



Global Food Safety Monitor

December 2014

A note to the reader:

Readers of this too-occasionally published Monitor may recall that it has attempted to cover food safety as both a public health and trade policy related issue. Due in part to the editor's non-food safety responsibilities, the Monitor has struggled to publish frequently enough to guide our readers through the often complex interface of trade-related food safety news. In an effort to make the Monitor a more timely publication relative to food safety policy developments and to target a few overlooked issues, the Institute for Agriculture and Trade Policy has decided to shorten the Monitor's content and increase the frequency of its appearance. We hope that you will find this new phase of the Monitor to be a useful and stimulating source of analysis for your own work in food safety and food policy.

Given all the controversy about the proposals for "WTO plus" trade agreements to remove "unnecessary" non-tariff trade barriers^[1], this new phase of the Monitor begins with an article that reviews some of the basic concepts of trade-related food safety policy.

– Steve Suppan, Editor

Back to basics: On the role of science and cost-benefit analysis in trade policy and food safety

This editor began to work more than 20 years ago on trade-related food safety and animal and plant health issues, or Sanitary and Phytosanitary (SPS) issues in trade policy jargon. During that time, U.S. officials and agribusinesses have repeated a constant refrain that U.S. SPS policy and practice is "science-based" and that "science" and nothing but "science" decides what food is safe to eat and therefore mud by importing countries. For example, U.S. Trade Representative Michael Froman recently stated, "we do feel like the decision as to what is safe

should be made by science."^[2] However, "science" is not the sole or even final arbiter of which SPS rules do not violate trade agreements.

Trade policy negotiators have assigned to "science," or rather "science-based" risk assessment, the role of providing authoritative evidence to settle agricultural and food trade disputes. However, risk assessment is not science, but an expert consensus about scientific studies, some of them authored by scientists working for or financed by the corporations who are lobbying for a standard that will enable international trade of their product. (Conflict of interest rules are not enforceable in trade policy.) For example, the Food and Agriculture Organization/World Health Organization expert group that provided a risk assessment for the very controversial Codex Alimentarius Commission standard for ractopamine, an animal veterinary drug, reviewed just six, 15 to 20 year old studies, three of which were authored by drug manufacturer scientists.^[3]

Parties to the World Trade Organization Application of Sanitary and Phytosanitary Measures (SPS agreement) are urged to participate in the international standards setting bodies, such as the Codex Alimentarius Commission. The standards of Codex and other WTO recognized bodies are presumed to be authoritative for WTO members, with an important caveat discussed below. But in general WTO members are obliged to accept that the SPS regulations, implementation measures and enforcement practices of an exporting Party provide the "appropriate level of sanitary or phytosanitary protection" (Article 4) for consumers, and animal and plant health in the importing country.

However, WTO members may maintain a standard that does not conform to an international standard, such as the European Union ban on ractopamine, if the EU continues to review new information towards conducting a "more objective risk assessment" to determine whether their non-WTO conforming SPS measures are "least trade restrictive" while providing that "appropriate level" (Article 5.7). Importing countries must provide risk assessments to show to other WTO members that their non-conforming SPS measures still are justified by "science" and are not "disguised" trade barriers. In the WTO, the burden of proof is presumptively on governments to show why a product should not be traded internationally.

How is scientific evidence used in practice to justify the "appropriate level" of protection that is then harmonized among WTO members according to the terms of SPS "equivalence"? Scientific evidence is used by food safety managers to determine risks to health. However, in the SPS agreement, determining whether SPS measures provide "appropriate levels" of

protection also involves analysis in terms of several other criteria, including “the relative cost-effectiveness of alternative approaches to limiting risks” (Article 5.3).

Scientific evidence does not suffice to justify an SPS measure. Governments must also demonstrate that their approaches to “determining the appropriate level of sanitary or phytosanitary protection, take into account the objective of minimizing trade negative effects” (Article 5.4) Determining the “cost-effectiveness” of an SPS measure, hardly a science, is given a high evidentiary standing in the determination of “alternative approaches” to providing the “appropriate level” of protection. How does this determination work in practice?

In the U.S., the Office of Management and Budget (OMB), a presidential office with no statutory obligation to protect public health or the environment, amends “based in science” regulations according to cost-benefit analysis. We know this because the Food and Drug Administration (FDA), which has statutory obligations to protect public health, has published OMB text changes comments, deletions and additions to FDA rules to implement the Food Safety Modernization Act.^[4] Many edits amount to copy reading, but others comprise major additions or deletions to the FDA proposed rules.

For example, OMB prefaces FDA three proposed options for preventative food safety regulation for “very small businesses” with this red lettered text change: “We are unable to estimate the benefits of the proposed rule. Instead we show the Breakeven Illness Percentage for each of the three options for the proposed rule. This is calculated by dividing the number of illnesses that would have to be prevented annually under each option by the total estimated number of illnesses attributable to FDA regulated food products under the scope of each option of the proposed rule. This ignores the costs to foreign firms and benefits to foreign consumers.”^[5]

While the cost of foodborne illness can be estimated after the fact, estimating the benefits of specific policy options for preventing foodborne illness before any one option is implemented are beyond OMB’s ability. Therefore, OMB creates a statistical proxy for an “appropriate level of protection” in terms of illness prevented relative to the estimated costs of implementing the food safety policy option. And OMB provides an estimate of how many illnesses must be prevented to “break even” with the costs of implementing the food safety policy option. The OMB econometric estimates do not include their policy assumptions, but it is safe to say that

this influential factor in implementing the “appropriate level” of consumer protection is not science.

For businesses with less than \$250,000 annual revenue per year, OMB estimates the cost to implement the FDA proposal rule at \$475 million over seven years, adjusted for a seven percent annual increase in costs. It is difficult to estimate how burdensome for small food businesses these regulatory costs will be relative to sales, since small business food sales are not disaggregated from overall U.S. food sales. However, as of the end of October, the U.S. Department of Agriculture reported that U.S. food sales totaled about \$1,146 billion for 2014.^[6] (Foreign governments will have to estimate their own costs and benefits of importing these FDA regulated products.)

The Breakeven Illness Percentage for these very small businesses is estimated at 24 percent. This number is the OMB proxy for defining the benefit of the first FDA proposed option for preventing foodborne illness in FDA regulated foods processed, packaged and/or sold in very small businesses. For this policy option to be OMB cost effective relative to the \$475 million, seven-year implementation cost, the implementation of the policy option would prevent 24 percent the illness attributed to the consumption of FDA regulated food products manufactured and/or consumed in very small businesses. In other words, for the cost of the policy option to “break even” with the benefits of its implementation, FDA would have to show a 24 percent reduction in very small business related foodborne illness cases. This Breakeven Illness Percentage requires a steep burden of proof that could prevent the implementation of FDA’s preventative measures rule to provide the “appropriate level” of consumer protection.

In the practice of SPS regulation, “science” does not have the only or even the last word about the application of SPS measures to protect consumer health. When a “science-based” food safety rule is subjected to pre-implementation “cost-effectiveness” analysis, the final rule may be weakened, using the assumptions and quantified results of cost-benefit analysis. A notorious example of lowering the “appropriate level” of consumer protection is FDA’s recent decision to factor into its calorie count rule the food industry’s argument about the cost of “lost pleasure” in not consuming high-calorie junk food.^[7] Cost-benefit analysis of such “lost pleasure” may readily overwhelm the nutritional science used to propose the calorie count rule.

This is not to say that SPS and other regulations are not cost-effective, relative to much higher public health and environmental costs of deregulation or non-regulation.^[8] It is to say that in

the application of U.S. SPS measures, the role of science in the determination of the “appropriate level” of protection is far from absolute.

[1] Steve Suppan, “Trade above all: the draft food safety chapter of TTIP,” Institute for Agriculture and Trade Policy, July 2, 2014. <http://www.iatp.org/blog/201407/trade-above-all-the-draft-food-safety-chapter-of-ttip>

[2] Cited in Anthony Faiola, “Chlorine chicken, hormone beef? European fears over American ‘Frankenfoods,’” *The Independent*, December 5, 2014.

[3] “An exceptional vote in the Codex Alimentarius Commission: the fallout to come,” *Global Food Safety Monitor*, Institute for Agriculture and Trade Policy, October 1, 2012. <http://us5.campaign-archive1.com/?u=26fee7f7d268bc1c653da5892&id=5d37c1767e>

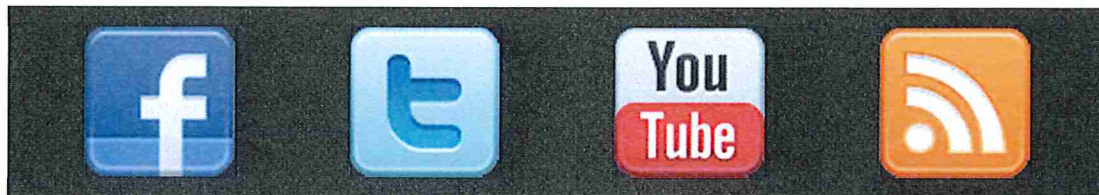
[4] “HHS Publishes OMB’s Edits to FSMA Preventative Controls Proposal,” *PackagingLaw.Com*, April 18, 2013.

[5] “TAB B Compared Part 1 of 3,” February 28, 2013, at 16. <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0920-0014>

[6] “Historical food sales,” Economic Research Service, U.S. Department of Agriculture, November 17, 2014. <http://www.ers.usda.gov/data-products/food-expenditures.aspx#26634>

[7] Sharon Begley, “Exclusive: FDA prices ‘lost pleasure’ in its calorie count rule,” *Reuters*, December 8, 2014.

[8] E.g. Ronald White, “2014 OMB Report Shows Substantial Public Protections Achieved At Low Cost,” *Center for Effective Government*, June 10, 2014. <http://www.foreffectivegov.org/node/13089>



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