

THE BRIEF HISTORY OF FOOD ALLERGEN LABELING IN THE U.S. AND IDEAS FOR FOR ALPHA-GAL

**STEVEN M. GENDEL, PH.D.
VP, DIVISION OF FOOD ALLERGENS
IEH LABORATORIES AND CONSULTING GROUP**



THE 1990s

- **Initial recognition of food allergy as an important public health issue**
 - **Advocacy by patients and families**
 - **Key medical publications**
 - **Recalls**
 - **Safety evaluation of bioengineered foods**
- **Identification of most important food allergens**
 - **FDA GMO guidance**
 - **UN Food and Agriculture Organization – Codex Alimentarius Commission**



THE 2000s

- **Food Allergen Labeling and Consumer Protection Act (FALCPA)**
 - **Defined “Major Food Allergens”**
 - **Mandated format options for declarations**
 - **Plain language**



THE 2010s

- **Food Safety Modernization Act**
 - **Explicitly designated allergens as food safety hazards**
 - **This extends the regulatory umbrella for allergens to processing as well as labeling**
- **Proposed Food Labeling Modernization Act**
 - **Adds to list of Major Food Allergens**

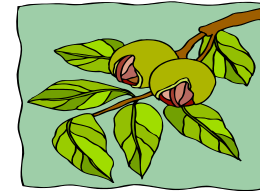


WHAT IS A MAJOR FOOD ALLERGEN?

Milk



Tree Nuts *



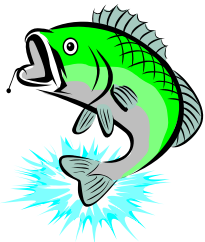
Egg



Wheat



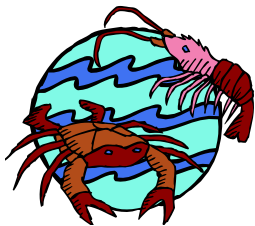
Fish*



Peanuts



Crustacean Shellfish*



Soybeans



➤ **And any ingredient that contains protein from one of these**

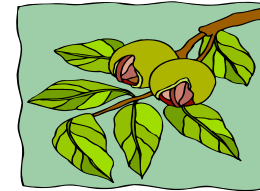


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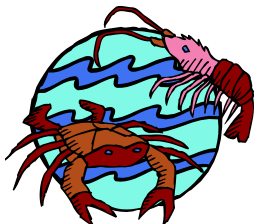


Peanuts



Crustacean Shellfish*

Soybeans



➤ **FLMA would add sesame**



INTERNATIONAL COMPARISON

- **Canada**
 - **“Big 8” plus Sesame, Mustard**
- **European Union**
 - **“Big 8” plus Sesame, Mustard, Celery, Lupine**

HOW WERE SIGNIFICANT FOOD ALLERGENS IDENTIFIED?

- **At First**
 - **Expert clinical opinion**
- **Later – Multiple criteria**
 - **Expert opinion**
 - **Prevalence (including special populations)**
 - **Severity**
 - **Public health impact**
 - **Use as a “hidden allergen”**



LEGAL ISSUES

- **FALCPA (and Proposed FLMA) amend the Federal Food Drug and Cosmetic Act**
 - **Directly apply only to FDA regulated foods**
 - **USDA/FSIS and Treasury/TTB issued regulations for consistency**
 - **The Major Food Allergens are listed in the FD&C Act**
 - **No specific mechanism to modify the list**
 - **Two mechanisms to exempt specific ingredients**



LEGAL ISSUES AND ALPHA-GAL

- **Meat labeling is regulated by FSIS**
 - **Do consumers need additional labeling for meat?**
- **Ingredient labeling is regulated by FDA**
 - **Major Food Allergens must be amended by Congress**
 - **FDA has limited options**

FDA DECISION MAKING

- **FDA has**
 - **Wide ranging responsibilities for food**
 - **Many stakeholders**
 - **Limited resources**
- **FDA prioritization considers (in no particular order)**
 - **Legal mandates and limitations**
 - **External influences**
 - **Public health**
 - **Practicality**

IDEAS TO MOVE FORWARD

- **Raise awareness**
- **Consumer support organization**
- **Combination of a public health issue with the hidden nature of problematic ingredients is important**
- **Talk to Congress**
 - **Opens doors to regulatory agencies**
- **Visit FDA and FSIS to educate**
 - **? Submit Citizens Petition to formally engage agency**
- **Engage internationally if possible**

THANKS FOR YOUR TIME



IEH Laboratories & Consulting Group

Steven Gendel

Vice President,
Division of Food Allergens

15300 Bothell Way NE
Lake Forest Park, WA 98155
p 206.940.5308 | f 206.306.8883
Steven.Gendel@iehinc.com