



**THE INTERNATIONAL ALOE  
SCIENCE COUNCIL**



IASC Update

**To: IASC Members**  
**From: Devon Powell, IASC**

Please find below an article that was originally run in the *AHPA Report* on the pending federal legislation on food safety (H.R. 2749). This article will likely offer useful information to many IASC members in helping to outline the current aspects and possible effects of the bill should it pass as-is, and please feel free to contact me with any questions.

Best regards,

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## **Pending federal legislation on food safety (H.R. 2749)**

*By Michael McGuffin, President, AHPA with some Commentary by Anthony L. Young, Esq. (Kleinfeld, Kaplan & Becker), General Counsel, AHPA*

### **H. R. 2749: Elements of the Bill**

*The “Food Safety Enhancement Act” delineates actions and establishes authorities for the Food and Drug Administration (FDA) to prevent, intervene, and respond to unsafe food, and also includes additional provisions related to such issues as country of origin labeling and whistleblower inspections. The following is a description of elements of the bill that are of interest to members of the American Herbal Products Association (AHPA).*

*A copy of the current version of the full bill is available here:*

[http://www.ahpa.org/portals/0/pdfs/09\\_0617\\_HR\\_2749\\_Food\\_Safety\\_Enhance\\_Sub\\_Waxman.pdf](http://www.ahpa.org/portals/0/pdfs/09_0617_HR_2749_Food_Safety_Enhance_Sub_Waxman.pdf)

One of the priority issues before the current 111<sup>th</sup> U.S. Congress (and in some state legislatures as well, see sidebar TK) is to consider legislation to address

problems with food safety that have become apparent due to contamination of pet foods, peanuts, pistachios, etc. The federal bill that is being most actively considered by the Congress is H.R. 2749, the “Food Safety Enhancement Act,” which was introduced on June 8 by Rep. John Dingell (D-MI).

The “Food Safety Enhancement Act” has been amended twice and passed out of the House Energy & Commerce Committee. As currently amended (on June 17), it creates numerous additional requirements for industry<sup>[1]</sup> – often by amending federal definitions of “adulteration” and “misbranding.” Most elements of the new law would come into effect 18 months to three years after passage.

Commentary: In recent years, Congress has become more “directive” with federal agencies. As evident in H.R. 2749, Congress is now legislating not only what an agency should do to address an issue but detailing how “the what” is to be accomplished. Thus, environmental legislation, and now food safety legislation, reads more like a regulation than legislation mandating that a federal agency solve a problem. The reason for this is that agencies plainly bend to the will of the Executive, and move resources to those places that more effectively address their political goals. Accordingly, what we see here is micro-managing at the legislative level. And, as you will note in the first footnote, the legislation does not address “protein,” as red and white meat sources have come to be called.

It is too soon to know if this exact legislation will pass both the full House and the Senate, but it is nearly inevitable that something very much like this bill will be signed into law before the end of the 111<sup>th</sup> Congress. Senator Richard Durbin (D-IL) has a similar bill pending in the Senate and it is likely that the Durbin bill, the FDA Food Safety Modernization Act of 2009, and HR 2749 will end up in conference and a compromise reached. There is also some desire both from the legislature and from the Obama Administration to create a single food safety agency. In fact, Rosa DeLauro (D-CT) introduced legislation in February that would establish a “Food Safety Administration” (H.R. 875, Food Safety Modernization Act of 2009). Whatever legislation is enacted to address food safety now, look for efforts at consolidating the U.S. Department of Agriculture’s Food Safety and Inspection Service and the U.S. Department of Health and Human Services’ Center for Food Safety and Nutrition, to continue.

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## **Food Safety: Prevention**

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<sup>[1]</sup> The bill specifically exempts food products regulated by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act; and also exempts farms that raise such food products.

## **Sec. 101. Changes in registration of food facilities**

- Modifies the current FDA facility registration requirement (as established by the “Bioterrorism” law):
  - from a no-charge and one-time process to one that would need to be renewed annually at a cost of \$500 in 2010 and at an inflation-adjusted cost from this 2010 level each year thereafter until a 2014 sunset date (collected fees are required to be used “to defray the costs of food safety activities”)
  - to expand this registration requirement to cover facilities that manufacture food for export
  - to establish as statutory requirements numerous of the details now required by the implementing regulations at 21 CFR 1, Subpart H
  - to authorize the Secretary of Health & Human Services (“the Secretary”) to suspend a facility’s registration (after notice and an opportunity for an informal hearing) “for a violation of this Act that could result in serious adverse health consequences or death to humans or animals.”

## **Sec. 102. Hazard analysis, risk-based preventive controls, and food safety plan, finished product test results from category 1 facilities**

- Establishes requirements for hazard analysis and risk-based preventive controls for all food facilities. More specifically, facilities would be required to:
  - “(1) conduct a hazard analysis (or more than one if appropriate);
  - (2) identify, implement, and validate effective preventive controls;
  - (3) monitor preventive controls;
  - (4) institute corrective actions when—(A) monitoring shows that preventive controls have not been properly implemented; or (B) monitoring and verification show that such controls were ineffective;
  - (5) conduct verification activities;
  - (6) maintain records of monitoring, corrective action, and verification;
  - and
  - (7) reanalyze for hazards”

This section of the bill includes seven pages of details as to what is intended by the above-listed seven requirements.

- Requires each food facility to establish a food safety plan. Such plan would need to describe how the facility has addressed its above-described requirements regarding hazard analysis and risk-based preventive controls, and also to describe procedures for recall; for tracing distribution of articles of food; to “ensure a safe and secure supply chain for the ingredients or components used in making ... food;” and “to implement the science-based performance standards issued under section 419” (see below).

- Requires a “category 1 facility” (later defined as a “high-risk facility that manufactures or processes food;” the term “high-risk” does not appear to be defined elsewhere) to submit to the Secretary finished product test results “documenting the presence of contaminants in food ... posing a risk of severe adverse health consequences or death.” The Secretary could require such submissions “as the Secretary determines feasible and appropriate ... taking into consideration available data and information on ... potential risks posed....”

### **Sec. 103. Performance standards**

- Authorizes the Secretary to issue “science-based performance standards” on significant food-borne contaminants and hazards. Failure to comply with such standards would constitute adulteration.

### **Sec. 104. Safety standards for fresh produce and certain other raw agricultural commodities**

- Authorizes the Secretary to establish “scientific and risk-based standards for the safe growing, harvesting, processing, packing, sorting, transporting, and holding of those types of raw agricultural commodities—(1) that are from a plant or a fungus; and (2) for which the Secretary has determined that such standards are reasonably necessary to minimize the risk of serious adverse health consequences or death to humans or animals.” FDA would also be authorized to set forth “reasonably necessary” procedures, processes and practices to address these standards. FDA would be required to issue a proposed rule for this section within 18 months, and a final rule within 3 years. Failure to comply with this section would again constitute adulteration.

### **Sec. 105. Risk-based inspection schedule**

- Establishes a facility inspection schedule: Category 1 (high risk manufacturer or processor) at least every 6-12 months; Category 2 (low-risk manufacturer or processor, or food packer or labeler) at least every 18 months to 3 years; Category 3 (holder) at least every 5 years. The bill authorizes the Secretary to modify the schedule for Category 2 or 3, but not for 1. Domestic inspection would be conducted by a federal, state or local official; non-domestic inspections by “an agency or a representative of a country that is recognized by the Secretary.”

### **Sec. 106. Access to records**

- Establishes the Secretary’s records inspection authority to all records relating to food “bearing on whether the food may be adulterated, misbranded, or otherwise in violation of this Act, including all records collected or developed to comply with” the food safety plan and finished product test results that would be enacted by this law. The bill also states that such records would include “all records relating to the production,

manufacture, processing, packing, transporting, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location.”

- Extends the physical inspection and records inspection authority of the Secretary HHS to include farms and restaurants, but states that inspection authority does not extend to “recipes for food,” while maintaining the existing inspection exclusions for “financial data, sales data other than shipment data, pricing data, personnel data (other than data as to qualification of technical and professional personnel performing functions subject to this chapter), and research data” (with exceptions).

### **Sec. 107. Traceability of food**

- Defines new food tracing requirements to be established by the Secretary by regulation and which would allow food companies to “maintain the full pedigree of the origin and previous distribution history of the food,” among other details. Some exemptions would apply to food sold directly from a farm (or fishery) to a consumer or grocery, though such farms and groceries would be required to make and keep records for six months to identify the distribution. The Secretary would be authorized to exempt other foods or facilities from this process if it determines that the process “is not necessary to protect the public health,” though any exempt entity would still be required (as now) to maintain records of the immediate previous source of a food.

### **Sec. 108. Reinspection and food recall fees applicable to facilities**

- Authorizes the collection of fees from any facility that requires reinspection due to “a violation of any requirement of this Act relating to food, including any such requirement relating to good manufacturing practices,” or is subject to a recall, which fees are to cover all costs of reinspection or recall.

### **Sec. 109. Certification and accreditation**

- Creates a certification scheme for imported foods which the Secretary may require as a condition of import if the food is imported from a particular country or region where such certification would “assist the Secretary in determining” whether to refuse to admit such article or whether the article poses a significant risk, “based on the adequacy of government controls in such country or region or other information relevant to such food;” or for “a type of food that could pose a significant risk to health;” or for “an article imported from a particular country [where] there is an agreement between the Secretary and the government of such country providing for such certification.”

### **Sec. 110. Testing by accredited laboratories**

- Requires that any testing conducted as part of testimony related to the Secretary's refusal to permit a food for import be conducted at a certified analytical lab, and sets up a scheme for the lab certification.

### **Sec. 111. Notification, nondistribution, and recall of adulterated or misbranded food**

- Requires food companies to notify the Secretary "as soon as practicable" if they have "reason to believe that an article of food ... is adulterated or misbranded in a manner that presents a reasonable probability that the use or consumption of, or exposure to, the article (or an ingredient or component used in any such article) will cause a threat of serious adverse health consequences or death to humans or animals."
- Authorizes the Secretary to order a company to cease distribution of and/or recall any food described in the last paragraph.

### **Sec. 112. Reportable food registry; exchange of information**

- Expands the applicability of certain elements of the existing Reportable Food Registry to include farms, restaurants, and retailers. The registry was established by the FDA Amendments Act (FDAAA) of 2007 and sets up requirements for notifying FDA of certain adulterated foods and for the agency to post certain information publically; dietary supplements were exempted from the registry requirements due to the existing requirement to submit serious adverse event reports to FDA.

### **Sec. 113. Safe and secure food importation program**

- Authorizes establishment of the "Safe and Secure Food Importation Program," to allow some faster track for imports if the importer complies with specified guidelines.

### **Sec. 114. Infant formula**

- Sets new misbranding rules for infant formulas.

## **Food Safety: Intervention**

### **Sec. 121 to Sec. 123. Surveillance; Public education and advisory system; Research**

- Instructs the Secretary to enhance systems for food-borne illness surveillance systems; develop and implement strategies to enhance State and local agency's food safety and defense capabilities; design and implement a national public education program on food safety; and conduct research to further the implementation of this law.

## **Food Safety: Response**

### **Sec. 131 and Sec. 132. Procedures for seizure; Administrative detention**

- Amends the Secretary's authority for administrative detention of a food to allow such detention if an inspector has "reason to believe" that the food is "adulterated, misbranded, or otherwise in violation" of the Act, rather than the current need for "credible evidence or information indicating" that the food "presents a threat of serious adverse health consequences or death."

### **Sec. 133. Quarantine authority for foods**

- Establishes the Secretary's authority to quarantine food in any geographic area.

### **Sec. 134 and Sec. 135. Criminal penalties; Civil penalties for violations relating to food**

- Sets criminal penalties of fines and not more than 10 years imprisonment for knowing violations of most of the adulteration and misbranding provisions of the Federal Food, Drug and Cosmetic Act (FFDCA), including § 301 (v) (21 U.S.C. 331 (v)): "The introduction or delivery for introduction into interstate commerce of a dietary supplement that is unsafe under section 350b of this title," that is, the "new dietary ingredients" section of the law; and sets civil penalties for any violation of the FFDCA (for individuals: not more than \$20,000 not to exceed \$50,000 in any proceeding; others: \$250,000 and \$1 million) as well as for knowing violations (individuals: \$50,000-\$100,000; others: \$500,000-\$7.5 million). This section also would state that "each violation ... and each day during which the violation continues shall be considered to be a separate offense."

### **Sec. 136. Improper import entry filings**

- Establishes as prohibited acts submission of inaccurate or incomplete information related to food imports or failure to submit such information.

### **Miscellaneous:**

*Additional provisions of interest to AHPA members<sup>[2]</sup>:*

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<sup>[2]</sup> Section 203, "Exportation certificate program"; Sec. 205, "Registration for customs brokers and filers; fee"; Sec. 206, "Unique identification number for food facilities, importers, custom brokers, and filers"; Sec. 209, "Plan and review of continued operation of field laboratories"; and Sec. 214, "Support for training institutions" are not specifically addressed in this article. See the text of the bill for details on these provisions:

[http://www.ahpa.org/portals/0/pdfs/09\\_0617\\_HR\\_2749\\_Food\\_Safety\\_Enhance\\_Sub\\_Waxman.pdf](http://www.ahpa.org/portals/0/pdfs/09_0617_HR_2749_Food_Safety_Enhance_Sub_Waxman.pdf)

**Sec. 201. Food substances generally recognized as safe**

- Requires FDA to acknowledge receipt of a request for a GRAS determination within 60 days of such receipt, and to post notices on its web site within 60 days of making any such determination.

**Sec. 202. Country of origin labeling; disclosure of source of ingredients**

- Requires each processed food to identify on its label the country where it was last processed, and each nonprocessed food to be labeled with its country of origin.

**Sec. 204. Registration for commercial importers of food; fee**

- Establishes a registration requirement for food importers; sets fees for this registration at the same level as other registered facilities (i.e., \$500 in 2010 and inflation-adjusted levels thereafter) except that companies that are required to register as both a food facility and an food importer would be required to pay only one fee.
- Requires food importers to conform with “good importer practices” (which the Secretary is required to promulgate within 24 months of passage of the bill) which “shall include the verification of good manufacturing practices and preventive controls of the importer’s foreign suppliers, as applicable.”

**Sec. 207. Prohibition against delaying, limiting, or refusing inspection**

- Adds to the definition of an adulterated food one from a domestic or foreign food facility that “delays or limits an inspection, or refuses to permit entry or inspection.”

**Sec. 208. Dedicated foreign inspectorate**

- Instructs the Secretary to create a permanent “dedicated foreign inspectorate.”

**Sec. 210. False or misleading reporting to FDA**

- Establishes as a prohibited act submission of a required report with respect to food that is “false or misleading in any material respect.”

**Sec. 211. Subpoena authority**

- Extends the Secretary’s subpoena authority.

**Sec. 212. Whistleblower protections**

- Provides certain “whistleblower” protections to employees who refuse to violate the laws for food facilities or disclose such violation.



### **Sec. 213. Extraterritorial jurisdiction**

- Claims “extraterritorial federal jurisdiction” over any violations related to foods intended for import to the U.S.; and establish as prohibited acts commerce in an adulterated or misbranded “with the knowledge or intent that such article will be imported” into the U.S.

### **Sec. 215. Bisphenol A in food and beverage containers**

- Requires the Secretary by the end of 2009 to notify the Congress whether the “available scientific data” support the safe use of bisphenol A in food and beverage containers, especially for sensitive populations.

### **State legislation: Food safety**

Some state legislatures have acted to establish their own food safety laws. In March the governor of Georgia (the state at the center of the recent peanut recall) signed a bill that allows new requirements for specific analyses related to food safety. It also sets mandatory submission to health authorities of lab results that confirm the presence of “a substance that would cause a manufactured food bearing or containing the same to be adulterated” within 24 hours of receipt of any such analysis. The law also strengthens the state’s inspection authority.

California’s legislature also considered food safety bills this spring, including one that would have, among other things, required submission to the Department of Public Health of certain food safety related lab analyses within 60 minutes of a California manufacturer’s receipt. This section was ultimately withdrawn, and California is likely to limit its attention to establishing new state authority to implement regulations for voluntary food recalls.

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<sup>[1]</sup> The bill specifically exempts food products regulated by the Secretary of Agriculture under the Federal Meat Inspection Act, the Poultry Products Inspection Act or the Egg Products Inspection Act; and also exempts farms that raise such food products.

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