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Introduction: "based on science:" the search for a god in the trade policy machine

If trade policy were a Greek tragedy, surely one of its <u>deus ex machina</u> would be food safety standards "based in science." Many trade disputes, e.g. over agricultural export dumping, go unresolved. But "based on science" as a *deus ex machina*, is a plot device that is expected to resolve trade conflicts, such as that between food production methods, however unsavory, and consumers' right to know what is in their food, however "irrational" from the viewpoint of those food companies for whom "based on science" is a mantra whose very utterance should vanguish every foe.

In this issue of the Monitor, familiar "trade-related" food safety issues reappear, now reframed in new trade negotiations whose proponents wish to vanquish the troublesome non-tariff barriers that have reduced their exports. Less familiar issues, like the production line speeds that cause the contamination that require the technological solutions "based on science,"

play a minor role, if any, in trade disputes, because there are no binding protections for food workers in trade policy.

Trade policy, even in trade dispute briefs, is often inchoate relative to the underlying cause of the dispute. There is no Greek chorus to tell the food safety audience that the latest technological fix to the food production and trade problem may not produce the "safest and most affordable food in the world." This issue of the Monitor summarizes some of the debates about "based on science" from relatively simple technological fixes, such as a chlorine and peracetic acid-based poultry rinse to the complexities of protection of food by plastic film impregnated with nanomaterials.

Do you want a U.S. food safety standard with that chicken?

To export agricultural goods, the U.S. also exports food safety standards, or at least gets other countries to accept our way of growing raw materials and processing them into food as justified by standards "based on science." The U.S. Department of Agriculture and the U.S. Trade Representative will soon see if the member governments of the Trans Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP) negotiations, launched by the Obama administration, will accept the way U.S. chicken processors butcher the bird. A National Chicken Council press release welcomed the launch of the TTIP negotiations: "When TTIP negotiations are successfully concluded, U.S. poultry producers look forward to marketing \$500 million of products to the EU on an annual basis."

The death of a U.S. federal poultry inspector, reported on April 25 in the Washington Post, shone a bright light on the high speed processed, chlorine rinsed chicken that the U.S. wants to export not just to the EU, but globally. The inspector, 37 year old José Navarro, worked for five years in the midst of a chemical spray that the USDA allows processors to use to decontaminate the feces on chickens that results from ever faster processing line speeds. Navarro's lungs bled out. The U.S. Occupational Health and Safety Commission (OSHA) has not determined the cause of Navarro's bleeding to death. An OSHA spokesperson said the agency was so understaffed, it would take 131 years to inspect every facility under its authority for worker safety violations.

Both the USDA and the National Chicken Council (NCC) defended the use of the poultry rinse, pointing out that the Food and Drug Administration had accepted the poultry industry's claim that the rinse was Generally Recognized As Safe (GRAS). GRAS is only a food safety designation, not a worker safety rule. Stan Painter, the president of the federal meat and poultry inspectors union, said his poultry inspectors reported weekly about coughing, sneezing, tight throats and itchy eyes that clear up only on the weekends when they are not working. However, "based on science" standards only protect traded goods, not the workers who produce them.

An NCC press release repudiated the Post's conclusion that the faster line speeds, up to 175 carcasses per minute, which the NCC has petitioned for in a new USDA rule, would mean more use of the rinse. The new rule would expand the use the HACCP (Hazard Analysis Critical Control Point) Inspection Models Project (HIMP), in which only food processing plant employees physical inspect the poultry, while federal inspectors inspect the plant's HACCP paperwork. Former USDA undersecretary Richard Raymond points to Research Triangle Institute studies of poultry plant data that ascribe reduction in fecal contamination of chicken to HIMP. Dr. Raymond charges that the only reason that HIMP has not been adopted in all U.S. poultry plants is the loss of federal poultry inspector jobs.

Food and Water Watch's Tony Corbo responded to Dr. Raymond that "HIMP does not work" to improve food safety and that the Public Health Information System developed under Dr. Raymond's supervision is an \$82 million "boondoggle." Corbo said that to reduce pathogens in meat and poultry, the Food Safety Inspection Service "needs regulatory authority to enforce its pathogen reduction standards," rather than turning over inspection to the meat and poultry industry. USDA undersecretary for food safety Elizabeth Hagen has indicated that USDA may expand HIMP to pork and beef processing.

In May, the USDA's Office of the Inspector General reported the results of its audit of 30 hog slaughtering facilities, including five that were in a HIMP pilot project. The headline conclusion: "The Food Safety Inspection Service's (FSIS) enforcement policies do not deter swine slaughter plants from becoming repeat violators of the Federal Meat Inspection Act (FMIA). As a result, plants have repeatedly violated the same regulations with little or no consequence." (For more on this report, see the resource note below.)

As the Monitor reported in 2009, the U.S. initiated a World Trade Organization dispute against the European Union, which refused to allow the poultry imports sprayed with a chlorine rinse that enabled production line speeds of up to 140 carcasses per minute. The dispute has not advanced, as there is no agreement on a Codex Alimentarius standard on the safety of the rinse components, including peracetic acid, an ingredient in the spray used in the plant in which Navarro worked. The WTO assumes that Codex standards

are authoritative for the purpose of enabling international trade, even if the standards are not implemented in WTO member country legislation.

In 2008, the Monitor reported that the NCC preferred to resolve the poultry rinse trade dispute through negotiations in the Transatlantic Economic Council, rather than through the WTO. It seems likely that the U.S. will try to cut a TTIP deal to export U.S. chicken to Europe, rather than go through a WTO trade dispute, which will require establishing a Codex standard for a poultry rinse ingredient associated with federal poultry inspector health problems and now a death.

(For a mini-history of the post-World War II poultry industry see, IATP's "How the Chicken of Tomorrow Became the Chicken of the World." Former IATP Board member and USDA official Rod Leonard was a co-plaintiff in a lawsuit that resulted in a U.S. appeals court in 2001 declaring that HIMP violated the U.S. Meat and Poultry Inspection Act. The appeals court instructed the USDA to change the implementation of HIMP to comply with the law.)

Sources: Amber Healy, "Inspector's death blamed on anti-microbial spray: might be tip of the iceberg," *Food Chemical News*, May 3, 2013; Amber Healy, "Hagen hints at expanding HIMP to pork and beef processing," *Food Chemical News*, May 3, 2013; Richard Raymond, "HIMP will enhance food safety," *Feedstuffs*, May 6, 2013.

Industry claims technical and sanitary barriers to trade "not based on science"

Agribusiness and food processing groups, anxious to increase export and import sales, are proposing various ways to circumvent what they and the Office of the U.S. Trade Representative (USTR) characterize as barriers to trade "not based on science." For example, the acting Trade Representative, Ambassador Demetrios Marantis, presenting the USTR's 2013 Report on Sanitary and Phytosanitary Measures in early April, stated, "there is a disturbingly common failure by some U.S. trading partners to base their SPS measures on science."

Industry and USTR proposals for in the Trans Pacific Partnership (TPP) and the Transatlantic Trade and Investment Partnership (TTIP) negotiations give some insight into their ideas for "going beyond" the World Trade Organization SPS agreement and the standards setting process of the Codex Alimentarius Commission. An industry groups' letter in March to the USTR recommended the TPP as an "excellent model" for the TTIP negotiations set to begin June

17–18. The letter accuses European Union member states of "unjustifiable restrictions on production methods," "costly and ever changing political and regulatory barriers to agricultural biotechnology" exports and "arbitrary sustainability requirements on the production of feedstocks" for biofuels.

What is so "excellent" about the TTP negotiations on SPS issues that the industry wishes to apply it to the TTIP negotiations? One industry proposal that the USTR has floated, without tabling a formal text, is for a TPP Rapid Response Mechanism to decide SPS disputes in a matter of weeks, rather than the years normally required for the resolution of a formal WTO trade dispute settlement. Furthermore, a Canadian TPP proposal would require all TPP members to accept provisional standards for pesticide Maximum Residue Levels, even in the absence of agreed Codex MRLs.

Provisional pesticide MRLs are established by the U.S. Environmental Protection Agency without full risk assessments of pesticides. Provisional permits to sell pesticides can last for years, so if Codex members could not agree on a pesticide MRL of interest to industry, the TPP standard could be binding for TPP members for an indefinite future. The Canadian proposal would require that provisional standards must be set by TPP members with "robust" regulatory regimes. If the Canadian proposal becomes part of the TPP SPS chapter, it is likely that provisional SPS standards set by the United States, Canada, Australia, New Zealand and Japan would become binding on other TPP members.

Despite 20 years of USTR and agribusiness criticism of EU agricultural biotechnology rules, the U.S. and EU biotech industry are seeking to minimize the breadth of disagreement with the EU on SPS issues in the TTIP negotiations. Rather than challenge EU biotech laws directly, the U.S. will seek to accelerate EU member country adoption of European Food Safety Authority (ESFA) risk assessments based on a review of industry provided biotech test data. EFSA has determined thus far that event GMO "events" in crops pose no greater risks than the risks of their "conventional counterparts."

However, even this tactic seems headed for controversy because of the U.S. and EU government difference in understanding what "based on science" means. For example, when EFSA posted on its web site studies in support of the application to commercialize Monsanto's NK603 transgenic corn, Monsanto requested that EFSA take down the studies from the web site. Monsanto denied rumors that it had threatened to sue EFSA if the studies "based on science" remain available for public review.

EFSA is apparently unaware that data to support U.S. biotech commercialization is neither fully scientific nor available for public review.

Under U.S. regulations, biotech companies are not required to submit studies to demonstrate the safety of their products. The companies voluntarily submit only summaries of data vetted by company risk managers and without the methodological explanations of the studies that permit the peer review that is characteristic of scientific method. EFSA's posting of the Monsanto submissions in support of the NK603 "event" violated the Confidential Business Information provision of U.S. law used universally in biotech company commercialization applications. Monsanto is seeking an "amicable solution" with EFSA.

Sources: Joan Murphy, "New report lists top SPS barriers to trade for U.S. exporters," *Food Chemical News*, April 5, 2013; Stephen Clapp, "U.S. ag groups question EU's commitment to dealing with SPS issues in trade talks," *Food Chemical News*, March 15, 2013; U.S. Floats 'Consultative Mechanism' for SPS Disputes in TPP Agreement," *Inside U.S. Trade*, March 6, 2013; "Canadian Grain Growers Seek Potential Harmonization of MRLs in TPP," *Inside U.S. Trade*, March 9, 2013; "Monsanto denies threatening to sue EFSA over biotech corn data," Food Chemical News, April 5, 2013;

Not "based in science": the Office of Management and Budget rewrites U.S. food safety rules

A Food Chemical News reporter searching the U.S. Department of Health and Human Services website in March inadvertently discovered a "stunning set of documents." The documents show the extensive deletions and additions by the presidential Office of Management and Budget (OMB) to Food and Drug Administration rules in proposed 2011 to implement the "Food Safety Modernization Act" (FSMA). HHS also published the original FDA draft rules prior to the OMB edits. The documents include a memo from a HHS regulations policy staffer that justifies the release of the OMB edited documents on the grounds of a 1993 presidential Executive Order. Because foreign readers of the *Monitor* may not understand the role of the powerful but non-scientific OMB in delaying and/or weakening food safety rules "based in science," a brief review is in order.

Some of the hundreds of OMB edits to documents to rules on preventive food safety controls are proofreading and "editorial" in the strict sense of the word. However, substantive deletions include those to FDA proposed requirements for food companies to do environmental and finished product testing, to verify the safety of their suppliers' raw materials, and to register and respond to

consumer complaints about their products. The executive summary to the rules on preventive controls is now largely the work of the OMB.

OMB does not explain reasons for specific edits and deletions. However, David Plunkett, a food safety attorney at the Center for Science in the Public Interest, said in general of the OMB edits, "It's OMB once again protecting corporate bottom lines at the expense of protection for public health. Testing is critical to verification. I don't think a preventive food safety system can be effective without it. Unfortunately, OMB bean counting of the wrong costs results in a less effective prevention program and ultimately continuing food safety problems." The "bean counting" refers to OMB cost-benefit analysis, which usually claims to show that proposed rules to protect the environment, public health and worker safety, are "too burdensome" to the regulated industry.

Another set of documents that FCN discovered shows OMB edits to produce safety regulations, one of the core issues of the FSMA. The FDA recently granted the produce industry an extension of the deadline to comment on the produce safety rule. The Monitor has reported on numerous cases of produce contaminated by pathogens of animal origin, often the result of growing the crops in fields fertilized with non-composted manure and/or irrigated with contaminated water. As a result of the extension, it is unlikely that the FDA will issue a final produce safety rule to implement the 2011 FSMA before 2014.

Food industry attorneys criticized the HHS for publishing the before and after OMB food safety rules. They suggested that publishing the original FDA draft rules might be part of a legal strategy to pre-empt or weaken a possible industry lawsuit to prevent implementation of parts of the FSMA. One attorney said that there was no clear proof that finished product testing verified the efficacy of preventive controls. The senior vice president for food safety and technology at the United Fresh Produce Association said that he had anticipated more OMB changes to the draft rule. He said that produce processing facilities changed suppliers in response to harvest conditions, so the FDA requirement to provide an approved supplier list would be a "hardship" on the industry.

The Office of Information on Regulatory Affairs (OIRA) in OMB is under no legal obligation to explain why it has held 24 of 149 major rules since 2011, thus thwarting the will of Congress and the authority of federal agencies to issue rules to implement legislation. The HHS release of OMB edits to the draft rule shows that at least one federal agency is tired of waiting for OMB to do its job.

Sources: 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.

A new avian influenza strain and the WHO budget for food safety and preparation for pandemic diseases

As of May 2, the World Health Organization has reported 128 cases, with 26 deaths in China caused by a new strain of avian influenza A(H7N9). Most of the infected patients have been severely ill. Thus far no human transmissions have been reported. WHO has not advised restrictions on travel or trade as a result of the outbreak. Influenza viruses in well-cooked poultry or pork (no pink parts) do not survive.

WHO has published a fact sheet on the A(H7N9) and its relation to other avian influenzas. At this point, it is not known how people have become infected, but WHO investigators are visiting live bird markets to determine possible causes of infection. Hand-washing and respiratory hygiene are recommended for those who handle live poultry and other birds. There is no vaccine for the virus and it is not known if anti-viral drugs will be effective in combating the A(H7N9).

WHO member governments at the May 20-26 World Health Assembly will be asked to approve a proposed 2014-15 budget of about \$4 billion, about \$69 million of which will be dedicated to epidemic and potentially pandemic (human to human transmission) diseases, such as A(H7N9) (page 93). According to the proposed budget, since 2009, just 10 of 194 WHO member governments have developed or updated plans of "national resilience and preparedness for pandemic influenza and epidemic or emerging diseases" (page 83). A report on WHO member country preparation for pandemics gives further detail. The WHO secretariat believes that 116 of the member governments have "adequate mechanisms in place for preventing or mitigating the risks to food safety" (page 87). Ninety-seven members have a "mechanism for multi-sectoral collaboration on foodborne public health risks."

About \$3 billion of the WHO's 2014-2015 budget comes from voluntary contributions of multilateral and bilateral donors, with the remaining \$1 billion coming from member government dues, assessed on a sliding scale. The WHO food safety budget for that period is about \$32 million, \$19 million of

which is dedicated to the food safety program at the WHO headquarters in Geneva.

Resource notes:

"Food Safety Inspection Service: Inspection and Enforcement Activities at Swine Slaughter Plants," Office of the Inspector General, U.S. Department of Agriculture, Audit Report 24601-0001-41, May 2013. http://www.usda.gov/oig/webdocs/24601-0001-41.pdf

Despite a beautiful cover with photos of free range chickens, fresh vegetables and a schoolgirl with a presumably USDA subsidized lunch, this report makes for grim reading. Precisely because, as noted above, the USDA hopes to expand its largely privatized HIMP inspection plan from poultry to hogs, and because it plans to export HIMP inspected meat, this report should be of interest to foreign, as well as U.S. readers. Although USDA is not required to implement the recommendations of the Office of the Inspector General (OIG), the OIG's independence from the industries the Food Safety Inspection Service regulates give the OIG's conclusions and recommendations an authority that the FSIS cannot ignore.

For example, how does FSIS respond to this conclusion?: "We could not determine whether the goals of a pilot program – Hazard Analysis Critical Control Point (HAACP)- based Inspections Model Project were met because FSIS did not adequately oversee the program. In the 15 years since the program's inception, the FSIS did not critically assess whether the news inspection process had improved food safety at each HIMP plant, a critical goal of the program." The response: "FSIS will complete an evaluation of HIMP hog market establishments . . . and determine if a permanent program is warranted by March 31, 2014."

There are more gory details of inhumane treatment of hogs and bureaucratic non-response than can be summarized here. But the bottom line is that after 15 years of HIMP, federal meat and poultry inspector protection of their jobs has not been the greatest impediment to successful implementation of the HIMP.

"Na-no or nan-yes for nanotechnology in packaging?" a special edition of www.foodproductiondaily.com, April 26, 2013:

Reporters from foodproductiondaily.com have reviewed a suite of articles that focus on the food safety and food packaging applications of nanomaterials, atomic to sub-molecular sized materials whose researchers are receiving

both public and private investments. One of the studies reviewed, part of a four year European Commission project, is an attempt to provide the basis for consensus for a common methodology for evaluating the degree of toxicity and exposure posed by nano-materials. Without such a consensus, it is difficult to debate the safety of the application of nanomaterials and nanotechnologies in food and agriculture.

Another article summarized a March 26 presentation to members of the European Parliament. The presenter, a food safety official from the German province of Bavaria, said that there was no evidence that nanomaterials, such as nano titanium dioxide (TiO2), migrate from food packaging to the packaged food. Nano-TiO2 retards the spoilage of wrapped meat and vegetables by blocking ultra-violate rays while still allowing the consumer to see the wrapped product. However, a review of the use of nano-silver as an anti-microbial in packaging material did find migration that increased with the time that the wrapped food was stored. While the researchers found that the amount of migrated silver was below that of other silver migrations to food, there were too many unknowns for the research to determine whether nano-silver in food packaging presented a risk to human health.

Finally, the foodproductiondaily.com reporters reviewed, "Slipping Through The Cracks" an issue brief on nanomaerials in food by the corporate social responsibility NGO, As You Sow. The report sought to determine whether food processing companies knew if their ingredient suppliers used nanomaterials by surveying the companies and doing some product testing. Just 26 of 2,500 companies responded to an initial survey, plus 38 to a later Facebook based survey. As You Sow also reported that nanoparticles in the 10 nanometer range were detected in Dunkin' Donuts, doughnuts. The NGO is crowd-sourcing funds to test more commercial food products for the presence of nanomaterials.