HR 2749: What about Food Security?

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The U.S. House of Representatives passed **HR 2749**, "The Food Safety Enhancement of 2009", by a vote of 283 to 142 on July 30, 2009 [pages reference the **engrossed version**]. HR 2749 was assigned August 3 to the **Senate Committee on Health, Education, Labor, and Pensions**. When the Senate takes up the issue of food safety, they could either use HR 2749 as a starting point or **S. 510** (a bill introduced by Sen. Richard Durbin, IL); or the Senate could start with a bill that has yet to be introduced. **Passage of HR 2749 into law would benefit industrial food processors and food imports at the expense of the 'local food movement'. HR 2749 would increase our reliance on imported food while reducing food security in this country. It would federalize food regulation in this country, diminishing much of what is left of the states' power to regulate food in intrastate commerce.**

HR2749 contains provisions which directly preempt state regulation of food. The bill would empower the Secretary of Health and Human Services (HHS) to establish, by regulation, performance standards for food or food classes which "minimize, prevent or eliminate hazards resulting from food-borne contaminants" [Sec. 103(b): Sec. 419(a)—pp. 46-47]. It also charges the Secretary with issuing national standards for various types of produce [Sec. 104(b): Sec. 419A(a)—p. 49]. Although **HHS** has charge of eleven agencies, the provisions of HR 2749 will be executed primarily through the Food and Drug Administration (**FDA**).

The Federalization of Food Regulation

In addition to directly reducing state power, HR 2749 contains a section — 105, the "Risk-Based Inspection Schedule" for registered food facilities — that could ultimately lead to extensive federal influence, even control, over state agriculture and health departments. The inspection schedule will almost certainly lead to considerable federal funding for state-conducted inspections, placing states in the service of FDA. To explain further, under this section of the bill [Sec. 105(a): Sec. 704 h(4)—p. 54],

''(4) Such risk-based schedule shall provide for a frequency of inspections commensurate with the risk presented by the facility and shall be based on the following categories and inspection frequencies:

''(A) CATEGORY 1.—A category 1 food facility is a high-risk facility that manufactures or processes food. The Secretary shall randomly inspect a category 1 food facility at least every 6 to 12 months.
''(B) CATEGORY 2.—A category 2 food facility is a low-risk facility that manufactures or processes food or a facility that packs or labels food. The Secretary shall randomly inspect a category 2 facility at least every 18 months to 3 years.

‘‘(C) CATEGORY 3.—A category 3 food facility is a facility that holds food. The Secretary shall randomly inspect a category 3 facility at least every 5 years. *[“Hold” means the storage of food, e.g., warehouses, cold-storage facilities, etc.—21 CFR §1.227]*

The bill permits FDA to designate state or local officials to conduct inspections on its behalf, and the agency will need all the help it can get from state and local levels. Although there are approximately 150,000 registered domestic food facilities **[1]**currently, the FDA conducted only 6,562 inspections of domestic facilities for fiscal year 2008 **[2]**. State agricultural officials currently perform meat and poultry inspections for the federal government; but the federal work they already do would increase significantly with passage of HR 2749. Most states are in poor financial condition and would welcome the money from FDA to conduct the inspections; many states have cut back on the number of people working in their department of agriculture. The federal money will give FDA leverage to influence intrastate regulation to a greater extent than it does at present, resulting in a loss of autonomy.

FDA could use its financial leverage to change state laws on raw milk. FDA’s goal is a total ban on the sale or distribution of raw milk, and the agency has been pressuring states for years to either prohibit or place stricter controls on the sale of raw milk, even though FDA has no jurisdiction over intrastate sales of raw milk. Under HR 2749, the agency would have the power to institute a total ban by issuing a performance standard regulation requiring all milk to be pasteurized; but it could also avoid the political fallout by using federal funding to push state agencies to ban raw milk.

Increased Reliance on Food Imports

If applied equally to foreign facilities, the risk-based inspection schedules would call for a massive increase in inspections. The majority of registered food processing facilities (over 220,000 or about 60%) are located outside the United States **[1]**; and many of these foreign facilities fall within Categories 1 or 2, which means they should be inspected frequently. Yet only 152 inspections of foreign facilities were conducted during 2008 **[2]**.

Section 208 (entitled “Dedicated Foreign Inspectorate”—p.144) provides “the Secretary shall establish and maintain a corps of inspectors dedicated to the inspection of foreign food facilities. This corps shall be staffed and funded by the Secretary at a level sufficient to enable it to assist the Secretary in achieving the frequency of inspections as described in this Act.” But there is nothing in HR 2749 explaining how HHS shall institute a “corps of inspectors” to accomplish this. Moreover, although the Secretary

can require that an article of food being imported into the U.S. be issued a certificate by a qualified entity indicating compliance with the Federal Food, Drug and Cosmetic Act, the exercise of this power by the Secretary is optional.

So what will FDA do? For domestic inspections, it has the existing infrastructure of the state and local officials conducting inspections. Yet it has little to no infrastructure for foreign inspections. FDA will likely have to rely on officials of foreign governments to conduct the inspections. How can we expect these officials to place American interests above the interests of their own domestic producers who export to the U.S.?

Rep. John Dingell (D-MI) has commented that the U.S. will be importing a greater percentage of its food in the future **[3]**; if HR 2749 becomes law, it will be easy to see how this would happen. Domestic facilities would be forced to comply with requirements in the bill that many foreign facilities most likely will not.

The paperwork requirements alone indicate the advantage imports could have if these requirements are not enforced to the degree on foreign facilities that they will be on domestic facilities. Under the bill, both foreign facilities and those domestic facilities engaging interstate commerce must develop a 'food safety plan' and a 'food defense plan'.

Food Safety Plan

Under the 'food safety plan' required by HR 2749 [Sec 102: Sec 418A(b)—pp. 33-34], the operator of the food facility must have in writing: (1) a hazard analysis; (2) preventive controls to address those hazards identified including those hazards identified by the HHS Secretary through regulation or guidance; (3) a description of the procedures for monitoring preventive controls; (4) a description of procedures for taking corrective actions; (5) a description of verification activities for preventive controls including:

(a) validation that the system of controls will prevent, eliminate, or reduce to an acceptable level the identified hazards,
(b) review of monitoring and corrective action records,
(c) procedures for determining whether the system of controls as implemented is effectively prevent, eliminate, or reduce to an acceptable level the occurrence of identified hazards . . . .;

(6) description of the facility's procedures for recordkeeping *[under HR2749, all "persons who manufacture, process, pack, transport, distribute, receive or hold food in the US or for import into the US" whether they are a facility or not are required to keep records. {Sec 106(b)—p. 65}]*; (7) a description of the facility's procedures for the recall of articles of food; (8) a description of the facility's procedures for tracing the distribution history of articles of food; (9) a description of the facility's procedures to ensure a safe and secure supply chain for the ingredients or components used in making a food manufactured, processed, packed, transported, or held by such facility; (10) a description of the facility's procedures to implement science-based performance standards issued by HHS.

Food Defense Plan

Any foreign facility or any domestic facility engaging in interstate commerce must have a written 'food defense plan' containing the following information:

''(1) A food defense assessment to identify conditions and practices that may permit a hazard that may be intentionally introduced, including by an act of terrorism. This assessment shall evaluate processing security, cybersecurity, material security (including ingredients, finished product, and packaging), personnel security, storage security, shipping and receiving security, and utility security.
''(2) A description of the preventive measures being implemented as a result of such assessment to minimize the risk of intentional contamination.
''(3) A description of the procedures to check for and identify any circumstances in which the preventive measures are not fully implemented or were ineffective.
''(4) A description of the procedures for taking corrective actions to ensure that when preventive measures have not been properly implemented or have been ineffective, appropriate action is taken—
''(A) to reduce the likelihood of recurrence of the failure; and
''(B) to assess the consequences of the failure.
''(5) A description of evaluation activities for the preventive measures, including a review of records provided for under paragraph (6) and procedures to periodically test the effectiveness of the plan.
''(6) A description of the facility's record-keeping procedures, including records documenting implementation of the procedures under paragraphs (3), (4), and (5)."
[Sec. 102: Sec. 418C(b)—pp. 41-43]

No Food Security Plan

According to FDA, "food safety" is the prevention of unintentional contamination of food; whereas, "food defense" is prevention of the intentional contamination of food. But there is a third term that needs to be considered: "food security," "the ability of a nation to be self-sufficient in food production."

HR 2749 ignores "food security" and instead promotes a regulatory scheme that will increase reliance on imported food (i.e., reduce food security). The way to increase food production in this country is to deregulate small farms and local producers, increasing their numbers so that local communities can feed themselves and, in the aggregate, the US can feed itself. HR 2749 will be a massive stumbling block to the growth of this movement. Many local food producers will not have the economies of scale to comply with the bill's requirements–benefiting industrial processors and food imports, the two sectors of the food system most responsible for our food safety problems. FDA needs to leave any necessary regulation of local food to state and local agencies. If the country has food security through the ability of small farmers and local producers to feed the communities in which they live, America will achieve food safety and food defense as well. There is a higher level of accountability and traceability with local food. A decentralized food system is less vulnerable to being weakened by a terrorist attack.

The nation needs to decrease its reliance on imports. According to Congressional findings **[4]**, from 2003 to 2007 the value of food imports increased from 45.6 billion dollars to 64 billion dollars. Moreover, 31% of fruits, juices and nuts; 9.5% of red meat; and 78.6% of shellfish were imported into this country. Food safety will suffer if this trend continues. Yet, only about one percent of imported food is actually inspected, according to statements made before the House Energy and Commerce Committee during its consideration of HR 2749 **[2]**. USDA's Food Safety and Inspection Service estimates that about 43 million pounds of meat and poultry are illegally imported into the United States each year **[5]** . Moreover, as the U.S. imports more food, the country will be increasingly subject to international law on food safety standards. Food safety standards inferior to what the American people would consider acceptable would govern the regulation of imported food. One example would be foods containing melamine.

Codex and Melamine

According to the World Health Organization (WHO), the food contaminant melamine "is produced in large amounts (1.2 million tons in 2007) primarily for use in the synthesis of melamine formaldehyde resins for the manufacture of laminates, plastics, coating, commercial filters, glues or adhesives, and dishware and kitchenware . . . ." **[6]** In

March 2007, FDA received reports of kidney failure among cats and dogs as well as a report that "cats died during taste tests of certain brands of cat foods" **[7]**. In the agency's subsequent investigation, melamine and melamine-related compounds were found in products labeled as "wheat gluten" and "rice protein concentrate" that had been imported from China. These ingredients are common in many pet foods sold in the United States. FDA determined that melamine and its related compounds caused the illnesses and deaths; more than 5,300 melamine-contaminated products were recalled **[8]**. Melamine and its related compounds are not approved for use as an ingredient in this country in either animal or human food.

In September 2008, it was reported that a total of 52,857 cases of kidney disease (nephrolithiasis) in China had been linked to consumption of powdered infant formula containing melamine **[9]**. According to FDA, the incidents concerning the pet food and the infant formula had the following similarities **[10]**:

- Melamine, a nitrogen-based compound, was apparently added to bolster the apparent protein content in foods or in ingredients used in processed food products intended to contain protein.
- The recipients of the ingredients using a test for nitrogen content would not have been able to distinguish between melamine and the desired protein.
- Melamine contamination became public only after numerous adverse health events, including deaths, were reported and associated with the use of contaminated products.

In November 2008, FDA responded to the growing public concern over melamine by publishing a document, entitled "Interim Safety and Risk Assessment of Melamine and its Analogs in Food for Humans". The risk assessment determined that "based on currently available data and information, there is too much uncertainty for FDA to establish a level of melamine and its analogs in infant formula that does not raise public health concerns. In foods other than infant formula, FDA concludes that levels of melamine and melamine-related compounds below 2.5 ppm do not raise public health concerns" **[9]**. The tolerance level set for melamine by the agency was widely unpopular with many believing there should be a zero tolerance standard. Unfortunately, it now looks like that even if FDA does change its risk assessment, imported food containing melamine will still be allowed into the country. An international standard establishing a tolerance level for melamine is in the process of being adopted by the Codex Alimentarius Commission (Codex).

Codex is a creation of two United Nations organizations, the Food and Agricultural Organization (FAO) and the World Health Organization (WHO); it "is the principal international organization for encouraging fair international trade in food and protecting the health and economic interests of consumers. Through adoption of food standards, codes of practice, and other guidelines developed by its committees and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers, ensure fair trade practices in the food trade, and promote coordination of food standards work undertaken by international governmental and non-governmental organizations." **[11]** The World Trade Organization (WTO), of which the United States is a member, uses the Codex food standards as binding guidelines in disputes between member nations.

This past summer Codex approved a "proposal for new work on maximum levels of melamine for food and feed"; the proposal was to establish maximum levels for melamine in food and feed products "resulting from non-intentional and unavoidable presence from different sources." **[12]** It was not to apply to the deliberate addition of melamine in food and feed which was not to be tolerated under the Codex standard. The proposed standard was to be 2.5 ppm in food and feed products and 1.0 ppm in infant formula products **[13]**. These standards could be adopted by Codex as early as 2010. If the standard is adopted, it is unlikely that the U.S. would be able to prevent foods containing melamine with levels below 2.5 ppm from entering the country even if tolerance levels were subsequently lowered for domestically produced foods. If the U.S. then tried to refuse entry for such an imported food, it would be vulnerable to a claim filed with the WTO's Dispute Settlement Panel by the originating country of the import. In violating an agreement governing an international standard, the U.S. could be subject to sanctions imposed by the WTO. As a member nation of the WTO, the U.S. is bound by any ruling.

Conclusion

The government needs to change its overall policy on food for there to be any chance of true food safety. HR 2749 rightly tries to strengthen regulation of imported food and foreign food facilities; however, given the immense resources needed to effectively police imported food and foreign facilities as well as the limitations on food safety measures effectively imposed by international agreements, food safety problems with imports will continue. Resources that would be spent regulating small producers, if HR 2749 passed into law, should be redirected toward regulating imports.

The U.S. needs to end its policy of food dependence and scale back considerably on the amount of food imported into the country. The way to do this is to support the

growth of small farms and local producers, not impede it as passage of HR 2749 would do. The more small farmers and local producers are deregulated, the greater the potential for the country to become self-sufficient in food production. According to the USDA's National Agricultural Statistics Service, over 291,000 new farms began operation from 2002 to 2007 **[14]**. This trend needs to accelerate for the country to attain food security. Contrast the 'carbon footprint' left by a self-sufficient nation with the enormous 'carbon footprint' left by international free trade. Passage of HR 2749 would put an end to any chance of achieving food security.

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Endnotes

1. "Agriculture and Food: Critical Infrastructure and Key Resources Sector-Specific Plan as input to the National Infrastructure Protection Plan", May 2007; Food section submitted by the U.S. Food and Drug Administration, Table 1-2 "Total Registrations by Establishment Type", p. 11

2. Hearing on HR 2749 before the Health Subcommittee of the House Committee on Energy and Commerce, June 3, 2009; dialog during Questions between Rep. John Dingell (D-MI) and Pamela G. Bailey (President and CEO of the Grocery Manufacturers Association); WMV recording Part 2, time segment from 1:00:50 to 1:04:03

3. Hearing on HR 2749

4. United States Code, 21 USC § 2101(4)

5. USDA-FSIS Podcast, "Illegally Imported and Smuggled Food Products", script posted July 8, 2009 at www.fsis.usda.gov/News_&_Events/Script_Illegally_Imported_Products/index.asp

6. "Overall Conclusions and Recommendations" (8 December 2008, p. 1) from the 'WHO Expert meeting to review toxicological aspects of melamine and cyanuric acid' In collaboration with FAO and Supported by Health Canada, Ottawa Canada, 1-4 December 2008

7. Federal Register, 74 FR 15497

8. Federal Register, 73 FR 59034

9. Federal Register, 73 FR 67186

10. Federal Register, 74 FR 39704

11. Federal Register, 74 FR 26188

12. Report of the 3rd Session of the Codex Committee on Contaminants in Foods, ALINORM 09/32/41, Appendix X, p. 90; posted online at ftp://ftp.fao.org/codex/Alinorm09/al32_41e.pdf

13. Ibid., p. 91

14. 2007 Census of Agriculture Fact Sheet: Farm Numbers, p.3 “A Look at New Farms”; posted at www.agcensus.usda.gov

HYPERLINKS for PDF version:

HR 2749 – online posting of the status of House bill H.R. 2749 including actions taken
http://www.thomas.gov/cgi-bin/bdquery/z?d111:h.r.02749:

engrossed version – The version of HR 2749 that was passed by the House on July 30, 2009
http://www.ftcldf.org/docs/hr2749_eh_073009-getdoccgi.pdf

Senate Committee on Health, Education, Labor, and Pensions
http://www.senate.gov/general/committee_membership/committee_memberships_SSHR.htm

S. 510 – online posting of the status of Senate bill S. 510 including actions taken
http://www.thomas.gov/cgi-bin/bdquery/z?d111:s.0510:

HHS – Department of Health and Human Services website; scroll down to view ‘Agencies’ [click ‘Show Details’]
http://www.hhs.gov/about/

FDA – Food and Drug Administration website
http://www.fda.gov/