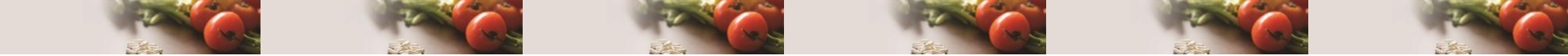


Food Ingredients and Food Contact Substances

Assessing the U.S. Approach To Safety

FDLI

Today's Agenda

- The GRAS Process
  - What does GRAS mean and how does it work?
  - What recent GRAS Notices tell us
- Allergen Management
  - Now the "Big 9": FASTER Act adds sesame
  - Risks in product innovation
  - Why allergens continue to cause recalls
- Regulation at the State Level
  - PFAS in Food Packaging
  - DC Consumer Protection Procedures Act
  - CA Prop 65 Update and First Amendment defenses

GRAS: Pathway to Food Innovation

The Food Additive / GRAS Divide

- Many ingredients are intentionally added to foods for specific technical or functional effects, *e.g.*, texture, preservation, flavoring, coloring, etc.
- In the 1950s, concerns were mounting over the safety of modern, artificial food additives and the absence of a regulatory framework
- As a result, Congress enacted the 1958 **Food Additives Amendment,** creating a system by which ingredients were sorted into two groupings:
  - Those which were already ***"Generally Recognized As Safe" (GRAS*)** and
  - ***"Food Additives,"*** which required a premarket review for safety by FDA

The Law…

- The Food, Drug, and Cosmetic Act, as amended, now holds that a food is adulterated:
  - if it bears or contains any **“food additive”** that is unsafe within the meaning of FDCA § 409 [FDCA § 402(a)(2)(C); 21 USC 342(a)(2)(C)]
- Under FDCA § 409, a food additive or food contact is deemed adulterated unless its use conforms to a regulation prescribing conditions under which it may be safely used
  - A petition process to establish the safety of a “food additive”
  - Notification process for food contact substances
- The Food Additive Amendments defined **“food additive”** with a critically important carve-out…

“Food Additive”

“… means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or other wise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), ***if such substance is not generally recognized, among experts qualified by scientific training and experience to evalute its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under conditions of its intended use*****[.]**”

− FDCA § 201(s), 21 USC § 321(s) (Emphasis added)

How Does “GRAS” Work?

- Under FDCA §§ 201(s) and 409 and FDA’s implementing rules at 21 CFR, Part 170, a substance can gain GRAS recognition through either:
  - Experience based on common use in food before 1958, or
  - “Scientific procedures”

GRAS Process

- A food manufacturer can “self-affirm” that an ingredient is GRAS
  - A first step in innovation whenever a common food ingredient is put to a novel use, *e.g.*, caffeine in gum or energy drinks, or another new application is found
  - A manufacturer typically convenes a “GRAS Panel” of independent experts to examine published, historical, peer-reviewed data and make a safety determination
- Meaning of GRAS eligibility through “scientific procedures”
  - Scientific data establishing a “reasonable certainty” of no harm for the ingredient under the conditions of its intended use
    - Same level as data for a food additive, based on information that is published or generally available, though data may include corroborated unpublished information; may also be based upon experience outside the United States, provided it meets GRAS criteria
    - Optional to submit data to FDA; agency may review and advise that it has no objection; GRAS decisions may also be kept private and used only in the event of an FDA inspection or other regulatory action
- FDA can also, on its own initiative, determine the GRAS status of a substance (See, *e.g.*, 21 CFR parts 182, 184)

FDA Definition of “Safe”: A Science-Based Risk Assessment

- “A reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use.
- “It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance.
- “Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:
  - (1) The probable consumption of the substance and of any substance formed in or on food because of its use.
  - (2) The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet.
  - (3) Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognized as appropriate.”

21 CFR § 170.3(i)

GRAS Notification

- GRAS Notification rules modified in 2016; conceived as a fast route to market based on a simple idea:
  - *"Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of Section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use."*
    - *21 CFR § 170.205*
- The Notification Process:
  - Convene scientific panel, study potential exposures, conduct a careful review of published data and literature, summarize findings and submit them to FDA
  - Notification, **not** approval or even affirmation: FDA receives data, asks questions, issues "no objection" letter – ***and offers no opinion of its own***
    - Since setting up the process in 1998, FDA has received over 1,000 GRAS notices

Submission to FDA

- FDA expects the GRAS notification to include:
  - *Ingredient identity / specification*
  - *Method of Manufacture*
  - *Physical or technical effect*
  - *Dietary Exposure*
  - *Self-limiting levels of use*
  - *Experience based on common use in foods before 1958, if any*
  - *Supporting data*

GRAS Notice Inventory

918	Partially defatted almond protein flour		Pending
917	Preparation containing three bacterial phages specific to Salmonella	Sep 10, 2020	FDA has no questions (in PDF) (540 kB)
916	Dihydroquercetin		Pending
915	Calcium L-methylfolate		Pending
914	Alpha-linolenic acid diacylglycerol		Pending
913	Algal oil (minimum 35% DHA)		Pending
912	Trehalose		Pending
911	Rebaudioside I		Pending
910	Thaumatin II	Sep 9, 2020	FDA has no questions (in PDF) (541 kB)
909	Whey protein containing 41% alpha-lactalbumin		Pending
908	Lipase from *Penicillium camemberti*		Pending
907	Wheat seed oil	Aug 21, 2020	FDA has no questions (in PDF) (593 kB)
906	Wheat seed polar lipids	Aug 24, 2020	FDA has no questions (in PDF) (573 kB)
905	*Bacillus subtilis* SG188	Jun 8, 2020	FDA has no questions (in PDF) (659 kB)
904	Fungal protein from fermented *Fusarium* sp. mycelia		Pending
903	Quillaia extract type 2		Pending
902	Neohesperidin dihydrochalcone		Pending
901	Glucosyl hesperidin		Pending
900	Corn oil		Pending
899	Citric acid esters of mono- and diglycerides		Pending

https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=GRASNotices

“FDA Has No Questions”

“Based on the information that [submitter] provided, as well as other information available to FDA, we have no questions at this time regarding [submitter’s] conclusion that [the ingredient] is GRAS under its intended conditions of use.

“This letter is not an affirmation that [the ingredient] is GRAS under 21 CFR 170.35. Unless noted above, our review did not address other provisions of the FD&C Act. Food ingredient manufacturers and food producers are responsible for ensuring that marketed products are safe and compliant with all applicable legal and regulatory requirements.”

Food Contact Substances

- "Any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting or holding food ***if such use is not intended to have any technical effect in [the food].***" FDCA § 409(h)(6), 321 USC § 348(h)(6) [emphasis added]
  - Examples: coatings, plastics, adhesives, antimicrobials, antioxidants
- Manufacturer must submit a Food Contact Notice ("FCN") to FDA prior to use
  - Conditions and contents of FCN specified in FDA rule at 21 CFR part 170, Subpart D
  - Proprietary and confidential; effective only for the manufacturer, substance and intended use that are identified in the FCN
  - An FCN is effective if FDA raises no objections within a 120-day response window
  - FDA proposing a process for repealing FCNs it deems no longer effective, 21 CFR § 170.105, 87 Fed. Reg. 3949 (January 26, 2022), giving manufacturers notice and opportunity to respond; clarifying reasons for FDA action

Other Pathways

- Under the Food Additives Amendment and other provisions of the FDCA, substances subject to other regulatory systems are not subject to the GRAS affirmation process:
  - An approved color additive, FDCA §§ 701-772, 21 USC §§ 371-379dd-2 (Color Additive Amendments)
  - An approved pesticide chemical (FIFRA)
  - A permitted residue
    - An unavoidable contaminants regulated via tolerances, Defect Action Levels
    - FDCA § 408, 21 U.S.C. § 346a (Food Quality Protection Act of 1996)
  - An approved new animal drug
  - An new dietary supplement ingredient
- If the ingredient it is not GRAS and does not fit into one of these other categories, it is a “food additive” requiring FDA review and approval

GRAS Controversy

- In September 2020, scientific and advocacy groups petitioned FDA, arguing that it must that it consider an ingredient's "cumulative and synergistic effects" in a GRAS determination
  - GRAS rule, however, requires just such an analysis, 21 CFR § 170.3(i)
- In October 2021, a federal court dismissed a lawsuit by some of the same groups challenging the GRAS process
  - Complained of "the secret GRAS process," alleged improper delegation of FDA authority to private industry
  - Case dismissed on summary judgment; court found that delegation was proper and plainly contemplated by the wording of the Food Additive Amendment

CENTER FOR FOOD SAFETY

Breast Cancer Prevention Partners
Exposing The Cause Is The Cure

EDF ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

Center for Science in the Public Interest

Protecting Public Health

June 2015 – Based on a thorough review of scientific evidence, FDA determined that partially hydrogenated oils (PHOs), a primary source of trans fat in processed foods, were not generally recognized as safe (“GRAS”) for use in human food.

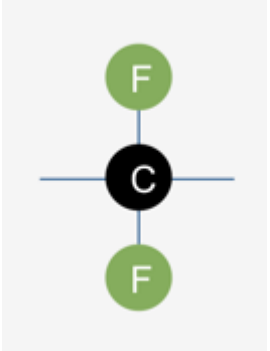
The Agency set a three-year compliance window for manufacturers to remove this ingredient from foods; denied a food industry food additive petition

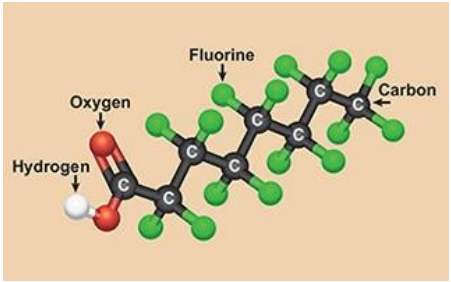
FDA predicted its actions would significantly reduce coronary heart disease and prevent thousands of fatal heart attacks every year.

https://www.fda.gov/food/food-additives-petitions/final-determination-regarding-partially-hydrogenated-oils-removing-trans-fat

PFAS in Food Packaging

- Per- and Poly-fluoroalkyl substances (PFAS)
- Group of over 4,000 manmade chemicals
- Commonly known as “forever chemicals”
- Commonly defined as any material containing one fully fluorinated carbon
- PFAS include many different substances with very different properties
- Litigation and regulatory focus on **long-chain** PFAS, generally containing more than 6 carbons, including PFOA (known as “C8”) and PFOS (not likely in food packaging)
- Repels water, oil, grease, and heat





California Ban

- AB 1200 effective Jan. 1, 2023
  - No sell-through provision
- Affects food packaging comprised of paper, paperboard or other plant fibers
- Bans all intentionally added PFAS at any level
- Bans total organic fluorine > 100 ppm
  - Even though total organic fluorine is not PFAS

Other States on PFAS

- NY bans all intentionally added PFAS at any level in food packaging as of 12/31/22
- CT ban is similar, effective 12/31/23
  - NY and CT do not expressly use total organic fluorine measure
- Maine bans all intentionally added PFAS at any level in all products after 1/1/30 unless Maine DEP determines it is “unavoidable”

DC Consumer Protection Procedures Act

- D.C. Code section 28-3901 et seq.:
  - A “public interest organization” can sue
  - “on behalf of the interests of a consumer or class of consumers”
  - so long as it has a “sufficient nexus” to “adequately represent those interests.”
- Significant expansion of standing

DC Consumer Protection Procedures Act

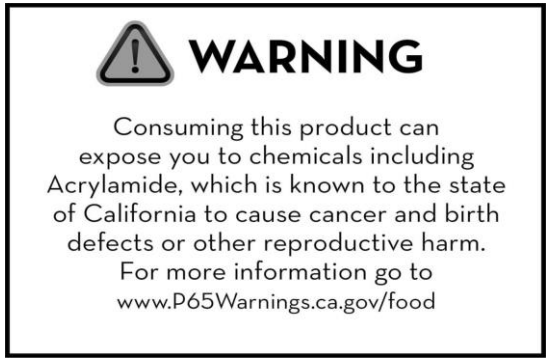
- No Article III standing for public interest organizations under Lujan v. Defenders of Wildlife
- DC Superior Court is not an Article III court
  - Typically applied Article III standing
  - But not under the DC CPPA: *Animal Legal Defense Fund v. Hormel*, 258 A.3d 174 (2021)

Prop 65 Update: Heat-Formed Carcinogens

- Acrylamide, Furan, Furfuryl Alcohol, etc.
- OEHHA Proposed Regulation (sec. 25505)
  - Lowest level currently feasible
  - Specific levels based on prior settlements
  - Rejected by Office of Admin. Law (3/4/22)
- Litigation continues

Prop 65 Update: First Amendment

- *Zauderer* Compelled Speech Test
  - First Amendment prohibits compelled commercial speech that is false or misleading
  - Compelled warnings must be:
    i. purely factual and uncontroversial
    ii. reasonably related to a substantial government interest
    iii. neither unjustified nor unduly burdensome



Prop 65 Update: First Amendment

- *Nat'l Ass'n of Wheat Growers v. Becerra*
  - First Amendment lawsuit challenging warnings for glyphosate
  - Feb. 26, 2018: E.D. Cal. grants preliminary injunction
    - "As applied to glyphosate, the required warnings are false and misleading."
  - June 22, 2020: E.D. Cal. grants permanent injunction
  - Attorney General has appealed to Ninth Circuit
    - OEHHA has proposed special safe harbor warning for glyphosate
    - Case effectively stayed pending completion of OEHHA rulemaking

Prop 65 Update: First Amendment

- *Cal. Chamber v. Bonta*
  - First Amendment lawsuit challenging warnings for acrylamide in food
  - Mar. 30, 2021: E.D. Cal. grants preliminary injunction
    - "The Chamber is likely to succeed on the merits of its First Amendment claims."
  - Intervener CERT appeals. Cal. AG does not appeal.
  - May 27, 2021: Ninth Circuit stays injunction
  - Mar. 17, 2022: Ninth Circuit upholds injunction
    - OEHHA has proposed special safe harbor warning for glyphosate
    - Case effectively stayed pending completion of OEHHA rulemaking

Prop 65 Update: First Amendment

- **Science on Acrylamide**: dietary acrylamide does not cause cancer **in humans**
- Dr. Loren Lipworth (Professor of Medicine, Vanderbilt University)
  - 2012 meta-analysis: *no consistent or credible evidence* associating dietary acrylamide with any type of cancer

American Cancer Society®

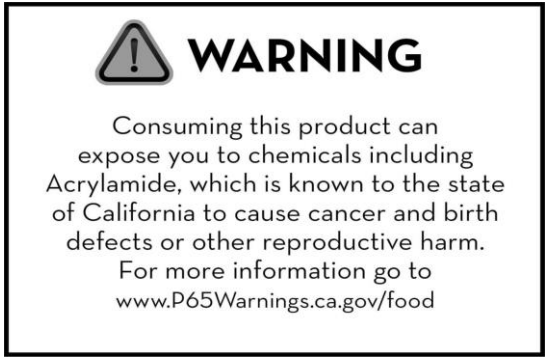
Acrylamide is classified by the International Agency for Research on Cancer (IARC) as a "probable carcinogen," based mainly on experiments in animals. However, a large number of studies in humans have found no strong evidence that dietary acrylamide is linked with an increased risk of any type of cancer.

NIH NATIONAL CANCER INSTITUTE

Studies in rodent models have found that acrylamide exposure increases the risk for several types of cancer (10–13). In the body, acrylamide is converted to a compound called glycidamide, which causes mutations in and damage to DNA. However, a large number of epidemiologic studies (both case-control and cohort studies) in humans have found no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer (9, 14). One reason for the inconsistent findings from human studies may be the difficulty in determining a person's acrylamide intake based on their reported diet.

Prop 65 Update: First Amendment

- **Consumer Survey**: consumers read warning as meaning **human** cancer risk
- 87.7% almond consumers: safe harbor warning means human cancer risk
- 73.2% almond consumers: short form warning means human cancer risk



- Sept. 27, 2021: OEHHA proposes new safe harbor warning for acrylamide
- **CALIFORNIA WARNING**: Consuming this product can expose you to acrylamide, a probable human carcinogen formed in some foods during cooking or heat processing at high temperatures. Many factors affect your cancer risk, including the frequency and amount of the chemical consumers. For more information including ways to reduce your exposure, see www.Prop65warnings.ca.gov/acrylamide.

THANK YOU

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Keller & Heckman

Food Ingredients and Food Contact Substances: Assessing the US Approach to Safety

March 30, 2022

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Agenda

- Update on GRAS Notice program
- Update on the impact of allergens on food safety
  - Issues with “major food allergen” definition in FD&C Act
- New/updated FDA guidance documents related to food safety anticipated in 2022

GRAS Update

- Review time for GRNs
  - Date of receipt v. date of filing
  - Statutory review period: 180 days + 90 days
  - Additional questions
  - Variability in GRAS reviewers

Allergen Recalls

- Undeclared food allergen #1 cause of recalls and 1/3 of Reportable Food Registry (RFR) reports

FDA's Response to Allergen Safety Threat

- FDA Steps Up Efforts to Protect Consumers from Food Allergens (January 2021)
  - Increasing enforcement efforts
    - Warning Letters (WLs)
      - WLs to facilities that manufacture/distribute foods with undeclared allergens; typically linked to failure to implement preventive controls to significantly minimize or prevent allergen hazard
      - WL to Whole Foods and Constituent Update (Dec 2020): more than 30 recalls in past year; pattern of misbranded food
    - Inspections – controls for cross contact and labeling
    - Monitor RFR, consumer complaints and adverse event reports
    - Sampling (e.g., dark chocolate for milk protein)
    - Recalls, import refusals, seizures
  - Investigating new detection methods for allergens
    - Currently two ELISA test kits used
    - Evaluating whether to use new assay xMAP that can detect up to 14 allergens in future
  - Guidance

Major Food Allergens

- Allergens that trigger mandatory allergen labeling are expressly listed in the Food, Drug and Cosmetic Act (FD&C Act) under the definition of “major food allergens” in Section 201(qq)
- Milk, egg, fish (e.g., bass, cod), Crustacean shellfish (e.g., crab, shrimp), tree nuts (e.g., almonds, pecans), peanuts, wheat, and soybeans
- What does FDA do when evidence suggests a new allergen warrants allergen labeling?

Case Example: Sesame

- 2014: petition from CSPI and others
- October 29, 2018: FDA requested information about prevalence and severity of sesame allergies
  - Allergenicity frequency reported to be similar to soy and fish: > 0.1%
- July 26, 2019: Illinois HB 2123 amended Illinois FD&C Act to require packaged foods sold in IL to label presence of sesame; food would have been misbranded if it contained sesame that was not declared

FDA Voluntary Guidance - Sesame

- FDA Draft Guidance on Voluntary Disclosure of Sesame as an Allergen (November 10, 2020)
  - Encourages disclose of sesame even when not required: "tahini (sesame)," "spice (sesame)," "flavor (including sesame)"
  - FDA has authority under FD&C Act to require labeling for other food allergens and authority to regulate common or usual name

FDA Voluntary Guidance - Sesame

- ". . . Section 403(x) of the FD&C Act gives us authority to require the disclosure of spices, flavorings, colorings, or incidental additives, that are, or contain, allergens other than the eight major food allergens by regulation if needed."
- FDA comments that they have not yet established scientific criteria to determine "priority allergens" or "allergens of public health importance."
  - Criteria may include prevalence of allergy in the population, severity of reactions experienced, potency of the allergen
- Guidance not legally enforceable, not required; current thinking, recommendation, suggestion

FASTER Act 2021

- April 23, 2021, President Biden signed into law the Food Allergy Safety, Treatment, Education and Research (FASTER) Act, making sesame the ninth allergen
- Effective for foods are introduced or delivered for introduction into interstate commerce on or after January 1, 2023
- Also requires that FDA collect data on the prevalence of food allergies and prepare a report to Congress on the development of effective food allergy diagnostics, the prevention of food allergies, and the scientific criteria for defining a food or food ingredient as a “major food allergen”

New FDA Draft Guidance

- Draft guidance, "Evaluating the Public Health Importance of Food Allergens Other Than the Major Food Allergens Listed in the Federal Food, Drug, and Cosmetic Act" send to OMB on 2/10/22. See Pending EO 12866 Regulatory Review (reginfo.gov).

- A copy of the draft guidance is not yet available but it is being published in response to requirements set forth in the FASTER Act.

- The draft guidance will presumably explain how FDA intends to approach the treatment of new allergens that emerge and how to prioritize new allergens.

Allergen Best Practices

- Make sure food safety plan adequately address allergen hazards
- Have a system to check allergen statements for all ingredients used in the finished product
- Check allergen labeling when new ingredient or new supplier is used
- Confirm you have appropriate substantiation for allergen-free claims
- Ensure the “contains” statement includes all allergens in the product
- Check if dairy ingredients are used that milk is declared somewhere

New FDA Guidance

- Additional food safety related guidance (draft and final) expected by December 2022
  - Questions and Answers Regarding Food Allergens, Including the Food Allergen Labeling and Consumer Protection Act of 2004 (Edition 5); Draft Guidance for Industry
  - Action Levels for Lead in Juice; Draft Guidance for Industry
  - Inorganic Arsenic in Apple Juice: Action Level; Guidance for Industry
  - Action Levels for Lead in Food Intended for Babies and Young Children; Draft Guidance for Industry
  - Compliance Policy Guide Sec. 555.320 Listeria monocytogenes in Human Food; Draft Guidance for FDA Staff
  - Premarket Consultation on Cultured Animal Cell Foods: Draft Guidance for Industry

Foods Program Guidance Under Development | FDA

Thank You

Any questions?

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FDLI Food and Dietary Supplement Safety and Regulation Conference

Food Ingredients and Food Contact Substances

Assessing the U.S. Approach to Safety

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Nury Yoo helps clients in the food and beverage, fresh produce, cosmetics, dietary supplement, OTC drug, personal care, medical device, restaurant, and alcohol beverage industries to navigate regulations, anticipate and manage risk, and defend against challenges. Her areas of focus include regulatory compliance, labeling, claims and substantiation, marketing and advertising, food safety, product recalls, due diligence reviews for private investment, consumer and competitor challenges, and California's Proposition 65. She also advises clients on the complex federal and state issues in the use of cannabidiol (CBD) and related cannabinoids in consumer products.

As a litigator, Nury represented clients in state and federal trial and appellate courts. Clients now seek her counsel on litigation risk analysis and management, negotiation of pre-dispute demands, and strategy in active litigation.

Legal Disclaimer

- This presentation provides information about the law. Legal information is not the same as legal advice, which involves the application of law to an individual's specific circumstances. The interpretation and application of the law to an individual's specific circumstance depends on many factors. This presentation is not intended to provide legal advice.
- The information provided in this presentation is drawn entirely from publicly available information. The views expressed in this presentation are mine alone.

Why do allergens continue to persist as a major basis for recalls?

- Supply Chain and Manufacturing (processing, cross-contact, adulteration, misbranding, hidden allergens)
- Innovation (new processing methods, ingredients)
- Cross-reactivity and emerging allergens
- Increasing State involvement and consumer impact
- Unknown (information gaps, evolving data, regional variation, demographics, beyond the Top 9)

Supply Chain and Manufacturing

- Supply Chain (cross-contact, storage, adulteration, processing)
- Manufacturing (cross-contact, storage, adulteration, processing)
- Undeclared – labeling errors and omissions
- Hidden allergens

Potential Hidden Allergens

Dark chocolate

Flavorings
Spices

Lecithin

Binders
Coagulants
Thickeners
Stabilizers
Bulking Agents
Emulsifiers

MSG

Dressings

Whey

Textured or Hydrolized Protein

Caseinate

Margarine

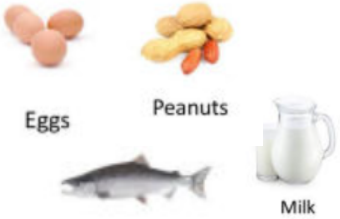
Potential Hidden Allergens

Lecithin

Whey

Caseinate

Dressings



Binders
Coagulants
Thickeners
Stabilizers
Bulking Agents
Emulsifiers

Margarin

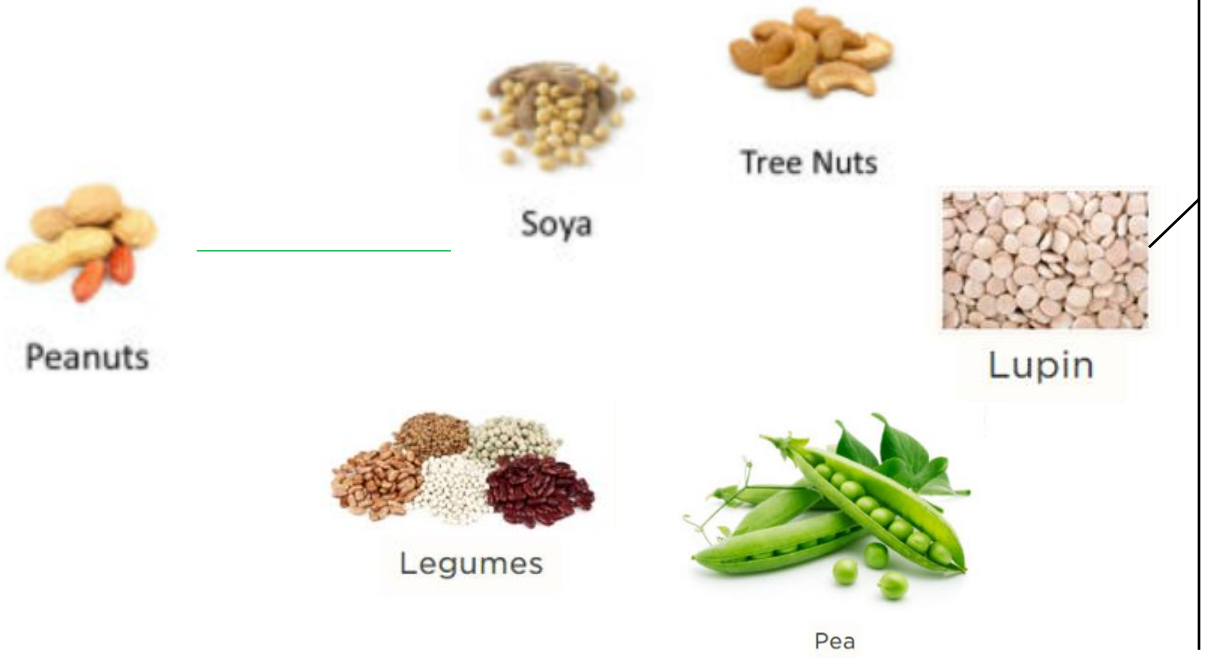
Flavorings

Dark chocolate

MSG

Textured or Hydrolyzed Protein

Potential Cross-Reactivity



FDA Consumer Advice on Lupin (1/4/18)

"People who are allergic to peanuts may also be allergic to lupin, a legume belonging to the same plant family as peanuts (also spelled lupine or lupini). These reactions can be severe and life threatening.

If you are allergic to peanuts, you should be aware of the potential for a reaction to lupin.

Lupin can be eaten as a whole bean, but lupin flour is increasingly used in baked goods and pasta, especially gluten-free products.

To identify products that contain lupin, look for it by name in the ingredient list on the label."

"Lupin beans and lupin-containing products are commonly eaten in Europe, where they are recognized as a potential allergen and are labeled as such.

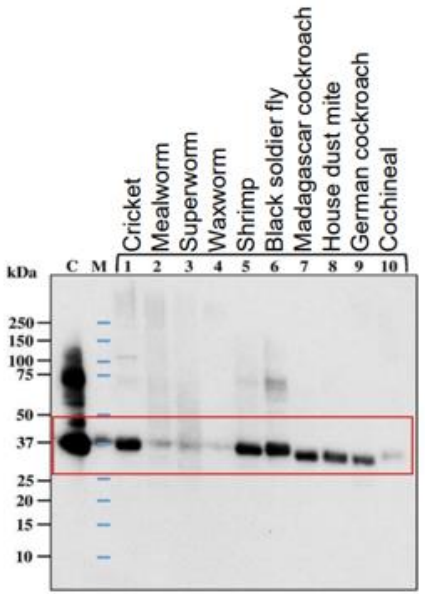
This labeling is not currently required in the US, so consumers allergic to peanuts need to know to check for lupin in the ingredients list on the label."

Potential Cross-Reactivity

Crustacean
Shellfish

Mollusks

Insects
(Tropomyosin, Chitin, etc.)



U.S. FDA
@US_FDA

Yep! We have to say it!

Don't eat #cicadas if you're allergic to seafood as these insects share a family relation to shrimp and lobsters. go.usa.gov/xHg69

10:00 AM · Jun 2, 2021 · Sprout Social

1,150 Retweets **1,294** Quote Tweets **1,939** Likes

Isolated/Concentrated Proteins

Pea

INGREDIENTS

Water, pea protein*, expeller-pressed canola oil, refined coconut oil, rice protein, natural flavors, dried yeast, cocoa butter, methylcellulose, and less than 1% of potato starch, salt, potassium chloride, beet juice color, apple extract, pomegranate concentrate, sunflower lecithin, vinegar, lemon juice concentrate, vitamins and minerals (zinc sulfate, niacinamide [vitamin B3], pyridoxine hydrochloride [vitamin B6], cyanocobalamin [vitamin B12], calcium pantothenate).

*Peas are legumes. People with severe allergies to legumes like peanuts should be cautious when introducing pea protein into their diet because of the possibility of a pea allergy. Contains no peanuts or tree nuts.

State Recall Activity

NEW YORK STATE Services

Department of Agriculture and Markets

The recall was initiated after routine sampling by New York State Department of Agriculture and Markets Food Inspectors and subsequent analysis by Food Laboratory personnel revealed the presence of undeclared milk allergens in the 4 ounce packages of "Kopper's Dark Chocolate Gummy Bears" which did not declare a milk ingredient on the label.

EXAMPLES OF CLASS I RECALL SITUATIONS

- LISTERIA MONOCYTOGENES
- CONFIRMED CLOSTRIDIUM BOTULINUM
- E. COLI O157:H7
- ALL SALMONELLA IN READY-TO-EAT FOODS
- UNDECLARED PEANUTS
- UNDECLARED TREE NUTS
  (Pecans, Hazelnuts or Filberts, Walnuts, Cashews and Brazil Nuts)
- UNDECLARED EGGS *(250 ppm or greater)*
  (Protein, Albumen, Yolk, Etc.)
- UNDECLARED FISH
- UNDECLARED MILK PROTEINS
  All foods (150 ppm or greater
  Dark Chocolate only (600 ppm or greater)*

*Note: Consistent with the FDA, action will be taken on products that are labeled as "dairy free" or have other similar "free-of-milk" claims. https://www.fda.gov/food/sampling-protect-food-supply/fy1819-sample-collection-and-analysis-domestically-manufactured-dairy-free-dark-chocolate-products

- UNEVISCERATED FISH *(Kapchunka)*
- UNDECLARED SULFITES
  (10 MG. or More Per Serving)
- UNDECLARED SHELLFISH
  (Crustaceans and Mollusks)
- UNDECLARED SOY
  *(*Soybeans, soy protein, and soy flour; does not include soy oil*)*
- LEAD LEVELS *(above 25 ppm)*

Thank you!

Any questions?

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