



Global Food Safety Monitor

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Introduction: When the past is not yet history

When I began to work at the Institute for Agriculture and Trade Policy in August 1993, one of my first assignments was to translate and summarize articles from a German veterinary journal on a new animal drug, recombinant Bovine Somatotropine (rBST) produced by Monsanto and marketed as Posilac. The drug was more popularly known as recombinant Bovine Growth Hormone (rBGH), used to increase milk production but with a long list of negative side effects listed on the Posilac label. I was new to both the veterinary drug and the process of expanding trade in a product by convincing other governments to approve a standard for, in this case, rBST, at the Codex Alimentarius Commission.

I don't remember much about the translation summary I wrote, but I do remember that the article stated the German veterinary oath prohibited inflicting pain on animals for non-therapeutic purposes. Given the pain caused to dairy cows, as listed in the Posilac label, for the non-therapeutic purpose of increasing milk production, even then I recognized "there's going to be trouble about this drug." And, as noted below, in the story about the Codex fight over a standard for another animal drug, ractopamine, and involving another powerful drug maker, Dow Elanco, there's still trouble.

Food safety, even in a news monitor with a global outlook, shouldn't be reduced to a by-product of international trade objectives. But despite the billions of dollars of cost to human health in the United States alone, to say nothing of the millions of lives lost to foodborne illness in developing countries (much of which goes undetected), food safety for public health objectives is still a budget beggar. People on the front line of foodborne illness detection and prevention have much more cause than this writer to be dismayed at how stingy both food companies and public budgets are in

funding food safety, even as government and industry officials spend a lot more money to pry open new markets with the leverage of Codex standards.

Nevertheless, even nearly 20 years after beginning this work and now looking into the Brave New World of unregulated nanomaterials in food, it is hard to foresee a major change for the better in global food safety history. One man's outlook: ever more use of food standards to pry open markets, while food safety for public health awaits the next big outbreak of foodborne illness, which if reported, might bring a temporary increase of money, regulation and perhaps even enforcement of food safety rules.

Global food safety and its (budgetary) discontents

Government and food industry officials announced the start of the [Global Food Safety Partnership](#) (GFSP) at a side meeting of the Asian-Pacific Economic Cooperation Forum in November. Tellingly, the event was hosted by U.S. Trade Representative Ron Kirk. According to the Grocery Manufacturers Association, [the aim of the program](#) is to build food safety capacity among Asian company exporters in the form of "training modules" that could be applied in other developing countries [\[BL1\]](#). (The World Health Organization continues [to lead food safety capacity building](#) in developing countries to achieve public health, as opposed to trade, objectives. However, per the resource note below, it does so with an inadequate budget and too much dependence on volunteer labor.)

However, at a mid-June meeting hosted by the U.S. Food and Drug Administration to discuss its plan for [international food safety capacity building](#), the gap between the very modest funding for export facility capacity building to supply U.S. markets and the budgetary demands for globalizing food safety was made evident by François Le Gall, a World Bank advisor. Le Gall said that the Bank, which manages the GFSP, had budgeted \$25 million of its global food safety fund's \$42 million for programs in Turkey. To globalize food safety, he said "the scope and scale of what we're talking about is in the billions of dollars," and the time scale for implementation would need to extend beyond the initial GFSP five-year program to decades of sustained commitment to food safety.

For the more than two trillion dollars in global annual sales that the International Council of GMA claims for its more than 300 corporate members, billions of dollars spent over decades hardly seems like too high a price to pay to enable imports from their developing country suppliers. According to a recent academic report based on data from a study published in the Centers for Disease Control and Prevention's [Emerging Infectious Diseases](#), foodborne illness caused by 14 major pathogens cost U.S. residents alone \$33 billion annually, including hospital expenses and estimates of the value of Quality Adjusted Life Years, including for loss of life.

Despite these enormous health costs, the Obama administration's proposed \$220 million in facility registration fees to fund part of the FDA's *Food Safety Modernization Act* (FSMA) was unpopular with the food industry and rejected by the U.S. Congress. According to the [FDA's 2012 Annual Report](#) on food imports and domestic food facilities, the agency regulates \$49 billion of food imports and \$417 billion in domestic food sales.

More popular with the food industry is FSMA's Voluntary Qualified Import Program, which, though fee-based, would expedite imports, without the regulatory "burdens" of port of entry inspection and testing, for companies whose suppliers meet FDA food safety criteria. However, a crucial part of the import program is the accreditation of independent third-party auditors to verify that the suppliers' export facilities comply with FDA criteria. China is the most prominent agricultural exporting country to resist the FSMA requirement for third-party auditing.

Even these modest proposals are languishing in regulatory limbo. Notwithstanding the U.S. congressionally set deadlines for FDA implementation of different parts of FSMA, the Obama administration's Office of Management and Budget (OMB) continues to review the legislation to determine whether its measures are cost effective for the food industry. FSMA, signed by President Obama on January 4, 2011, was [three years in the making](#). Two theories prevail to explain the [delay in implementing the legislation](#): 1) FSMA is so complex that it takes an extraordinary amount of time beyond the 150 day limit to take into account industry and consumer group comments to finalize rules; 2) the Obama administration doesn't want to be characterized as "anti-business" during the election season as the result of any rule, and so will wait until after the elections to let FDA to release the rules.

On August 30, the Center for Food Safety and the Center for Environmental Health, [sued FDA and OMB](#) for "undue delay" in implementing FSMA. The [lawsuit charges](#) that FDA has "missed seven critical deadlines" for rulemaking and that FDA can issue some rules without waiting for OMB cost analysis reporting. It notes "increased reliance on imported foods (e.g. sixty percent of our seafood is imported) with unknown safety standards puts the U.S. food supply at risk."

Sources: Joan Murphy, "Food safety capacity building will cost billions, World Bank official predicts," *Food Chemical News*, June 29, 2012; "14 Pathogens are costly," *Food Chemical News*, July 13, 2012; Murphy, "FDA issues new FSMA fee rates, floats ideas for other industry fees," *Food Chemical News*, August 3, 2012; Stephen Clapp, "China seen balking at FDA requirements for third-party audits," *Food Chemical News*, August 3, 2012.

An exceptional vote of the Codex Alimentarius Commission: the fallout to come

At the July meeting of the Codex Alimentarius Commission in Geneva, a standard to approve the use of ractopamine, a veterinary hormone drug mixed in animal feed to promote livestock muscle growth, was approved by a 69 to 67 member government vote. According to the Codex Chair, Sanjay Dave, "more than 35 countries spoke and another 36 countries wanted to take the floor" before Ghana requested a vote to be taken. This was the third vote on a food safety standard in Codex's nearly 50 year history. All three concerned veterinary drugs used in major meat and dairy exporting countries.

More specifically, the standard established a Maximum Residue Level (MRLs) and Average Daily Intake (ADI) for ractopamine that would be allowed in internationally traded cattle and pig meats for human consumption. The controversies that lead to the vote are at least three-fold.

First, there is the question of whether the 2010 [risk assessment](#) by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) was based on scientific studies that included a sufficient number of human subjects [\[BL2\]](#) monitored for their ADIs of meats with ractopamine residues. (Codex numerical standards are usually based on expert group recommendations.) Furthermore, [three of six studies reviewed](#) were published between 1987 and 1995 by the manufacturer of ractopamine, Eli Lilly (whose animal drug division was subsequently bought by Dow Elanco). Relying on the drug testing data of the standard's industry advocate may pose a conflict of interest conflict of interest for JECFA, if any of its members have had studies funded by Dow Elance or Eli Lilly.

Second, the JECFA recommended MRLs for cattle and pig livers is 4 times as great as for muscle cuts and 9 times as great for kidneys. Therefore, consumers in countries where human consumption of kidneys and livers is greater, such as those of Asia, will have a greater ADI exposure to ractopamine. Codex standards do not take into account national food consumption patterns.

Third, Codex practice is to adopt standards by consensus that there a sufficient quantity and quality of data to agree on a standard. The JECFA risk assessment noted that there is far more data about ractopamine use in pigs than in cattle, so the standard for a cattle ractopamine MRL appears to be an extrapolation in part from pig data. To adopt a standard on the basis of a skewed data field is hardly "science-based."

The U.S. ambassador in Rome worked the phones all night prior to the vote (the decision to vote was adopted by a 68 to 64 vote with four abstentions) to ensure a result favorable to U.S. interests. The U.S. Department Secretary of Agriculture Tom Vilsack called the vote a victory for science-based standard setting, noting that FDA had approved the use of the drug 12 years ago and that the drug was used in 25 other countries. On August 24, the U.S. Food Industry Codex Coalition sent Secretary Vilsack a [letter of thanks](#) for the work of the U.S. government on behalf of their companies.

Dr. Michael Hansen, representing Consumers International at the Commission meeting, [said](#) "Ractopamine is a risky drug to use in livestock. It was originally developed as an asthma drug, and it may cause heart palpitations and other adverse effects in susceptible individuals. The test data on which this new Codex standard is based did not adequately assess possible effects of [ractopamine] residues on people with heart problems."

The U.S. delegation also pushed for approval of a Codex standard for recombinant Bovine Growth Hormone (rBGH), another controversial animal drug, which has remained in the Codex "parking lot" for proposed standards for more than a decade. But since the last international risk assessment of rBGH was from 1999, based on yet earlier data, the Commission decided to refer the matter to the JECFA for review of the peer-reviewed scientific literature on rBGH that has been published during the past 15 years.

Codex standards are presumed to be authoritative for all member governments of the World Trade Organization, even if those governments do not adopt Codex standards in their national regulations.

The standards are often used by trade officials to force open markets to allow their country's food and agricultural exports under threat of trade retaliation authorized as a result of a WTO dispute settlement ruling. The European Union and China ban the use of ractopamine domestically and in imported meat with the drug's residues. The European Commission announced that it would keep its ban on ractopamine in place, and that it would conduct a risk assessment of the drug, [as required by the WTO](#) (Article 5.7), when it had sufficient peer-reviewed data to do so.

Hansen said of the vote, "This is all about forcing open the markets in China and the EU," and speculated that the U.S. would seek to force open those markets through a decision by a WTO dispute settlement panel.

Sources: Stephen Clapp, "New Codex chair shares behind-the-scene details from contentious Rome meeting," *Food Chemical News*, August 24, 2012; Stephen Clapp, "U.S. and EU at loggerheads over Codex adoption of ractopamine MRLs," *Food Chemical News*, July 13, 2012.

Nanomaterials in food: Generally Recognized As Safe?

The Food and Drug Administration's [draft guidance](#) on Engineered Nanoscale Materials (ENMs) in food and food contact surfaces advises industry that it is unlikely to consider ENMs to be Generally Recognized As Safe (GRAS). (ENMs, such as nano titanium dioxide are used in food packaging to extend the shelf life of food. The FDA does not believe that nanofood packaging has entered the U.S. market place.) The draft guidance urges industry to submit data on any use of ENMs in food to the agency for a formal pre-market review. However, guidance documents are voluntary and impose no regulatory obligations on industry. The comments on the guidance have been [posted](#). These comments include [a file of 276 letters](#) generated by an IATP Action Alert on the draft guidance [Note: Due to sensitive personal information, these letters are not available for viewing directly].

IATP, in a July 24 [comment](#) on the draft guidance, agreed with the FDA's position on denying GRAS status to ENMs and urged the agency to retain this position in the final guidance. Our comment cited a General Accountability Office study that noted because industry does not have to report its GRAS self-determinations to FDA, absent pre-market review of ENMs by the agency, consumers could be exposed to ENMs in foods without their knowledge. We further suggested that in view of the few published studies on the effect of ENMs in the gastro-intestinal system and the manufactured identified food products with ENMs, the agency should fund such studies as a scientific basis for assessing whether foods and food contact surfaces with ENMs should be allowed in the marketplace. (IATP has just published a [general factsheet, entitled "Tiny, Scary, Unregulated"](#) on agri-nanotechnology, as well as a related [audio interview with IATP's Steve Suppan](#).)

Consumers Union noted that a study reviewing the use of food-grade nano-titanium dioxide in 89 food products found the highest concentration of ENMs to be in candy, with the result that children under 10 years of age were most exposed. In light of

such science, CU demanded a full pre-market safety assessment of food-grade nano-titanium dioxide. It also urged the FDA not to exempt the use of ENMs in food contact surfaces from an environmental assessment and that such ENMs must be subject to a full additive review by the agency. CU urged FDA to coordinate its analysis of nano-silver with the Environmental Protection Agency, which is beginning to collect data on the use of nano-silver in pesticides.

The Center for Food Safety called on FDA to make all ENM data submitted to agency available for public review on its web site, and to organize public consultation about this guidance documents and subsequent draft regulations. The Center urged the agency to withdraw from the marketplace all products with ENMs that "have not undergone pre-market safety assessments and been shown to be safe for human consumption." It agreed with the agency's position that ENMs will not be regarded as GRAS, and that industry should submit ENM data for FDA pre-market review.

The Nanotechnology Industries Association criticized the FDA proposal on ENMs. NIA wrote "Scientific information may shortly be available, which may be generally recognized by qualified experts to be sufficient to satisfactorily designate GRAS notification." NIA further suggested that the FDA guidance should discuss whether products with ENMs already in the marketplace may not require notification to the agency according to the "significant change in manufacturing process" criteria. The American Chemistry Council criticized the guidance for not being sufficiently clear about what size of ENM would constitute a significant manufacturing change.

The Pew Charitable Trust comment agreed with the draft guidance. Pew has given a grant to the [International Life Sciences Institute](#) to hold a workshop for evaluating ENMs. The date and place of the workshop are not yet on the ISLI web site.

Source: Stephen Clapp, "FDA's plan to exclude nano materials from GRAS status draws mixed reactions," *Food Chemical News*, August 24, 2012.

Resource notes:

"Global Foodborne Infections Network (GFN): Strategic Plan 2011-2015," World Health Organization, 2011.

http://www.who.int/gfn/publications/gfn_strategic_plan_2011-2015.pdf

The GFN begins with a stark reality: "Many countries still lack the necessary surveillance capacity for foodborne disease outbreak detection and response. In addition, many foodborne disease outbreaks go undetected, in part due to lack of communication among the human, veterinary and food sectors." The globalization of the food and livestock trade has left such countries yet more vulnerable to foodborne illnesses. WHO estimates that consumption of contaminated food results in diarrheal diseases kill more than two million people annually.

Since the GFN's inception in 2001, building this surveillance capacity to detect, control and prevent the spread of foodborne disease is its mission. This strategic plan summarizes Strengths/Weaknesses/Opportunities/Threats (SWOT) analyses of laboratory and epidemiology facilities affiliated with the GFN. The GFN comprises a steering committee and laboratories and training centers in 20 regionally dispersed

countries. While the potential for such a wide network is great, it is hampered by lack of adequate and consistent funding, and dependence on volunteer personnel, which lead to lack of follow-up training activities. With additional resources, the GFN [website](#) will expand to make crucial food safety outbreak information available in six languages. The report's annex outlines an ambitious plan for training, surveillance studies and publications in each WHO region.

