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Introduction: Who's afraid of inspection, testing and understanding?

The Monitor continues to be puzzled by the antipathy of the food industry and some governments toward government inspection and testing, and even more puzzled by the claim that privatization of inspection is part of the "modernization" of food safety.

We understand the government's budgetary argument for transferring most food inspection to the private sector. The fiscal crisis resulting from the global Great Recession has made all regulatory agencies, save those of the military, homeland security and intelligence agencies, the targets of budget cutting. So, for example, the U.S. Department of Agriculture's (USDA) Food Safety Inspection Service (FSIS) claims it will save about \$13 million annually by expanding its pilot project for privatizing poultry inspection from 25 plants to 200 plants. But this is not much savings in the 2012 FSIS [budget](#) of slightly more than one billion dollars.

The USDA proposes to expand that pilot program, which includes the HACCP (Hazard Analysis Critical Control Point) Inspection Models Project (HIMP), but FSIS will provide no new training on HIMP rules for the plant employees who are to implement the program. Training is apparently not part of what makes HIMP more modern than government inspection. The verification of the plant's HACCP paper work and other food safety programs, together with computer modeling of pathogen contamination risk, is apparently the modern in modernization.

Oddly, however, FSIS requires its own government inspectors to take months of classes to learn the FSIS rulebook. Because HACCP is an international standard of food safety management, FSIS requires imported meat likewise to have been inspected by trained government employees.

What about privatization? Is privatization essential to the modernization of inspection and testing? Previous USDA statements seemed to say that, but in a May 1 letter from Consumers Union to USDA, referenced below, we were reminded that the USDA forbids private enterprises from testing for Bovine Spongiform Encephalopathy, i.e. Mad Cow. In 2008, the USDA won a [judgment](#) at the U.S. Court of Appeals to prevent Creekstone Farms Premium Beef from testing for BSE to satisfy the demands of its Japanese importers. Indeed, IATP joined an NGO [letter](#) in 2004 to demand that USDA allow private testing of cattle for BSE both to protect consumers and to increase beef exports to Japan.

However, to use a key term from the World Trade Organization agreement on trade-related food safety and animal and plant health, the USDA apparently believes that allowing private testing for BSE is not “necessary” to promote the free trade of beef. Looking towards the future of inspection and testing, we report on the Food and Drug Administration’s release of voluntary guidance on nanomaterials in food products may result in the regulation of those products. Will inspection and testing of food products incorporating nanomaterials likewise be not “necessary”?

Source: Amber Healy, “No training requirement for poultry sorters in HIMP proposal,” Food Chemical News, February 24, 2012.

Analysis: U.S. Mad Cow risk communication plan overwhelmingly successful

Following the announcement of the detection of bovine spongiform encephalopathy (BSE, commonly known as Mad Cow disease) in a dairy cow in California on April 24, U.S. and beef industry officials used every available communications media to voice a common message: U.S. safeguards against BSE worked and U.S. beef is safe to consume.

Despite a fall in livestock futures prices to the exchange “circuit breaker” limit on April 24, by April 25 prices had stabilized, and by April 26 the last front -page story on the BSE case had been published in mainstream media. There would be no repeat of the 2003 risk management failure, following the announcement of the first detected U.S. case of BSE, when markets around the world closed to U.S. beef exports. Following the April 24

announcement, only Indonesia announced that it would block U.S. beef exports.

How did the United States manage largely to avoid adverse economic consequences following this latest BSE case? Apart from a very well executed and coordinated risk communication plan between the beef industry and the U.S. Department of Agriculture, at least three factors made successful crisis management possible in this case.

First, the animal tested positive for what USDA's chief veterinary officer John Clifford said was "atypical BSE, a very rare form of the disease not generally associated with an animal consuming infected feed." USDA's test results have been sent to World Animal Health Organization (OIE in the French acronym) laboratories in Canada and England for confirmation. But assuming that USDA's diagnosis is confirmed, U.S. officials can claim that their controls to prevent the feeding of cattle remnants to cattle, a cause of the most 'typical' strain of BSE, have worked.

Consumers Union (CU) [wrote](#) on May 1 to the USDA and the Food and Drug Administration, which has authority over feed formulation, that the 'L-strain' could be caused by infected feed, even if cattle remnants were not fed directly to cattle, a cause of the 'typical' BSE that causes death in humans who consume infected meat. CU urged that FDA should immediately prohibit feeding bovine blood, poultry litter, and all brains and other "specified risk materials" to cows, as all of these could carry the BSE infective agent. CU noted that a cycle of potential infection is created when cow remnants are feed to chickens and pigs, whose remains are in turn fed back to cattle in processed feed.

Secondly, the detection of BSE in one of the 40,000 cattle tested in USDA's BSE surveillance program was used by the industry and the USDA to justify the present frequency of testing among 35 million head of U.S. cattle. Following detection of two cases of BSE after testing 800,000 cattle in eighteen months, in 2006, the USDA said more frequent testing was like using a bazooka to kill a mouse, and reduced its frequency of testing program to 40,000 cattle a year.

CU [noted](#) that the European Union and Japan test every head of cattle slaughtered above a certain age for BSE and urged the USDA to increase its testing frequency to at least 350,000 cattle per year of the 35 million head herd. CU also argued that the USDA should test the herd mates and offspring of the BSE infected cow, since they would have eaten from the same feed. USDA, still struggling to establish a livestock identification program, was unable to find its herd mates and only one of the cow's offspring, which [did not test positive](#) for BSE.

A third factor that helped to limit the economic damage of the BSE case was the constant iteration to beef importers that the USDA testing frequency and procedure conformed to the OIE standard for BSE. Senators Debbie Stabenow and Pat Roberts of the U.S. Senate Agriculture Committee were among those who invoked "[international standards](#)" as a source of protection for global consumers of U.S. beef. "I look forward to a good

beef dinner tonight," said Senator Roberts in a press release.

USDA informed OIE of the [case](#), first detected by local veterinarians on April 19. The OIE [standard](#) in question is one that recognizes the United States to be a country of "controlled risk" for BSE, i.e., one from which beef products may be exported, because of conformity with measures in OIE's Terrestrial Code for BSE. "Controlled risk" does not specify a frequency of testing, only an ["appropriate level of control and audit,"](#) a definition advocated by the United States during the OIE negotiations on the BSE standard. Every OIE member that supports this standard is free to choose its level of "control," including frequency of post-mortem surveillance for BSE.

In March, the USDA's Animal and Plant Health Inspection Service (APHIS) proposed a new rule that would change the APHIS imported livestock policy to harmonize with the OIE standard. APHIS said that the changes would both increase U.S. beef imports from countries OIE deems to have "negligible risk" or "controlled risk" for BSE and increased exports for U.S. beef to those countries with the same OIE BSE risk classifications. R-CALF U.S.A. said the APHIS proposed rule was an "unilateral disarmament of our import health and safety standards" that would prevent exports to countries with stronger BSE standards than the OIE rule, including Brazil, Indonesia, Japan and Taiwan.

Sources: Stephanie Strom, "Case of Mad Cow Disease Found in U.S.," The New York Times, April 24, 2012; Jason Huffman, "Words to calm come fast after discover of 4th BSE cow in U.S.," Food Chemical News, April 27, 2012; Sara Muirhead, "BSE 'safeguards work,'" Feedstuffs, April 30, 2012; Stephen Clapp, "Consumers Union urges more BSE testing and tightening of feed ban," Food Chemical News, May 4, 2012; Stephen Clapp, "APHIS issues proposal to bring BSE rules into line with OIE," Food Chemical News, March 16, 2012.

New FDA guidance on nanotechnology in food and cosmetics takes a few steps forward

On April 20, the U.S. Food and Drug Administration (FDA) released for public comment two draft guidance to industry documents, about 25 pages each, on the use of [nanotechnology in food](#) and [cosmetics products](#), respectively. The incorporation of atomic to molecular-sized Engineered Nanoscale Materials (ENMs) into FDA regulated products is supposed to have benefits both for food manufacturers and consumers. For example, coating food conveyer belts with nano-silicon dioxide should, in theory, prevent pathogen growth, make the belts easier to clean, and reduce the likelihood of contamination of the food carried on the conveyor belts.

Despite [manufacturer identified evidence](#) that use of ENMs in consumer products, including food, continues to increase, and despite scientific literature that indicates ENMs may pose significant health risks, the FDA currently does not yet regulate ENMs. Strong final guidance documents can become a basis for subsequent mandatory regulation.

These guidance documents do not respond explicitly to a [lawsuit](#) filed by the International Center for Technology (ICTA) assessment, in which IATP is a co-plaintiff. The complaint requires FDA to respond to the May 2006 ICTA, et al. petition to regulate the use of nano-titanium dioxide in sunscreens and other FDA regulated products, including processed foods. On the same day that FDA responded to the lawsuit by finally responding to the petition, it also released the guidances.

IATP joined ICTA and Friends of the Earth in responding to the draft guidance. We strongly urge consumer organizations and the public in general to strengthen the draft guidance by submitting comments. There will be a 90-day comment period once the draft guidance is published in the [Federal Register](#).

The guidance documents are the result of an exceedingly deliberate process that began with a 2007 workshop, a 2008 workshop report and intensive industry-FDA dialogue to produce documents that have "voluntary guidance" and "not for implementation" written on every page. Relative to the demands of the ICTA, et al. petition, these documents do not demand much of ENMs manufacturers, nor of those who incorporate ENMs into FDA-regulated food and cosmetic products.

Generally speaking, the guidance on cosmetics is more specific than the "food substance" guidance concerning the environmental, health and safety issues that form the core of FDA's statutory duties. For example, the cosmetics guidance suggests that industry may have to revise its toxicology tests when ENMs are added to cosmetics because of the unique properties of ENMs relative to their macro-sized counterparts. FDA advises industry that it may wish to use "tiered testing" of products, which is similar to the EU's REACH program for registration and testing of chemicals, though REACH isn't named explicitly.

The "food substance" guidance advises that industry will have to determine on a case-by-case basis whether use of ENMs results in a "significant manufacturing process change" that would warrant submission of data to FDA for a formal pre-market approval. Much of this guidance is not specific to nanotechnology but is structured in such a way as to outline the legal framework for assessing the safety and regulatory conformity of a food substance, whether or not it incorporates ENMs. The guidance gives examples of cases where "significant process change" did not affect existing industry determinations that food substances were "Generally Recognized As Safe" (GRAS).

However, in probably the most important feature of the food substance guidance, FDA advises that ENMs “likely would not be covered by existing GRAS” and that industry would have to submit product data with ENMs for a “formal pre-market review.” According to a February 2010 [General Accountability Office report](#), industry self-determination of GRAS, could lead to the non-reporting to FDA of ENMs in FDA regulated products. Therefore, FDA’s announcement that ENMs would not be assumed to be GRAS is a significant step towards regulation. Lack of a formal definition of ENMs that could be applied by all agencies has hindered regulation of ENMs in food and food contact surfaces. Now the FDA has proposed to industry that it should count on a formal pre-market review of data on the nano-scale versions of GRAS designated materials. Consumer organizations, the scientific community and the general public should support this proposal.

Perhaps the least useful part of the food substance guidance concerns the discussion of “self-limiting levels of use,” according to which manufacturers would not knowingly add an ingredient that would make an FDA regulated product unsafe or unfit for consumption. The advice does not address the validity of “self-limitation” when so little is known about the levels of ENMS incorporation present environmental, health or safety risks. Here too, comments are urgently needed to document for FDA the irrelevance of advice on industry self-limitation in the use of ENMs in foods, when so little has been published on the effects of chronic exposure to ENMs in the gastro-intestinal tract.

New report: International Standards for Trade in Nano-coated Produce?

As nanotechnology is increasingly introduced into a rapidly expanding range of commercial products and processes—many involving food—research into potential health and safety impacts lags behind. Without such publicly available research, there is no basis for agro-nanotechnology standards to protect consumer health. The issue is not, “What happens if you eat one nano-coated banana?” but rather, “What happens if you eat nano-coated bananas, without knowing they are nano-coated, over your entire life?”

Given the lack of understanding about the potential health impacts of engineered nanoscale materials (ENMs) in the gastro-intestinal system, and resulting dearth of regulation, [IATP’s latest report](#) makes the case that more research and international standards are urgently needed before ongoing commercialization of ENMs exposes consumers to unnecessary and unjustifiable risks.

Read [International Standards for Trade in Nano-coated Produce?](#) on [iatp.org](#).

Resource notes:

Ensuring safe foods and medical products through stronger regulatory systems abroad, Committee on Strengthening Core Elements of Regulatory Systems in Developing Countries, Institute of Medicine, The National Academies Press, 315 pages, 2012,

http://books.nap.edu/openbook.php?record_id=13296

"Product safety in the United States depends on systems in faraway places," begins this report on how to improve regulatory cooperation among the U.S. Food and Drug Administration and foreign regulators to keep pace with the ever lengthening and more complex supply chains of transnational corporations. The Institute of Medicine (IOM) committee reviewed FDA's import product safety plan, evaluated its foreign office resource allocations and training programs and how it used an "enterprise risk management" model to maximize the public health effect of FDA's resources in the prevailing U.S. budget-cutting environment. In order to assess the regulatory systems of developing countries exporting foods and medical products to the United States, between March and December 2011, the IOM committee visited low and middle income developing countries, with a particular focus on Brazil, China, India, Mexico, South Africa and Thailand. Developing country regulators, food and medical product exporters, development bank officials and academics interviewed, and a comprehensive literature review were the basis for recommendations about how to identify and strengthen "core elements" of their regulatory systems. Such enhanced regulatory systems will not only export safer products to benefit U.S. consumers, but if applied domestically, will benefit consumers of food and medical products in developing countries.

"In the case of food safety," the report notes, "around the globe, the 20th century paradigm of a focus on food safety intervention at ports-of-entry is shifting to a focus on the accountability of those involved in the food enterprise from farm to table. . . This global shift suggests that the FDA's leadership in developing risk-based approaches and preventive controls in support of food safety could contribute to new global standards to be adopted through a multitude of networks, partnerships and information sharing venues" (p. 289). The approach to food safety advocated in the report not only entails ever less U.S. port of entry inspection, relative to the growing volume of food imports, but more reliance on standards developed not by intergovernmental bodies, such as the Codex Alimentarius Commission, but by public partnerships with private standards setting bodies, such as the Global Food Safety Initiative.

"Privatized Food Inspection: USDA's Pilot Project Results," Food and Water Watch, 2012.

<http://www.foodandwaterwatch.org/food/foodsafety/privatized-poultry-inspection-usdas-pilot-project-results/>

The Monitor has never written a resource note on data alone, but the private poultry inspection testing results

of the U.S. Department of Agriculture's now 14 year old pilot project compel a note because other countries, such as New Zealand and European Union member states, are emulating or considering emulation of the USDA inspection model. Under the pilot project, private inspectors largely would replace government inspection, enabling "modernization" of inspection at a USDA permitted rate of up to 175 carcasses per minute. Government inspectors currently examine ten carcasses per hour for pathogens and other defects that would remove the carcasses from the food supply chain.

By filing a Freedom of Information request, U.S. NGO Food and Water Watch obtained inspection test data and 115 pages of non-compliance records for March 1 to August 31, 2011 for 14 of 24 plants participating in the HACCP [Hazard Analysis Critical Control Point] Model Inspection Project (HIMP). In aggregate, USDA defined defects missed by plant inspectors ranged widely according to the classification of defects, with dressing defects concerning feathers, the trachea and oil glands missed by about 64 percent of the plant inspections to near zero percent missed for animal disease defects. The non-compliance records are slightly redacted raw REPORTS, and no doubt will be the subject of future Food and Water Watch analysis.

