



Global Food Safety Monitor

February 2014

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[While we've been away](#)

Since the previous *Monitor* (May 2013), there has been much food safety news to write about, e.g., foodborne illness outbreaks and food product recalls, e.g. a recall of tomatoes due to salmonella contamination. But there has been less policy change than might have been expected. For example, three years after the passage of the U.S. Food Safety Modernization Act (FSMA), FSMA rules have yet to be implemented for lack of an adequate budget to do so. Is it accurate to report on unimplemented legislation as policy change? Members of the World Trade Organization Committee on Trade-related Sanitary and Phytosanitary Measures have queried about FSMA import requirements. But unless and until the legislation is implemented, there is no import safety policy change and no FSMA related cause for trade complaint.

The food industry is opposed to paying for FSMA mandated inspection and registration of both domestic food facilities and the foreign facilities of their import suppliers. The Grocery Manufacturers Association and other industry groups charged again in a February 4 letter to the Food and Drug Administration that a facility inspection fee is really a disguised general tax on the industry. They contend that the FDA should seek funding

in a Congress that already has turned down two FDA proposals to fund FSMA through a fee for inspection services. In sum, there is a persistent contradiction between what the U.S. food industry says it wants in food safety and what it is willing to pay for. In the meantime, the FSMA remains unimplemented, to the detriment of consumers and to the confusion of U.S. trading partners.

The formal launch of the Transatlantic Trade and Investment Partnership (TTIP) negotiations in July certainly has some food safety policy change reporting potential. Industry is advocating numerous food safety related demands in TTIP, some of them summarized in a recent IATP report. However, the U.S. government and the European Commission have decided not to disclose draft negotiating texts except to security cleared industry advisors. So rather than speculate about how TTIP might change food safety law in the absence of negotiating texts, in this issue, we look at what the Commission is already doing to make EU food safety law more trade friendly.

IATP recently released a series of reports on China's move to industrialized meat production and possible impacts on food safety, public health and the environment. The reports look in at China's feed, pork, poultry and dairy sectors, the past and future trajectory of the industry, and global impacts of China's efforts to balance grain self-sufficiency and the desire to provide cheap meat. China's move will have far reaching implications for the global food system. Read [Global Meat Complex: The China Series](#) for the whole story.

If, as the great sociologist Max Weber once wrote, political change is the slow boring of holes into hard wood, how slow could food safety policy change be when there are no institutional tools with which to bore the holes? Africa has just started to discuss the creation of food safety cooperation across borders, targeted to increase trade. Funding for public health related food safety programs for African foods not traded internationally is in short supply. So if trade related food safety measures are the only way to attract funding to build food safety rulemaking and implementation capacity in African countries, then who is the Monitor to complain?

Last but not least, in a resource note, we summarize the very slow movement towards regulation of the very fast growing application of nanotechnology and nanomaterials to food and agriculture. And we plan to see you sooner next time than the interval since the last Monitor.

Other sources: Declan Conroy, "Editor's View: Funding NEMA," *Food Chemical News*, February 7, 2014; Joan Murphy, "HHS documents reveal OMB edits of original FSMA preventive controls proposal," *Food Chemical News*, March 22, 2013; Joan Murphy, "Industry attorneys question reasons for disclosing OMB's changes to food safety rules," *Food Chemical News*, March 29, 2013.

EU Novel Foods regulatory review to "create a positive environment for trade"

It is often said that trade policy changes or threatens to change domestic regulations, including food safety rules. However, just as often, domestic rules are changed in anticipation of trade agreements, which then codify the changes in broad "trade-related" language. This approach to trade oriented policy change appears to be the case with a December 2013 European Commission proposal to revise its 1997 Novel Foods regulation. According to the EU Impact Board assessment, the regulation has been under review since 2002.

The proposed regulation would greatly reduce the ability of European Union member states to vote to reject a novel food, feed or food ingredient that the European Food Safety Authority (EFSA) had evaluated as posing no greater risks than a traditional food counterpart. Furthermore, the EU would introduce a new system to expedite approval for import of foods that are "substantially equivalent to an existing food" consumed in EU member states, provided that EFSA does not object. EU Health and Consumer Protection Commissioner Tonio Borg said that the EU system to expedite approval of "substantially equivalent" food imports "will create a positive environment for trade." Food from cloned animals will be part of the Novel Foods review.

"Substantial equivalence" is likewise an underlying legal doctrine of the U.S. (de)regulatory approach to all novel products, e.g. medical devices, as well as novel foods. For example, genetically modified organisms are substantially equivalent to traditional hybrids, according to the 1986 "Coordinated Framework for Regulation of Biotechnology Products," finalized in 1992 by the Council on Competitiveness. Therefore, U.S. GMOs are not subject to any mandatory regulation beyond what may be required of non-GM food and feed products. The European Commission decision to adopt the

substantial equivalence doctrine for evaluating novel food imports should, indeed, expedite trade in GMOs.

However, the proposed revision of the Novel Foods regulation does not assume that the use of Engineered Nanoscale (atomic to molecular sized) Materials (ENMs) in food and as food ingredients is substantially equivalent to existing foods. EFSA has issued a Scientific Opinion about the use of nano-titanium dioxide in cosmetics, noting that much of the industry data presented was inadequate or irrelevant for a risk assessment. The use of ENMs in food has not been subject to risk assessment. For example, nano-titanium dioxide is used to whiten candy and frosting. ENMs in food and food packaging would have to undergo a regulatory review, including a risk assessment, in order to be approved for commercialization by EU officials.

Likewise, the U.S. Food and Drug Administration draft guidance informed the food industry in 2012 that it should not assume that ENMs in food will be Generally Recognized As Safe (GRAS), and recommended that the industry consult with the FDA about food products it wanted to commercialize with ENMs. According to a report by the General Accountability Office (GAO), industry determinations that a food is GRAS do not have to be reported to the FDA. (However, FDA maintains a GRAS inventory, for companies that wish to receive FDA "no questions" letters or regulatory advice from the agency about their GRAS determinations.) GAO worried that a nano-form of a GRAS food or food ingredient might bypass regulation under "substantial equivalence."

U.S. exporters could present GRAS determinations for the EU's "substantial equivalence" import review. Non-government organizations and the GAO have criticized the entire GRAS program and individual GRAS determinations have been litigated. Neither the EU nor the U.S. have specific mandatory rules about the application of nanotechnology to food and agriculture products and inputs.

If approved by EU institutions, following the May 22-25 European Parliament elections, the revised Novel Food Regulation will be applicable to genetically modified ingredients in foods. The EU policy on genetically modified crops has been under evaluation since 2009, with one of the criterion being "the need to provide more flexibility on cultivating GMO crops."

In a development not directly related to the Novel Foods revision, the thirteen year struggle by the U.S. government and agricultural biotechnology companies to approve genetically engineered corn in the EU may soon succeed. EU member states opposing

that approval failed to secure a weighted voting majority against approval in early February. DuPont Pioneer, which developed the insect resistant corn variety with Dow Chemical, said that the EU now has the “legal obligation to itself, to its farmers and scientists and to its trade partners” to approve the corn variety for cultivation throughout the EU. EU Health and Consumer Protection Commissioner Borg is seeking agreement on a rule that would allow EU member states opposed to growing the approved variety to not cultivate the crop on their territory.

Other sources: “Centralized EU authorization proposed for novel foods,” *Food Chemical News*, January 3, 2014; Stephen Castle, “Modified Corn A Step Closer To Approval in Europe,” *The New York Times*, February 12, 2014; Amber Healy, “Extensive comments could buy industry time if FDA removes GRAS status from PHOs,” *Food Chemical News*, November 29, 2013.

TTIP: make pesticide residue levels compatible for transatlantic human consumption?

A new European Union maximum residue level (MRL) for a pesticide used to keep apples fresh during storage, could become another “trade irritant” to be made less irritating as a result of the Transatlantic Trade and Investment Partnership (TTIP) negotiations. MRLs quantify upper thresholds of toxins that may be consumed without harm to human health, according to toxicological risk assessment.

The new EU MRL of diphenylamine (DPA), set to go into effect on March 2, is .01 milligrams per kilogram or 0.1 parts per million (ppm), when applied to post-harvest apples. In October, nine U.S. Senators wrote to U.S. Trade Representative Michael Froman to urge him to use the TTIP negotiations to remove “unscientific trade barriers,” citing the new DPA MRL for apples as an example of such a barrier. They charged that the new EU MRL will block all apple and pear exports to Europe.

U.S. apple exporters demand that EU member states accept import of apples with an MRL of 10 ppm, which is the standard of the U.S. and the Codex Alimentarius Commission. Codex standards are presumed to be authoritative by the World Trade

Organization and binding on WTO members, unless they can provide a risk assessment that justifies use of a more stringent standard.

The Codex DPA MRL for post-harvest apples was agreed in 2003, after a nearly 35 year debate among Codex members and experts at the Joint FAO/WHO Meeting on Pesticide Residues (JMPR). In 2011, the European Food Safety Authority found the JMPR risk assessment for DPA to be incomplete, but it did not recommend the default MRL of 0.1 ppm to protect human health in case of incomplete data, since DPA was no longer authorized for use in EU member states.

Just 0.1 ppm, the Codex MRL for DPA in milk, is the threshold value for what is toxicologically detectable. The lower DPA threshold for milk is due in part to assumptions made about average human exposure to DPA, including the average amount of daily consumption of DPA in a given commodity, the amount of time the toxin remains in the body before excretion, and the bio-persistence of the toxin.

With the U.S. allowing 100 times more DPA on post-harvest apples than the new EU MRL, it is difficult to imagine how a proposed TTIP food safety consultative committee would bridge the gap, unless the EU changes policy to agree that the JMPR risk assessment of DPA for apples in 2002 is adequate to protect human health. The likelihood of another JMPR review of DPA and like pesticides seems unlikely in the near term. As Codex Chair Sanjay Dave told delegates at the 50th meeting of the Commission in July, "the funding situation for scientific advice [for Codex standards] is difficult."

Other sources: David Thomas, "New EU Regulation Instituting Pesticide Limit Could Hit U.S. Apple Exports," *Inside U.S. Trade*, February 6, 2014; "Senators Call on Froman to Tackle Barriers to EU Apple, Pear Exports," *Inside U.S. Trade*, November 7, 2013.

[Private and public sector food safety work in Africa](#)

The latest (2007) food safety strategy paper for Africa published by the World Health Organization summarized a grim situation of widespread foodborne illness, but little financing or political will to implement diagnostic and preventive food safety programs. It appears that some African governments are turning to the private sector for food safety expertise and funding for trade related food safety measures.

The Global Food Safety Initiative (GFSI), a transnational agribusiness food safety project that supports private certification of public food safety standards implementation, met in September 2013 in Johannesburg, South Africa. GFSI aimed to advance in Africa its objective of "Once certified, accepted everywhere" in the international food trade. More than 250 participants from 17 African countries discussed the need to set and implement food safety standards to meet United Nations public health and food security Millennium Development Goals. According to one speaker, more than 2,000 Africans die a day due to food safety related problems.

In November, South Africa hosted two Food Safety System Certification (FSSC) training sessions for food industry employees. The certification is GFSI recognized, so food products from FSSC approved production and warehouse facilities can be traded internationally.

At the Codex Alimentarius Commission meeting in July, a representative from of the Codex Committee for Africa reported on several public sector initiatives on food safety. For example, World Health Organization activities in several African countries are integrating food safety and nutrition indicators into programs for infectious disease surveillance and response. An observer from the African Union reported on public sector activities to create an African Food Safety Authority and a Rapid Alert System for Food and Feed. The AFSA would be a risk assessment body, while the rapid alert system would enable communication to prevent the spread of foodborne disease illnesses and help facilitate the recall of contaminated food.

Resource notes

"State of the art on the activities and initiatives relevant to risk assessment and risk management of nanotechnologies in the food and agriculture sectors," United Nations Food and Agriculture Organization (FAO) and World Health Organization (FAO) Technical Report, September 2013; and "Nanomanufacturing: Emergence and Implications for U.S. Competitiveness, Environment and Human Health," U.S. General Accountability Office, February 7, 2014. GAO 14-181SP.

Agri-nanotechnology is embedded in a much broader technology and investment platform. This is important to recall when trying to comprehend the disparity between investment in product development and research and investment on the environmental health and safety (EHS) impacts of nanotechnology products and production processes.

For example, the \$18 million budget for U.S. Department of Agriculture 2014 budget for research for agri-nanotechnology product development contrasts with a near dearth of basic research into the effect of Engineered Nanoscale Materials (ENMs), such as nano-titanium dioxide in processed foods, on the gastro-intestinal system.

The General Accountability Office (GAO) report on nano-manufacturing, produced at the request of members of the U.S. Congress, is largely dedicated to proposals for maintaining the U.S. competitive edge over other countries in nanotechnology product development. But the report also has a short chapter on dealing with EHS impediments to reaching the competitive advantage.

GAO held a July 2013 forum that was the basis for this report. Forum participants describe "nano-manufacturing as a future mega-trend that will potentially match or surpass the digital revolution's effect on society and economy." Despite such high expectations for nano-manufacturing, whose global market value was estimated at about \$300 billion in 2010, the report notes "we have little information on the number of workers exposed to nanomaterials in the workplace, the extent of the release or transport of nanomaterials in the environment, or the effects on human health of such exposure. It is difficult to assess the risk of nanomaterials because they are too varied to permit generalizations about how they behave" (p. 7).

Most of this report concerns public investment strategy and public-private partnerships to increase U.S. competitive edge in product development and marketing. Foreign purchase of U.S. nanotechnology start-up companies and theft of intellectual property are outlined as problems for U.S. competitiveness. Agri-nanotechnology is not a signature initiative reviewed in this report, but some of the policy and investment strategies, as well as EHS issues, nevertheless apply to food and agriculture.

Some of the participants in the GAO forum stated the off-expressed fear that regulation to mitigate EHS risks would inhibit product innovation and competitiveness. Others said that without more nano-manufacturer cooperation, EHS risk would be difficult to identify, and risk oriented research would not be incorporated into "safe by design" products. One of report's four conclusions was that unless U.S. lead international standards for manufacturing were agreed, it would be difficult to maintain U.S. competitive edge in nanotechnology. A second conclusion was that a "lack of data on the long-term or chronic EHS impacts of new nanomaterials, makes it difficult to predict and manage relevant risks—and difficult to help the public distinguish between real and perceived risks" (p. 67).

The FAO/WHO nanotechnology report is based on keyword searches of the websites of its government members, international institutions and non-governmental organizations, supplemented by FAO and WHO staff work that included patent data base research and a review of scientific literature. As a result, private sector investment and product development in agri-nanotechnology, preponderant in many FAO/WHO countries, is not reported in any detail. The report is a follow-up to the 2009 report of the first FAO/WHO expert meeting on the use of nanotechnology in food and agriculture. The report references two NGO internet researched inventories of products whose manufacturers claim to incorporate ENMs.

Despite the report's methodological limitations, it does provide cautiously worded insight into the food safety challenges resulting from applications of nanotechnology manufacturing techniques to food processing. Furthermore, the report suggests that the physical and chemical properties and bio-persistence of ENMs "may go to a certain extent beyond the traditional borders" of food safety. But the report maintains that even in the absence of nano-specific legislation and regulation, consumers are protected by the application of current legislation and regulation to foods and food-related products, such as food packaging, that incorporate ENMs.

The very brief country reports show that, as in 2012, the governments' approach to nanotechnology is, for the most part, one of voluntary consultation about products with ENMs under development. For example, "Health Canada encourages stakeholders to communicate with the relevant regulatory authority early in the development process, especially for combination products that are, contain or make use of nanomaterials."

The paragraphs on the EU activities are the most detailed reported in terms of concrete steps towards regulation. The European Commission has recommended a definition of "nanomaterial" to be used in legislation and regulation. Beginning on December 13, 2014, any foods with ENMs will be required to include a list of ingredients followed by "(nano)" after each nanoscale ingredient. Food additives evaluated as safe in their macro- form will be re-evaluated for safety if they are used at the nano-scale. The European Food Safety Authority has issued guidance to industry on risk assessment of ENMs, while acknowledging that the current risk assessment paradigm is of limited utility for ENMs because of many uncertainties arising from a lack of nano-appropriate and valid testing methods. EFSA has thus far published four scientific opinions on ENMs used in food packaging, concluding that data about the ENMs was insufficient or inconclusive for a risk assessment. NanoLyse, a EU-Canadian agri-nanotechnology research consortium finds

there is “very limited knowledge on the potential impact of engineered nanomaterials on consumers’ health.”

The theme of “very limited knowledge” concerning consumer health impacts does not, however, dampen the expectations of governments for nanotechnology, e.g. “Nanotechnology has been identified by the National Innovation Council in 2009 as an essential element to meet the objective of turning Malaysia into a high-income developed nation by 2020.”

Given the high expectations of governments for and public investments in nanotechnology, the very slow movement towards regulation is disconcerting, to say the least. U.S. Food and Drug Administration private communication with FAO/WHO reveals, “the FDA does not maintain a list of nanomaterials that it has assessed.” While it may be comforting to know that FDA has apparently done risk assessment of some ENMs used or potentially for use in FDA regulated food and food ingredient products, it is disturbing that FDA has not published a list of the results of these assessments, a step towards regulating the use of ENMs in food, feed and food ingredients.



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