposure of farmers and farm workers to ENMs [Engineered Nanomaterials] in pesticides, whether through inhalation or through the skin, and the bioaccumulation of ENMs in species along the food chain, present potential public and environmental health risks. Recall of those pesticides with ENMs already in the marketplace and safety assessment of them based on pesticide manufacturer information and independent information submitted to EPA are urgently needed first steps towards regulation of ENMs in pesticide products."

Linda Bergeson, a nanotechnology industry lawyer, strongly criticized IATP's support for the EPA's preferred method for gathering information from industry on nanomaterials in pesticide products. The industry believes that the EPA's preferred method would stigmatize all of

nanotechnology. Acknowledging industry's concern, the draft guidance also invites comments on the case-by-case collection of information proposed by industry. EPA characterized this information gathering method as being less efficient and more expensive for both industry and the (budget-and politically-beleaguered) EPA.

The FDA has still failed to respond to a May 2006 petition of the International Center for Technology Assessment et al. to regulate nanomaterials in FDA regulated products. Non-response on nanotechnology also reigned at the July 4 — 9 meeting of the Codex Alimentarius Commission, the international food standards-setting body. There, Egypt reiterated its 2010 request for a Codex task force on nanotechnology (paragraph 252 of the Commission's meeting report). The reply from officials at the U.N. Food and Agriculture Organization (FAO) and the World Health Organization (WHO) was nearly identical to their response to Egypt's proposal in 2010 for a Codex nanotechnology task force. Identical: FAO and WHO had co-sponsored an expert group in 2009 to review possible risks of applications of nanotechnology in food and agriculture. Identical: FAO and the Brazilian government had co-sponsored a conference in 2010 on such applications with a panel on regulatory challenges of agri-nanotechnology. (See "Food Safety at the NanoAgri 2010 conference" in the Global Food Safety Monitor.)

The unique feature of the 2011 response to Egypt was this: "FAO and WHO would continue the work in relation to development on decision-tree approaches for assessment of nanotechnology applications in the food sector when the ongoing work in other entities had been finalized, to avoid duplication of efforts." (paragraph 253) In other words, Codex should not request risk assessments from FAO/WHO expert panels nor possibly make food nanotechnology standards part of its work program until "other entities," such as the U.S. government, the European Commission, and the Organization for Economic Cooperation and Development (OECD), had completed their work on nanotechnology. Codex should defer to these entities to assess whether and how products incorporating nanomaterials should be regulated or whether the unregulated commercialization of such products should continue. However, there is no end in sight for completion of this work by the "other entities."

IATP, as a member of the Nanotechnology Working Group of the TransAtlantic Consumer Dialogue (TACD), urged U.S. and EC regulators in first in 2009 and again in a June 2011 resolution, to require reporting of data on all nanomaterials produced to regulatory authorities and to establish an official registry of consumer products with nanomaterials. In addition to discussing the resolution with officials at the annual TACD meetings, TACD Steering Committee members have discussed the Nanotechnology Working Group resolutions with the Transatlantic Economic Council, the highest U.S.-EC economic cooperation body. However, the U.S. government, per its custom, does not respond in writing to TACD resolutions nor has the usually responsive European Commission responded in a way to indicate that there will be a transatlantic agreement on nanotechnology regulation in the near future. Without such an agreement, there will not be a FAO/WHO risk assessments nor Codex standards on food applications of nanotechnology, even as agri-nanotechnology products enter into commerce.

Source: Bridget Di Cosmo, "Activists Hint at Suit to Force Action on EPA's Stalled 'Nano' Pesticides Plan," Risk Policy Report: Inside EPA, January 28, 2011.

U.S. biotechnology regulatory framework decision: Waiting for Godot

In the famous play by Samuel Beckett, the characters wait for another character who never comes. If the U.S. food and agricultural regulatory system were a play, the absent Godot character would be a regulatory framework to apply to the various techniques for genetically engineering agricultural crops. The U.S. Department of Agriculture (USDA) has been revising its 1987 framework for regulating agricultural biotechnology products since 2004.

In an April 6 speech to the Organic Trade Association in April, USDA Secretary Tom Vilsack said that he hoped for a final framework rule by the end of 2011 to update current regulations. He noted that the agency was reviewing 66,000 comments on a draft proposal by the Bush administration in 2008.

One part of the regulatory framework debate concerns how to address adverse effects of GE crops to agriculture under the Plant Protection Act. One food safety consequence of the outcome of this debate resides in the increasing resistance of GE crops to pesticides, consequent increase in pesticide use, and likely consumption of more pesticide residues by consumers. A recent article by Iowa State University scientists confirms anecdotal reporting of resistance to insecticidal toxins engineered in maize.

On July 5, 60 (of the nearly 2,600) members of the National Academy of Sciences sent a letter to the Environmental Protection Agency (EPA) in response to a March 16 draft rule on data reporting requirements for crops engineered to produce toxins. The signatories declared themselves satisfied with USDA's oversight of virus, pest and weed resistance in GE crops. The letter stated, "Based on initial reviews of that draft proposal and recent EPA actions associated with biotechnology-derived crops, it is clear that the agency is departing from a science-based regulatory process, walking down a path towards one based on the controversial European 'precautionary principle.' The signatories also charged that the EPA-proposed rule "would impose steep barriers to scientific innovation and product development across all sectors of our economy." (We were unable to find a link to the letter in the docket of responses to the proposed EPA rule.)

Nina Federoff, a signatory to the letter and a Bush administration biotechnology promoter in the State Department, further inveighed against the EPA in a New York Times opinion piece, "Engineered Food For All." Federoff contended that the safety of GE crops had been proven beyond a shadow of a doubt. Furthermore, according to Federoff, GE crops are necessary to double yields to feed the world of 2050. A recent WikiLeaks release of State Department cables shows that agency funding academics, and NGO front groups to promote GMOs globally and intervening to change foreign food safety and environmental rules to enable planting and importing of GE crop varieties.

As if to rebut Federoff and her colleagues, on August 3, a group of 22 agricultural, consumer and environmental organizations wrote to Secretary Vilsack to propose an alternative to the aforementioned Bush administration rule. In a 17-page letter, the group contended that the Bush administration proposed rule would place most GE crops beyond USDA regulatory authority and would disregard the advice of a National Academy of Sciences report and the USDA's inspector general on how to regulate GE crops. In proposing the outlines of an alternative rule on GE crops, the group noted that the USDA's Animal and Plant Health Inspection Service (APHIS) "has not conducted a single environmental assessment of a GE crop field

trial in the past four years." Furthermore, they charged that APHIS did not know the location of many of the field tests of unapproved GE crops required under current law. The letter contains an appendix of incidents where gene outflow from unregulated GE crops contaminated convention or organic crops at great economic loss to the conventional and organic growers.

In what is perhaps the strangest case of the Obama administration's efforts to expand the planting of GE crops in the United States and worldwide, on July 21, the Public Employees for Environmental Responsibility (PEER), an association of local state and federal officials with responsibility to protect the environment, sued U.S. federal agencies to obtain their communications with industry lobbyists. The lawsuit, filed together with the Center for Food Safety (CFS) and Beyond Pesticides, charged that federal officials in the Agriculture Biotech Working Group worked with the Biotechnology Industry Organization to find ways to legalize the planting of GE crops on 75 refuges in 30 states. A spokesperson for the U.S. Federal Fish and Wildlife Service said that the USDA and EPA had approved planting corn, rice and millet, including GE varieties, on wildlife refuges for 14 years. Coincidentally, commercialization of GE crops began about 14 years ago.

(Given the millions of U.S. acres planted to GE crops, it may seem strange that the U.S. government would plant crops requiring pesticides on just 44,000 of the four million acres of land set aside by law to protect wildlife. However, the apparent legal rationale for doing so is to prevent other governments from being able to say that GE crops are unsafe for planting in U.S. wildlife refuges, and therefore unsafe for planting in their countries. Such is the science-based risk-management of agricultural biotechnology.)

PEER said that the groups were forced to sue after federal agencies met their document discovery requests with claims that their communications with industry would reveal Confidential Business Information (CBI) protected by law from public scrutiny. PEER has ridiculed the Obama administration's principles for scientific integrity of regulatory decision-making, developed after Bush administration lawyers had rewritten reports of government scientists to conform to industry views on climate change and other controversial science-based public policy issues.

Samuel Beckett bristled at the suggestion that "Waiting for Godot" was an absurdist drama. One wonders how he would have responded if tasked with writing a play about the U.S. regulatory process for GE crops.

Sources: Stephen Clapp, "Vilsack forecasts biotech overhaul rule this year," Food Chemical News, April 8, 2011; Stephen Clapp, "Scientists Protect EPA proposal to expand biotech regulation," Food Chemical News, July 22, 2011; Stephen Clapp, "Biotech crops need more regulation, not less, 22 groups tell Vilsack," Food Chemical News, August 5, 2011; Mike Ludwig, "New WikiLeaks Cables Show U.S. Diplomats Promote Genetically Engineered Crops Worldwide," Truthout, August 25, 2011.

Let's Work Together! or, Not

When Food Chemical News asked Lisa Shames, head of the U.S. General Accountability Office food safety and agriculture division, about the greatest challenge to implementing the 2010 Food Safety Modernization Act (FSMA), she didn't cite U.S. Congressional cuts to food safety budgets that would cripple FSMA implementation. This is a bit surprising given the House of Representatives Appropriation Committee vote in May to eliminate the FDA budget

for monitoring pathogens on fruits and vegetables. Instead, she said that the FSMA required FDA and USDA to coordinate their efforts, but that such coordination is "really the biggest challenge." To take one of our favorite examples, coordination is apparently difficult to prevent the increasing frequency of contamination of produce under FDA regulation by pathogens via agricultural waste originating in Confined Animal Feeding Operations (CAFOs) under USDA authority. (See, e.g., "A simple solution: Don't spread raw manure on your fields," Global Food Safety Monitor, August 2010.)

Failure to cooperate is not, of course, limited to U.S. agencies. After reading about a Chinese National People's Congress report that is highly critical of food safety regulations and enforcement, we went to the website of the State Food and Drug Administration to find examples of cooperation there with the Ministry of Agriculture. Granted the search was conducted in English only, but we could find only one example of cooperation, a joint urgent notice in 2008 that urged cooperation to prevent bulk veterinary ephedrine from "flowing into illegal channels," presumably to make methamphetamine.

The People's Congress report, to judge by the state-run Xinhua news service, called for better coordination among various agencies with food safety responsibilities, increasing staffing and the budget for food safety and cracking down "on illegal use of non-edible materials and food additives in animal cultivation and food processing." A committee of the People's Congress went on a "law enforcement tour" and considered whether harsher economic penalties might deter violations of the law, since China has applied the death penalty in a few cases of food safety crime, with no apparent decrease in crime.

A lawyer, who defended dairy producers convicted of adding the industrial chemical melamine to milk that killed at least six infants and sickened 300,000 in 2008, said that Congressional inspection tours were fine, but that food safety law enforcement failed to address an underlying cause of contamination: "It is also essential to ensure a reasonable profit for dairy farmers and reduce role of the middlemen, who try to keep dairy purchasing prices down." The tens of thousands of U.S. dairy and beef cattle farmers who have gone out of business during the past decade, while the USDA neglected to enforce anti-competitive business practices laws, would surely agree. Although the Inspector General audits can report on U.S. failure to enforce laws to ensure fair and transparent markets, the Inspector General cannot force the USDA or the Department of Justice to enforce the law.

Sources: Amber Healy, "Lisa Shames, GAO's top food safety investigator, Part 2," Food Chemical News, May 27, 2011; Joan Murphy, "House Appropriations Committee to gut pathogen monitoring program," Food Chemical News, June 3, 2011; William Neuman, "On Food Safety, a Long List, but Little Money," The New York Times, August 23, 2011; "Chinese lawmakers deliver damning report on food safety," Food Chemical News, July, 15, 2011.

Resource note:

"Food Emergency Response Network," Office of the Inspector General, U.S. Department of Agriculture, March 2011, <http://www.usda.gov/oig/webdocs/24601-6-AT.pdf>.

As the United States prepares to observe the tenth anniversary of the September 11, 2001 attacks in New York City, and Washington, D.C., the readiness of U.S. agencies to respond to the intentional biological, chemical or radiological contamination of food will be under scrutiny. As part of the post "9/11" government response, in 2005 the USDA and FDA launched a Food Emergency Response Network (FERN) in 2005. FERN should coordinate USDA and FDA

testing laboratories, local, state and regional labs covered by a cooperative agreement program (CAP) and non-CAP labs. According to the Office of the Inspector General (OIG); FERN's objectives are: "(1) prevent attacks on the food supply by providing an early means of detecting threat agents; (2) prepare member laboratories (federal, state, local and tribal) to respond to food-related emergencies; (3) provide and coordinate regional and national surge capacity for laboratories; and (4) assist in recovery efforts to restore confidence in the food supply following a threat or actual emergency."

The OIG report does not evaluate the entire FERN program, since it has only legal authority to audit the USDA's Food Safety Inspection Service role in the program. In the absence of a formal Memorandum of Understanding between FSIS and FDA, "FERN lacks some of the elements an effective interagency emergency network would need to succeed, such as standard operating procedures for the network's critical functions, sufficient staffing, and a clear strategic direction for the network as a whole." OIG investigators visited three non-CAP labs to verify that they had the testing capabilities that they had alleged to FSIS. The OIG determined that in aggregate the labs did not have sufficient staff nor testing capabilities for major pathogens such as E.Coli, *Campylobacter*, *Salmonella* and anthrax. The lack of adequate cooperation with FDA and verification of non-CAP capabilities are among the shortcomings that FSIS has committed to remedy by March 2012. FSIS also committed to working with other agencies on a pilot project to detect intentional contamination in U.S. commodity imports. However, all these commitments were made before the August 3 budget agreement to make major cuts to all U.S. federal agencies in exchange for increasing the U.S. government debt ceiling.

