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The Wall Street blow-up, the fiscal crisis and food safety

"There's no money for . . ." well you name it, at a time when all manner of government services are being cut, why should food safety be spared? (Well, not all services. Services to heal the self-inflicted damage to the banking system continue to be offered on the most generous terms. A recent_study by the Levy Institute estimates the cost of the U.S. Federal Reserve Bank system bailout of the U.S. and European financial services industry from 2007 to 2009, including loans at rock bottom interest rates and purchase of "toxic" (i.e., loss-making, otherwise unsellable) assets, at over \$29 trillion (not a typo)).

In May 2011, the World Health Organization's secretariat report to the World Health Assembly, "The Future of Financing for WHO," promised budget and program reforms, in light of "the new reality of financial austerity." The report promises, "Changes to the 2012-2013 budget have already moved in the direction of greater realism." (paragraph 65). New systems for priority setting and program evaluation will be part of the streamlining enforced by the budget cuts. More employment of short-term and project specific staff to deal with national and international health crises, including those of food and water borne illness and epizootic emergencies, such as avian influenza, will be part of the WHO redesign to be presented to World Health Assembly delegates in May 2012. Furthermore, in view of WHO member government fiscal crises, WHO will seek to widen its funder base to include foundations and corporations, "without compromising independence or adding to organizational fragmentation" (paragraph 78).

Just as WHO is triaging its programs and personnel, its member government food safety services haven't been spared the budget axe. Many of the source articles synthesized below report food safety issues affected by the budget cuts that have undermined the ability of food safety professionals, and indeed, of governments, to protect public health. The following overview concerns programs in the government with which the Monitor is most familiar, that of the United States, which is by no means a proxy for global food safety. However, given the global commercial and policy influence of U.S. agencies in food safety, we think the U.S. agency response to the "new financial austerity" is likely indicative of what is happening in many countries.

For example, the U.S. Food and Drug Administration (FDA) pleaded poverty on November 7 as the reason not to withdraw already approved animal drugs whose non-therapeutic use in feed the agency acknowledges as a factor in human antibiotic resistance. FDA, responding to petitions by medical associations and non-governmental organizations, the first of which were filed in 1999, alleged that the withdrawal of just one drug used in poultry production took five years and \$3.3 million, due to industry legal resistance. The agency said it cannot afford to

withdraw the many animal drugs used non-therapeutically to promote growth and prevent disease in confined animal feed operations.

Instead FDA proposes to begin a program with animal drug manufacturers to phase-out voluntarily some of these drugs. On November 14, Keep Antibiotics Working (KAW), a coalition to which IATP belongs, wrote to FDA to protest the agency's denial of its 2005 petition to withdraw the drugs. KAW noted that not only did the petition denial violate FDA's public health mandate, but "the FDA has not sought additional resources from Congress nor has it supported legislation, namely the Preservation of Antibiotics for Medical Treatment Act, aimed at easing the FDA's burden in addressing the problem."

On January 9, the U.S. Department of Agriculture (USDA) announced it would close 259 offices, laboratories and other facilities in the United States plus seven offices in foreign countries to save \$60 million in its \$145 billion budget. Among the offices to be closed are five of the 15 Food Safety Inspection Service (FSIS) offices. FSIS is responsible for ensuring meat, poultry and egg safety. USDA undersecretary Elizabeth Hagen said, "There will be no reduction in inspection presence in slaughter and processing facilities and no risk for consumers," as a result of the budget cuts, which will affect administrative staff, rather than inspectors.

In September 2011, USDA had <u>announced</u> that budget cuts would curtail or end data collection and reporting on pesticide use on fruits, vegetables and in livestock pens by the National Agricultural Statistics Service (NASS). NASS surveys are used to help formulate food and farm worker safety policy. In November, NASS announced cutbacks to its survey of pesticide and fertilizer use on field crops. Nongovernmental organizations protested the cutbacks, saying that the public would be forced to rely on pesticide and fertilizer companies for unverified reporting about agricultural chemical use.

Our thin budgetary margin for error in curtailing the spread of foodborne illness was brought home forcefully in a background story about the U.S. Centers for Disease Control and Prevention (CDC). The CDC took justifiable pride in tracing back a listeria monocytogenes infection to the packing facility of a melon farm in Colorado just ten days after the initial hospital report of listeriosis, which had led to 29 deaths by the end of November.

Thomas Frieden, the CDC director, noted in a speech to the National Food Policy Conference in early October in Washington, D.C. that his agency had absorbed the biggest budget cuts in its history in 2010 and 2011. (The U.S. House of Representatives is promising further cuts to the 2012 budget.) Furthermore, "there are 44,000 fewer people working at the state and local level because of the fiscal crisis" in the public health professions. As a result, in Colorado, college students used their own cell phones and a CDC questionnaire to interview those afflicted with listeriosis. The students helped to trace back to a single farm the source of the listeria, doing work that had previously been done by public health officials. (As a result of the listeria outbreak, U.S. melon growers said that they would be willing to implement mandatory FDA rules to ensure melon safety.)

"Doing more with less" (except for the banking, energy and military sectors) is a favorite slogan of the apostles of austerity for government and more freedom from regulation for the private sector. Yet, as the CDC and other agencies investigate the causes of the yet another outbreak of contamination of produce by pathogens of animal origin, the question arises "how much less," before students equipped with cell phones and a CDC questionnaire cannot trace back the source of foodborne illness before many more than 29 people die?

Furthermore, how will the CDC and other agencies be able to pay to implement programs and technologies to <u>prevent</u> incidents of pathogen contaminated produce? How will they be able to disseminate such programs and technologies to other countries or to learn from the experiences of

other countries, so that such contamination does not become more prevalent and more severe as the speed of pathogen evolution increases under the effect of climate change?

It should not take a spike in death or illness from foodborne disease to shock us into recognition that food safety is not cheap, nor can food safety be self-regulated among competing companies. It is an unhappy fact that failure to regulate the financial services industry has resulted in bailouts (with nothing required of the banks in return!) that have caused governments to plead poverty when it comes to paying for regulatory services. But there is no good reason to apologize for the costs of regulation or to believe, with the acolytes of more austerity, that less regulation will result in prosperity that will trickle down in the form of increased taxes to fund such services as food safety.

Sources: Amber Healy: "Loss of state and local health officials hurting CDC's efforts," Food Chemical News, October 7, 2011; John Murphy, "Costs too high to withdraw animal drug uses, FDA says in rejecting petitions," Food Chemical News, November 11, 2011; Joan Murphy, "Environmental groups protest USDA cutbacks in pesticide usage surveys," Food Chemical News, December 9, 2011.

Waiting for a definition and regulation of nanomaterials

In July 2011, officials from the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) told Egypt that the Codex Alimentarius Commission should wait to develop standards on the application of nanotechnologies to food and agriculture until "other entities" had finished their general framework for regulating all nanotechnology applications (paragraph 253). ("Other entities" refers to the U.S., European Commission and Organization for Economic Cooperation and Development guidelines for regulating nanotechnologies, all of which have been have been in process for several years.) Egypt reiterated its concern from the 2010 Commission meeting that food products with nanomaterials were being traded internationally without regulation. Reported applications include incorporating nano-scale particles of clay, silicon dioxide and titanium dioxide in food packaging to extend food shelf life and incorporating nano-silver to increase the surface contact of toxins in pesticides with the target pest. However, these and other applications are not yet regulated by the "other entities."

One of the impediments to regulation has been lack of agreement about a definition of "nanomaterials" that would be applicable by regulators and yet flexible enough to encompass the fast developing science about nanomaterials. On October 18, after more than two years of debate, the European Commission published its <u>recommendation of a definition</u> of "nanomaterials." The definition encompasses the science about the size range, shapes and unique properties of nanomaterials attributable to the size and shape of nanoparticles.

The definition includes a size range of one to 100 nanometers (a billionth of a meter). The Transatlantic Consumer Dialogue, of which IATP is a member, had recommended a one to at least a 300-nanometer range, with a 1000 nm limit for drugs with nanoparticles. The higher recommended limit reflects scientific research in which larger nanoparticles can breach the placenta and the blood-brain barrier.

However, at the insistence of the huge industry lobby in Brussels and the EC's Directorate General of Enterprise, aspects of the definition and its application may be modified for reasons of "competitiveness." For example, "In specific cases and where warranted by concerns for the environment, health, safety or competitiveness the number size distribution threshold of 50 % may be replaced by a threshold between 1 and 50 %." The European Environmental Bureau had recommended a one percent threshold of nanoparticles to qualify as a nanomaterial. The Commission's definition apparently tried to straddle the one percent—threshold called for by science and the 50-percent threshold demanded by industry.

The industry also lobbied successfully to include in the definition naturally occurring nanomaterials, e.g., smoke particles, as well as "incidental" nanomaterials produced during manufacture, rather than only engineered nanomaterials, the original subject of the definition. Critics of the definition believe that the changes to the draft definition will reduce regulators' ability to protect consumers and the environment from products incorporating nanomaterials. The recommended definition must be approved by the European Parliament and Council for use in legislation and rulemaking. It must be reviewed, in light of new scientific information, by December 2014. Nanotechnology is among the industries covered by the Corporate Europe Observatory's "Revolving Door Watch" project.

Notwithstanding intensive industry lobbying on the definition of "nanomaterials," Mike Knowles, a Coca-Cola executive, assured participants at the Fourth Nanotechnology Stakeholder Day on October 5 in Brussels, that food companies are not rushing to add nanomaterials to foods and food packaging materials. According to Knowles, "we've been living with nanostructures forever," such as those in fats and carbohydrates. He told attending journalists that the "European regulatory system has all the safety aspects covered" but that European technology aversion was delaying introduction there of products with nanomaterials.

According to an internet-based October 2010 European consumer organization survey of nanomaterials in consumer products, about 475 products claiming to incorporate nanomaterials are in European commerce. Given the prevalence of unregulated nanomaterials in consumer products, As You Sow, a U.S. nonprofit organization, has <u>published</u> a guide for helping food manufacturers to determine whether ingredients they source include nanomaterials or not.

In contrast to the problematic EC definition of nanomaterials, the "Working Definition" of engineered nanomaterials published by Health Canada does not qualify the scientific basis of the definition with trade-related terms, such as "competitiveness." The definition is accompanied by a list of the kinds of information that Health Canada might require to enable the agency to identify and evaluate a product developer's submitted material as a nanomaterial. The definition, like the European Commission's recommended definition, will be revised in light of ongoing science.

Another impediment to regulation of nanotechnology are inconsistencies in the toxicity testing of nanomaterials that prevent the development of testing standards. One study on the quality of toxicity testing of nanomaterials to be incorporated in food packaging concluded that 15 of 21 animal feeding studies reviewed failed to meet quality control criteria. A comment in December in Nature on the study, commissioned by food manufacturers, said that basic parameters for nano-toxicity, including dosage, particle size, shape and surface chemistry, were not reported in many of the studies reviewed. One of the many difficulties in testing for nano-toxicity is that there are no standards in the production of nanoparticles, so that, e.g., one batch of nano-silver can vary greatly from the next.

Sources: "EU food firms not rushing to use nano: Coca-Cola exec," Food Chemical News, October 14, 2011; Liz Buckley, "Health Canada issues working definition of nanomaterial," Food Chemical News, November 4, 2011.

Suing to regulate nanotechnology as the U.S. House of Representatives usurps regulatory authority

On December 21, IATP joined five other NGOs, headed by the International Center for Technology Assessment (IOTA), to sue the Food and Drug Administration for failure to regulate nano-particles. The lawsuit is the first concerning the health and environmental effects of nanoparticles and nano-technology enabled products. The FDA currently does not require pre-market health and environmental safety testing of nanomaterials prior to their introduction on the marketplace.

A June 9, 2011 White House memo acknowledged that a broad array of products containing sub-molecular sized particles, including those engineered for "disease detection" under FDA authority, are marketed in the United States. IATP's Steve Suppan said that part of the FDA response to the lawsuit must be the testing of engineered nanoparticles "as part of a pre-market safety assessment in a broader regulatory initiative to protect public health."

The decision to sue resulted from FDA's failure to respond substantively and specifically to a May 2006 IOTA et al <u>petition</u> to regulate nano-titanium dioxide in sunscreen and engineered nano-particles in FDA regulated products. Nano-titanium dioxide is mixed in sunscreen to provide enhanced protection against ultraviolate rays and penetrates the skin with little understood public health effects, particularly as a result of chronic exposure. Suppan said that nano-titanium dioxide is also <u>reportedly</u> an ingredient in a coating applied to fruits and vegetables to retard spoilage caused by ultra-violet rays.

The lawsuit was filed in a northern Californian court two weeks after the U.S. House of Representatives had passed "Regulations from the Executive in Need of Scrutiny" (REINS). The legislation, which President Barack Obama's advisors recommended that he veto if it were passed by the Senate, would require Congress to approve any major regulation it judged to have more than US\$100 million economic impact. REINS also would kill a major regulation if Congress did not approve it within 70 days. In early December, the U.S. Chamber of Commerce wrote in support of the legislation as its congressional allies praised the legislation as necessary for job creation.

It perhaps goes without saying that the Chamber opposes <u>"excessive government regulation"</u> of nanotechnology. Under REINS, any nanotechnology regulation would be regarded as "major" and hence subject to Congressional disapproval for broad reasons of placing U.S. companies at a competitive disadvantage, except in cases of public health emergencies. However, as IATP emphasized in its June 2011 report, <u>"Racing Ahead: U.S. Agri-Nanotechnology in the Absence of Regulation,"</u> minimizing research into the environmental, health and safety effects of nanotechnologies, while allowing industry to effectively "self-regulate" nanotechnology, will not enable the "New Industrial Revolution of the 21st Century" that nanotechnology promoters promise.

Source: Originally published on IATP's blog, Think Forward.

Means to an end: Feed them orange peels or more antibiotics?

In the midst of controversies over how livestock diets affect their pathogen load and hence the pathogens in meat after slaughter, comes a simple and promising way to reduce that load. Feed them orange peels.

U.S. Department of Agriculture researchers added the orange peels to the diets of 24 sheep prior to being injected with a Salmonella strain. The orange eaters showed a ten-fold reduction in incidence of Salmonella compared to a control group, according to research published in Foodborne Pathogens and Disease. The research, started in 1999, also includes experiments in how to process the orange rind into dry and more easily shipped pellets without losing the essential oils that combat the pathogens. Expanding the number of animals in a future feeding experiment will cost \$80,000 to \$150,000 per experiment, so don't expect to see an "orange-fed beef" label any time soon.

Sources: Tim Lundeen, "Orange peels cleanse cattle gut," Feedstuffs, November 18, 2011; Amber Healy, "Feeding organizes to livestock might help reduce pathogens," Food Chemical News, December 2, 2011.

Governments continue trend to deregulate genetically modified organisms

The Monitor has written little about genetically modified organisms (GMOs), not because there are no risks in GMOs, but because there is little scientific literature on the risks of GMOs for food safety. A data base <u>released</u> in mid-December on risks in GM varieties authorized for planting by the European Food Safety Authority (EFSA) points to an absence of feeding trials to livestock, part of the absence of premarket safety testing and post-market surveillance of GMOs. On December 7, EFSA released its <u>first guidance document</u> that advises companies how to conduct 90 day feeding trials of GMOs with rodents. The feeding trials are neither mandatory nor part of the EFSA risk assessment process.

An overview of the risk database, compiled by Testbiotech, a German nonprofit organization, stated, "Feeding trials with plants to examine effects on health are not mandatory and there is an almost complete lack of long term investigations" in feeding GMOs to livestock, to say nothing of humans. The rule of thumb seems to be unless there is potential for a GM crop to cause an allergenic reaction, deregulate it, and the faster, the better.

As of November 2011, the ESFA had approved 38 GM crops for food and feed purposes. GM acreage in EU member states is increasingly rapidly, albeit from a small baseline, e.g., 7,834 hectares in Portugal. EU commissioner for health and consumer protection John Dalli called on EU member states to work out territorial agreements to enable the co-existence of GM, conventional and organic crops. The EU group of the International Federation of Organic Agricultural Movements responded, "Organic farmers in regions where GMOs are grown suffer price losses of more than a third of their maize price in cases of GM contamination." The European biotechnology lobby, EuropaBio, counters that only by planting GM crops can Europe increase yields to feed its livestock. Mexico's assistant minister of agriculture cited similar reasoning in assuring the Mexican senators that GM maize varieties would be approved for planting in northern tier states in 2012.

But such debates don't directly bear on retail food for consumers, for which there is no labeling to identify ingredients as genetically modified. In the absence of labeling, consumers who don't wish to consume GMOs use <u>non-GMO buying guides</u>, such as that of the Center for Food Safety, now available as a cell-phone application.

Sources: Stephen Clapp, "APHIS outlines plans to speed up biotech deregulation process," Food Chemical News, December 16, 2011; "EU's Dalli calls for coexistence with biotech crops," Food Chemical News, October 21, 2011; Steven Lewis, "Mexico's pledge to allow GE corn commercialization hits a nerve," Food Chemical News, December 16, 2011.

Resource note: "Food and Drug Administration: Better Coordination Could Enhance Efforts to Address Economic Adulteration and Protect Public Health," U.S. General Accountability Office, October 2011. http://www.gao.gov/assets/590/585861.pdf

The Monitor began in 2008 to analyze reporting on the contamination in China of pet food and of dairy products by melamine, an industrial chemical used to increase protein in diluted dairy products. U.S. imports of the contaminated pet food caused the deaths of thousands of cats and dogs. A contaminated blood thinner, also imported from China, caused allergic reactions leading to illness and some deaths. The public health and economic consequences for importers of these incidents of intentional contamination prompted the Food and Drug Administration to enhance its program on import safety. The United States is increasingly import dependent in both food and active pharmaceutical ingredients.

Members of the U.S. House of Representatives requested the General Accountability Office (GAO) to conduct a performance audit on how FDA programs were performing to reduce incidents of "economically motivated adulteration", as defined by FDA for a May 2009 workshop. The GAO review found that some FDA programs had developed computer programs and toxicology tests to analyze ingredient and product supply chains for such adulteration. Other programs, such as the Center for

Veterinary Medicine (CVM), did not distinguish economically motivated adulteration from inadvertent adulteration, e.g., that which occurs by failing to follow good manufacturing practices. CVM was unaware of initiatives both within and outside of FDA to scrutinize high-risk ingredients that could be added to veterinary drugs or to animal feed to increase economic value. GAO reported that senior FDA managers had recognized in speeches that globalized trade requires FDA to become a globalized agency, both for reasons of economic security and public health. However, FDA program managers had yet to receive senior management guidance about coordinating program work to meet the challenges of economically motivated adulteration in a globalized economy.