Processed and Ultra-Processed Foods Science and Regulation

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Health Sciences

J.S. Held

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OUTLINE

- Company Overview
- Food Processing
- Ultra-Processed Food
- Food Safety and Regulation
- Impact of Science

OUR COMPANY OVERVIEW

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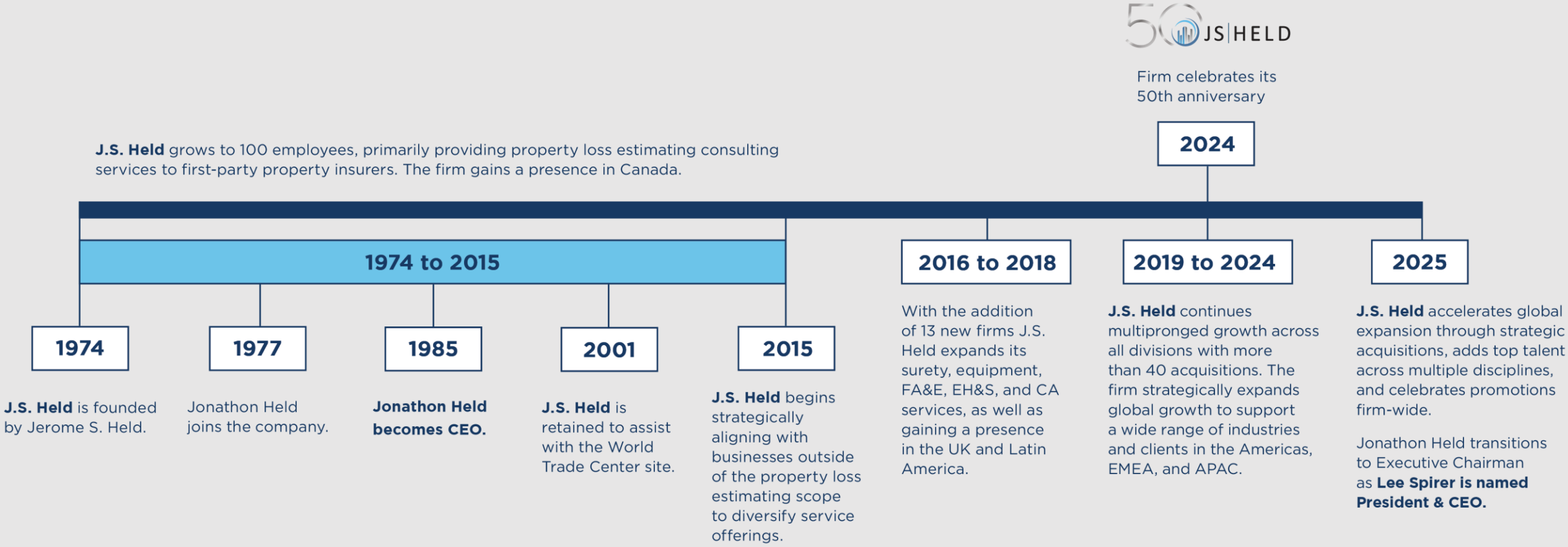
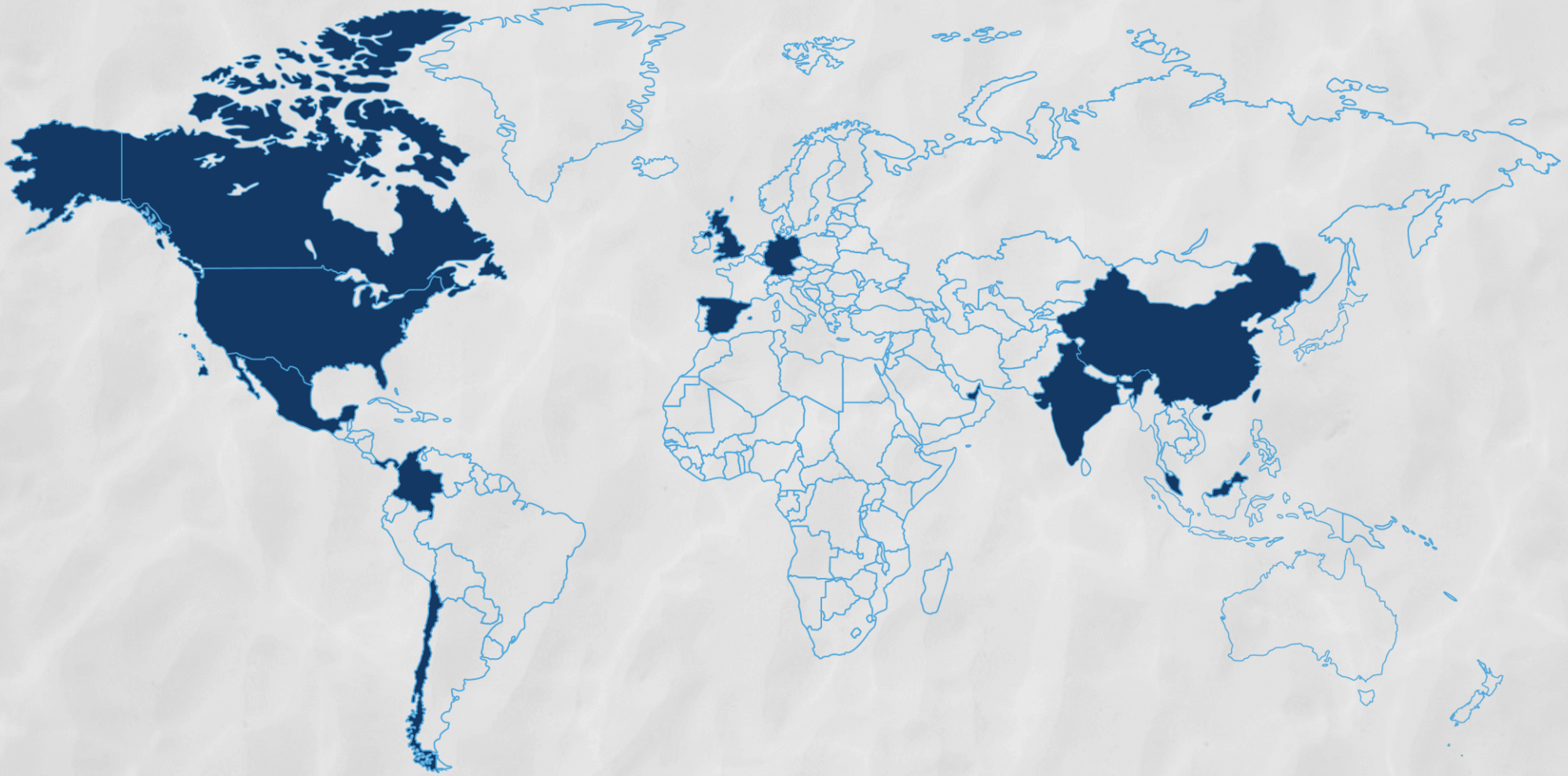
OUR HISTORY


Firm celebrates its 50th anniversary
2024
J.S. Held grows to 100 employees, primarily providing property loss estimating consulting services to first-party property insurers. The firm gains a presence in Canada.
1974 to 2015
1974
J.S. Held is founded by Jerome S. Held.
1977
Jonathon Held joins the company.
1985
Jonathon Held becomes CEO.
2001
J.S. Held is retained to assist with the World Trade Center site.
2015
J.S. Held begins strategically aligning with businesses outside of the property loss estimating scope to diversify service offerings.
2016 to 2018
With the addition of 13 new firms J.S. Held expands its surety, equipment, FA&E, EH&S, and CA services, as well as gaining a presence in the UK and Latin America.
2019 to 2024
J.S. Held continues multipronged growth across all divisions with more than 40 acquisitions. The firm strategically expands global growth to support a wide range of industries and clients in the Americas, EMEA, and APAC.
2025
J.S. Held accelerates global expansion through strategic acquisitions, adds top talent across multiple disciplines, and celebrates promotions firm-wide.
Jonathon Held transitions to Executive Chairman as Lee Spirer is named President & CEO.

MARKETS & INDUSTRIES WE SERVE

- Aerospace
- Agriculture
- Aviation
- Cannabis
- Construction
- Consumer Products & Services
- Cyber
- Education
- Energy & Power
- Financial Services
- Food & Beverage
- Government
- Healthcare
- Hospitality
- Industrial & Manufacturing
- Insurance
- Private Equity
- Real Estate
- Retail
- Seismic
- Technology, Media & Telecommunications
- Transportation Infrastructure

OUR OFFICES



- CANADA
- CHILE
- CHINA
- COLOMBIA
- GERMANY
- INDIA
- MALAYSIA
- MEXICO
- SINGAPORE
- SPAIN
- UNITED ARAB EMIRATES
- UNITED KINGDOM
- USA

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OUR EXPERTS WORK WITH:

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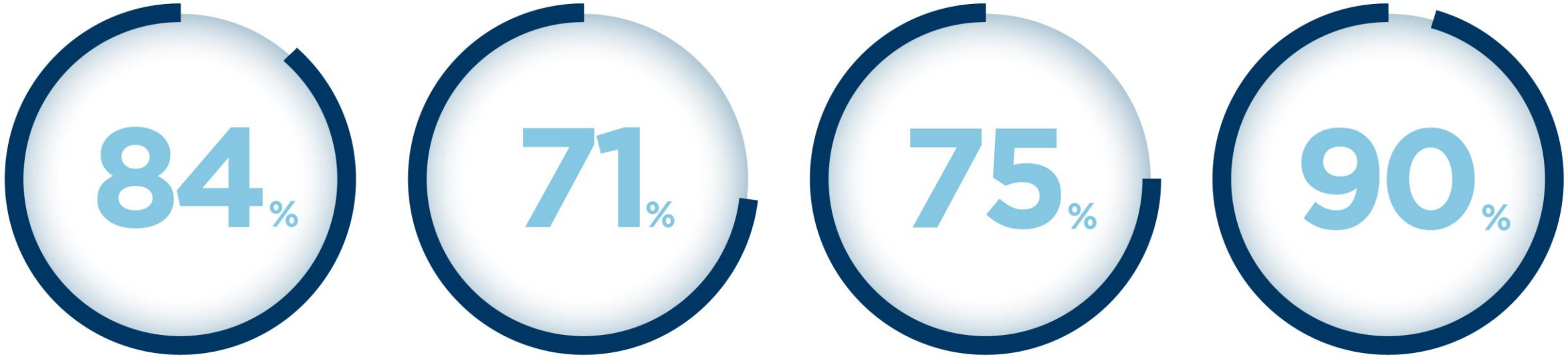

of the Global 200 Law Firms

of Fortune 100 Companies

of Forbes Top 20 Insurance Companies

of the NAIC Top 50 Property & Casualty Insurers

ENVIRONMENTAL HEALTH & SAFETY

Our practice group's expertise & service offerings is driven by an advisory, legal, regulatory and risk-based framework associated with the environment, human health & safety, and regulatory compliance.

FOOD IS PROCESSED

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FOOD PRODUCTION

- Familiar

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FOOD PRODUCTION

- Industrial Scale

FOOD INGREDIENTS

- Familiar

FOOD INGREDIENTS

- Industrial Scale

FOOD RECIPE

- Familiar

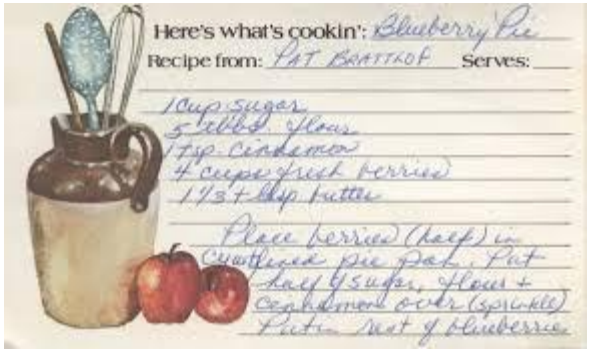
CHOCOLATE CHIP COOKIE BARS

INGREDIENTS

- ½ cup unsalted butter, melted
- 1 cup packed brown sugar
- 1 large egg
- 1 teaspoon vanilla extract
- 1 cup semi-sweet chocolate chips

INSTRUCTIONS

1. Preheat oven to 350°F (175°C). Grease a 9x9 inch baking pan, or line with parchment paper.
2. In a large bowl, mix melted butter and brown sugar until combined. Beat in egg and vanilla.
3. Stir in flour, baking powder, and salt, then fold in chocolate chips.
4. Spread the dough evenly in the prepared pan and bake for 20-25 minutes, until golden brown. Let cool before slicing.



Here's what's cookin': Blueberry Pie
Recipe from: PAT BRATTON Serves:
1 cup sugar
5 Tbls. flour
1 tsp. cinnamon
4 cups fruit berries
1½ + tbsp butter
Place berries (cheap) in
Crustless pie pan. Put
half ½ sugar, flour +
cinnamon over (sprinkle)
Put on rest ½ blueberries

FOOD RECIPE

- Industrial Scale

FOOD PROCESSING CONCEPTS: INSTITUTE OF FOOD TECHNOLOGISTS

- Institute of Food Technologists (IFT) - Founded in 1939 and is a global community working across industry, academia, and government reaching thousands of professionals at more than 3,000 companies, 500 universities, and 90 countries (https://www.ift.org/)
- IFT Food Processing Toolkit Resource (https://www.ift.org/policy-and-advocacy/advocacy/toolkits/food-processing)
  - **What is processed food? -** The combination of food ingredients (food formulation) and use of processing step(s) to design a food product with particularly desired attributes (formulated food) is termed as processed food).
  - **What is the need for processing food? -** Since before recorded history, mankind has been processing food to preserve it for later consumption (e.g., drying meat), make it more convenient to use or handle (e.g., grinding wheat into flour), and/or make seasonal produce available year-round (e.g., drying fruits or canning vegetables). Every day, most people employ simple (such as cooking eggs and toasting bread) or complex (e.g., preparing a multi-step, yeast-leavened sweet bread) processes to prepare food. Food processing makes it easier to provide shelf-stable, convenient to use, and tasty/palatable food products. Food processing also enables the delivery of a consistent food ingredient for repeated use. Food processing leads to a much more consistent end use as well as a continuous supply of ingredients and food products.
  - **Are there different types of food processes? -** There are a wide variety of food processes across a range involving one or a combination of steps (unit operations) that can be done from the scale of a home kitchen to large production factories employing thousands of people. Often, numerous food processing steps are used in concert with a variety of ingredients to create food products that are safe to consume even 12-18 months later, while still retaining the taste, texture, nutritional value, and appearance, thus becoming a processed food. Processed foods are often easier to store and transport, including exporting to other countries.
  - **Are there misconceptions about food processing? -** Most of us have a fundamental understanding of food processing primarily through our experiences at home but are unaware or know very little about the complexities associated with industrial food processing to make food products that are purchased frequently at grocery stores. Hence for many, it is a mystery. Ingredients such as flour, roasted coffee, and cooking oil, and food products like jams, canned vegetables, and ready-to-eat shelf-stable dinners all undergo food processing.

ULTRA-PROCESSED FOODS OVERVIEW: WHAT'S THE CONCERN

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WHAT ARE ULTRA-PROCESSED FOODS????

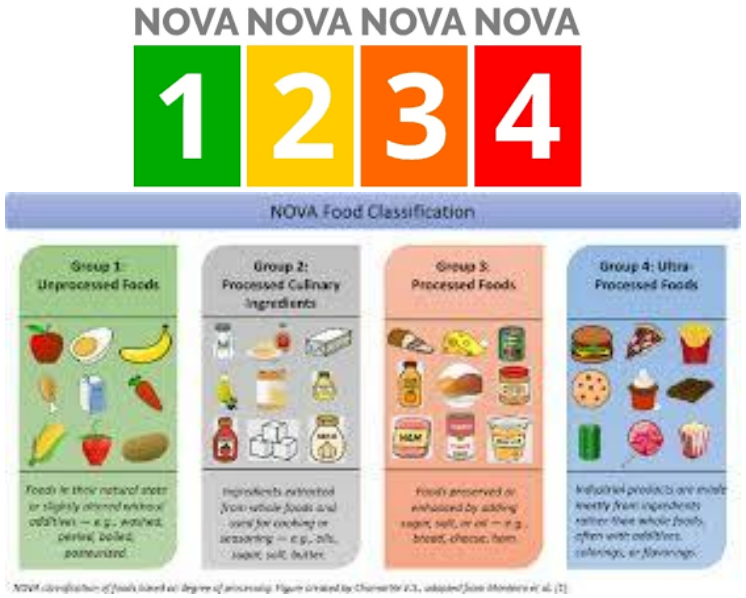
Ultra-processed foods have one or more ingredients that wouldn't be found in a kitchen, like chemical-based preservatives, emulsifiers like hydrogenated oils, sweeteners like high fructose corn syrup, and artificial colors and flavors. UPFs undergo processing techniques like pre-frying, molding, extrusion, fractioning, and other chemical alterations that leave the final products bearing almost no resemblance to the original ingredients.

These are formulated mostly or entirely from ingredients and typically contain no whole foods.

Industrial formulations typically with 5 or more and usually many ingredients.

'If You Can't Pronounce It, Don't Eat It'

Portugese: *nova classificação*, 'new classification'



Processed meat refers to meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavour or improve preservation. Most processed meats contain pork or beef, but processed meats may also contain other red meats, poultry, offal, or meat by-products such as blood. Examples of processed meat include hot dogs (frankfurters), ham, sausages, corned beef, and biltong or beef jerky as well as canned meat and meat-based preparations and sauces.

The FDA is working with the U.S. Department of Agriculture (USDA) as part of a joint effort to develop a uniform definition of UPFs. Establishing a uniform definition will enable federal agencies and others to develop consistent policies and programs focused on UPFs.

U.S. Health Secretary Robert F. Kennedy Jr. (RFK Jr.) – a federal definition for "ultra-processed foods" (UPFs) is coming as soon as April 2026.

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WHOLE FOODS ????

AN ALL-NATURAL BANANA

INGREDIENTS: WATER (75%), **SUGARS (12%)** (GLUCOSE (48%), FRUCTOSE (40%), SUCROSE (2%), MALTOSE (<1%)), STARCH (5%), FIBRE E460 (3%), **AMINO ACIDS (<1%)** (GLUTAMIC ACID (19%), ASPARTIC ACID (16%), HISTIDINE (11%), LEUCINE (7%), LYSINE (5%), PHENYLALANINE (4%), ARGININE (4%), VALINE (4%), ALANINE (4%), SERINE (4%), GLYCINE (3%), THREONINE (3%), ISOLEUCINE (3%), PROLINE (3%), TRYPTOPHAN (1%), CYSTINE (1%), TYROSINE (1%), METHIONINE (1%)), **FATTY ACIDS (1%)** (PALMITIC ACID (30%), OMEGA-6 FATTY ACID: LINOLEIC ACID (14%), OMEGA-3 FATTY ACID: LINOLENIC ACID (8%), OLEIC ACID (7%), PALMITOLEIC ACID (3%), STEARIC ACID (2%), LAURIC ACID (1%), MYRISTIC ACID (1%), CAPRIC ACID (<1%)), ASH (<1%), PHYTOSTEROLS, E515, OXALIC ACID, E300, E306 (TOCOPHEROL), PHYLLOQUINONE, THIAMIN, **COLOURS** (YELLOW-ORANGE E101 (RIBOFLAVIN), YELLOW-BROWN E160a), **FLAVOURS** (3-METHYLBUT-1-YL ETHANOATE, 2-METHYLBUTYL ETHANOATE, 2-METHYLPROPAN-1-OL, 3-METHYLBUTYL-1-OL, 2-HYDROXY-3-METHYLETHYL BUTANOATE, 3-METHYLBUTANAL, ETHYL HEXANOATE, ETHYL BUTANOATE, PENTYL ACETATE), 1510, NATURAL RIPENING AGENT (ETHENE GAS).

WHAT ARE ULTRA-PROCESSED FOODS (UPF)?

NOVA - Professor Carlos Monteiro and team, Center for Epidemiological Studies in Health and Nutrition, School of Public Health, University of São Paulo (2009)
Portugese: nova classificação, 'new classification')

Definition and Composition

Ultra-processed foods are industrially made from refined ingredients and additives, often unlike traditional foods.

Processing Techniques

UPFs undergo multiple processing steps like extrusion and hydrogenation altering their original food materials.

Characteristics and Examples

UPFs are hyper-palatable, convenient, affordable, and include snacks, beverages, ready meals, and baked goods.

Regulatory Challenges

Defining UPFs consistently is difficult; agencies work to develop uniform definitions for policy and research.

The FDA is working with the U.S. Department of Agriculture (USDA) as part of a joint effort to develop a uniform definition of UPFs. Establishing a uniform definition will enable federal agencies and others to develop consistent policies and programs focused on UPFs

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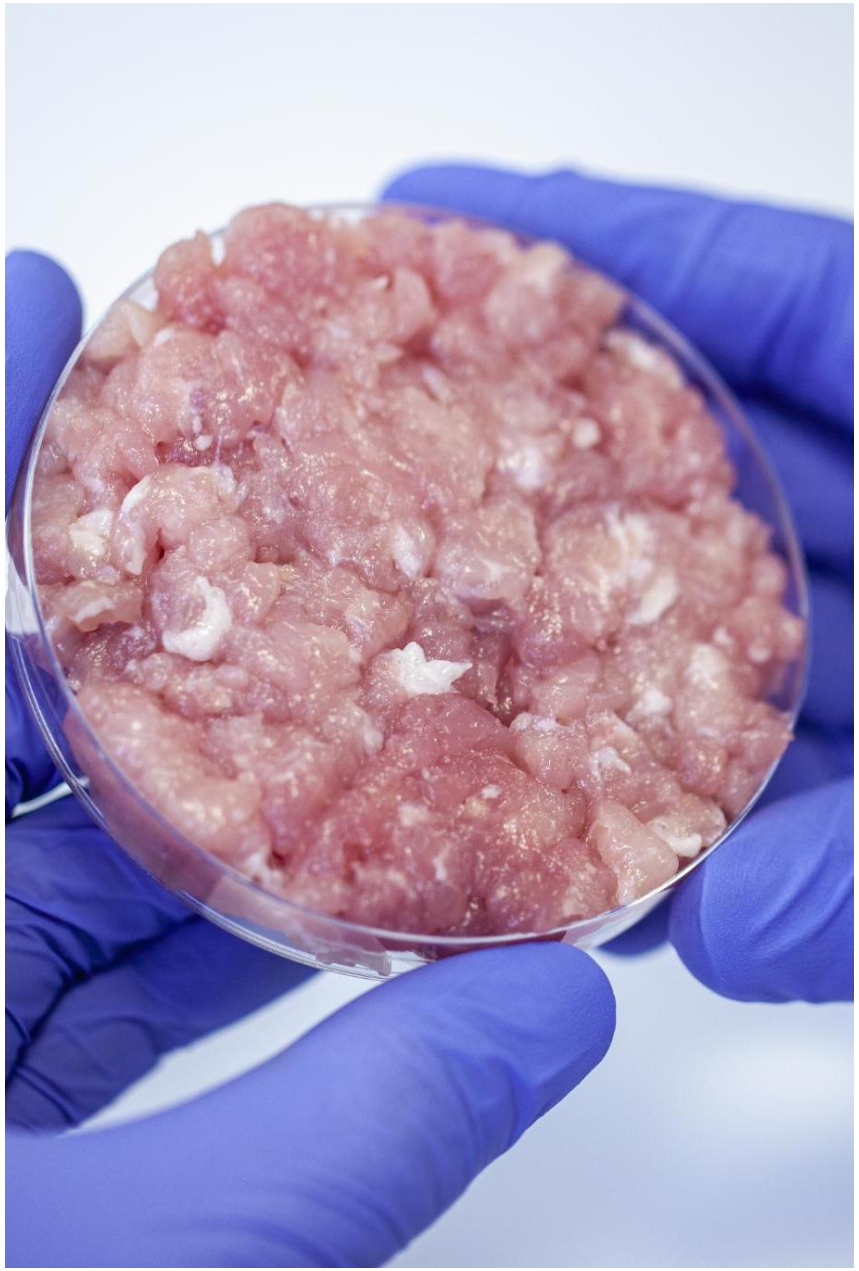

IARC CLASSIFICATIONS, CANCER EVIDENCE, AND IMPLICATIONS FOR ULTRA-PROCESSED FOODS

Processed Meat Definition

Processed meat refers to meat that has been transformed through salting, curing, fermentation, smoking, or other processes to enhance flavor or improve preservation. Most processed meats contain pork or beef, but may also include other red meats, poultry, offal, or meat by-products such as blood.

The World Health Organization's International Agency for Research on Cancer (IARC) Carcinogenic Classifications

IARC classifies **processed meat as Group 1 carcinogen** and **red meat as Group 2A**, indicating varying cancer risks.

Mechanisms of Carcinogenesis

Carcinogenic risks stem from compounds formed during curing and cooking, including nitroso compounds and aromatic amines.

Source: IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, Volume 114 – Red Meat and Processed Meat (2018); EPIC and related cohort studies. https://www.aicr.org/resources/blog/bacon-hot-dogs-and-lunch-meat-is-it-processed-meat/

NUTRIENTS AND OVERALL DIET QUALITY

Impact of Ultra-Processed Foods

High consumption of ultra-processed foods lowers intake of fiber, protein, vitamins, and essential minerals.

Nutrient Quality Decline

Increased ultra-processed food intake correlates with overall decline in diet quality in population studies.

Beneficial Processed Foods

Some processed foods like whole-grain cereals and fortified dairy provide important nutrients and support diet needs.

Challenges in Diet Assessment

Diet-quality indices often overlook food processing degree and calorie intake, complicating nutrition research.

HEALTH IMPACTS AND EVIDENCE SUMMARY

Health Risks of Ultra-Processed Foods

High intake of ultra-processed foods is linked to increased risks of mortality, cardiovascular disease, Type 2 diabetes, and mortality and cancer incidence, with varying risks across food types.

Limitations of Current Evidence

Most studies are observational with potential biases and confounding factors limiting definitive causal conclusions.

Proposed Biological Mechanisms

Mechanisms include poor nutrient profiles, additives exposure, altered satiety, and packaging contaminants affecting health.

Dietary Guidance

Experts recommend prioritizing nutrient-dense foods while considering convenience, accessibility, and affordability factors.

Emerging Research Pathways

Research investigates additives, contaminants, nutrient displacement, and combined effects as mechanisms in cancer risk from UPFs.

FOOD REGULATION AND SAFETY PRINCIPLES

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FOOD SAFETY AND REGULATION - TOXICOLOGY

- Food Chemical Hazards – The Dose Makes the Poison
  - All things are poison, and nothing is without poison; the dosage alone makes it so a thing is not a poison. —Paracelsus, 1538

  - Concept applies to ingredients seen as beneficial (vitamins and minerals)

FDA Publish Date: August 08, 2024

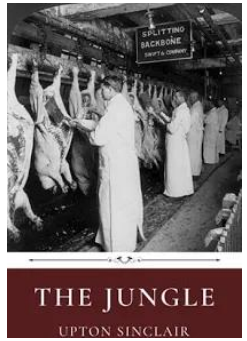
Product Type: Food & Beverages
Infant Formula & Foods

Reason for Announcement: Product contains levels of Vitamin D above the maximum level permitted

https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-issues-voluntary-recall-one-batch-premium-infant-formula-iron-milk-based-powder-due-elevated

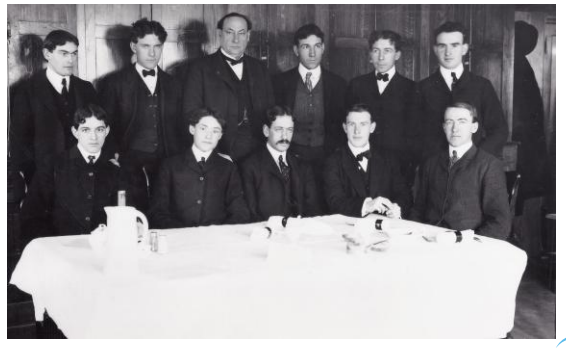
FOOD ADDITIVES – A HISTORY OF CONCERN

- Upton Sinclair's *The Jungle* (1906) described conditions workers faced in meatpacking factories, calling attention the unsanitary factory conditions, and noted the addition of chemicals, dead rats, and saw dust to meat products



- The "Poison Squad" (1912)
  - Harvey Wiley M.D. USDA Bureau of Chemistry

  - Twelve healthy young men volunteered, "Poison Squad", who ate chemicals used in foods and adulterated foods
  - Experiment lasted five years
  - Outcome – formaldehyde use as a preservative in food banned



FOOD REGULATIONS - EU

- **Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives** - https://eur-lex.europa.eu/eli/reg/2008/1333/oj
  - Food additives should be approved and used only if they fulfil the criteria laid down in this Regulation. Food additives must be safe when used, there must be a technological need for their use, and their use must not mislead the consumer and must be of benefit to the consumer. Misleading the consumer includes, but is not limited to, issues related to the nature, freshness, quality of ingredients used, the naturalness of a product or of the production process, or the nutritional quality of the product, including its fruit and vegetable content. The approval of food additives should also take into account other factors relevant to the matter under consideration including societal, economic, traditional, ethical and environmental factors, the precautionary principle and the feasibility of controls.
- **Precautionary principle** - https://food.ec.europa.eu/horizontal-topics/general-food-law/food-law-general-principles_en
  - Article 7 of the General Food Law
  - Reasonable grounds for concern that an unacceptable level of risk to health exists
  - Available supporting information and data are not sufficiently complete to enable a comprehensive risk assessment to be made
  - Decision makers or risk managers may take measures or other actions based on the precautionary principle, while seeking more complete scientific and other data.
- **Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety** - https://eur-lex.europa.eu/eli/reg/2002/178/oj
  - For the purposes of this Regulation, "food" (or "foodstuff") means any substance or product, whether processed, partially processed or unprocessed, intended to be, or reasonably expected to be ingested by humans.
  - "Food" includes drink, chewing gum and any substance, including water, intentionally incorporated into the food during its manufacture, preparation or treatment. It includes water after the point of compliance as defined in Article 6 of Directive 98/83/EC and without prejudice to the requirements of Directives 80/778/EEC and 98/83/EC.
  - "Food" shall not include:
  - (a) feed;
  - (b) live animals unless they are prepared for placing on the market for human consumption;
  - (c) plants prior to harvesting;
  - (d) medicinal products within the meaning of Council Directives 65/65/EEC(21) and 92/73/EEC(22);
  - (e) cosmetics within the meaning of Council Directive 76/768/EEC(23);
  - (f) tobacco and tobacco products within the meaning of Council Directive 89/622/EEC(24);
  - (g) narcotic or psychotropic substances within the meaning of the United Nations Single Convention on Narcotic Drugs, 1961, and the United Nations Convention on Psychotropic Substances, 1971;
  - (h) residues and contaminants.

FOOD REGULATIONS - EU

- **Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety - https://eur-lex.europa.eu/eli/reg/2002/178/oj**
  - SECTION 4; GENERAL REQUIREMENTS OF FOOD LAW: Article 14
  - Food safety requirements
  - 1. Food shall not be placed on the market if it is unsafe.
  - 2. Food shall be deemed to be unsafe if it is considered to be:
  - (a) injurious to health; (b) unfit for human consumption.
  - 3. In determining whether any food is unsafe, regard shall be had:
  - (a) to the normal conditions of use of the food by the consumer and at each stage of production, processing and distribution, and
  - (b) to the information provided to the consumer, including information on the label, or other information generally available to the consumer concerning the avoidance of specific adverse health effects from a particular food or category of foods.
  - 4. In determining whether any food is injurious to health, regard shall be had:
  - (a) not only to the probable immediate and/or short-term and/or long-term effects of that food on the health of a person consuming it, but also on subsequent generations;
  - (b) to the probable cumulative toxic effects;
  - (c) to the particular health sensitivities of a specific category of consumers where the food is intended for that category of consumers.
  - 5. In determining whether any food is unfit for human consumption, regard shall be had to whether the food is unacceptable for human consumption according to its intended use, for reasons of contamination, whether by extraneous matter or otherwise, or through putrefaction, deterioration or decay.
  - 6. Where any food which is unsafe is part of a batch, lot or consignment of food of the same class or description, it shall be presumed that all the food in that batch, lot or consignment is also unsafe, unless following a detailed assessment there is no evidence that the rest of the batch, lot or consignment is unsafe.
  - 7. Food that complies with specific Community provisions governing food safety shall be deemed to be safe insofar as the aspects covered by the specific Community provisions are concerned.
  - 8. Conformity of a food with specific provisions applicable to that food shall not bar the competent authorities from taking appropriate measures to impose restrictions on it being placed on the market or to require its withdrawal from the market where there are reasons to suspect that, despite such conformity, the food is unsafe.
  - 9. Where there are no specific Community provisions, food shall be deemed to be safe when it conforms to the specific provisions of national food law of the Member State in whose territory the food is marketed, such provisions being drawn up and applied without prejudice to the Treaty, in particular Articles 28 and 30 thereof.

FOOD ADDITIVES - EU

- **Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives** - https://eur-lex.europa.eu/eli/reg/2008/1333/oj
  - Defines as "any substance not normally consumed as a food in itself and not normally used as a characteristic ingredient of food, whether or not it has nutritive value, the intentional addition of which to food for a technological purpose in the manufacture, processing, preparation, treatment, packaging, transport or storage of such food results, or may be reasonably expected to result, in it or its by-products becoming directly or indirectly a component of such foods;"
  - Not considered to be food additives

    (i) monosaccharides, disaccharides or oligosaccharides and foods containing these substances used for their sweetening properties;
    (ii) foods, whether dried or in concentrated form, including flavourings incorporated during the manufacturing of compound foods, because of their aromatic, sapid or nutritive properties together with a secondary colouring effect;
    (iii) substances used in covering or coating materials, which do not form part of foods and are not intended to be consumed together with those foods;
    (iv) products containing pectin and derived from dried apple pomace or peel of citrus fruits or quinces, or from a mixture of them, by the action of dilute acid followed by partial neutralisation with sodium or potassium salts (liquid pectin);
    (v) chewing gum bases;
    (vi) white or yellow dextrin, roasted or dextrinated starch, starch modified by acid or alkali treatment, bleached starch, physically modified starch and starch treated by amylolitic enzymes;
    (vii) ammonium chloride;
    (viii) blood plasma, edible gelatin, protein hydrolysates and their salts, milk protein and gluten;
    (ix) amino acids and their salts other than glutamic acid, glycine, cysteine and cystine and their salts having no technological function;
    (x) caseinates and casein;
    (xi) inulin
  - Twenty-six classes of food additives in foods and of food additives in food additives and food enzymes

Sweeteners	Acidity regulators	Firming agents	Modified starches	Thickeners
Colours	Anti-caking agents	Flavour enhancers	Packaging gases	Flour treatment agents
Preservatives	Anti-foaming agents	Foaming agents	Propellants'	
Antioxidants	Bulking	Gelling agents	Raising agents	
Carriers	Emulsifiers	Glazing agents	Sequestrants	
Acids	Emulsifying salts	Humectants	Stabilisers	

U.S. FOOD SAFETY LAW & POLICY HISTORICAL CONTEXT

1862 – USDA Division of Chemistry

- **1906 Pure Food and Drugs Act**
  - Prohibited adulterated/ misbranded food and drugs
  - Regulation of product labeling

1930 – FDA (USDA)

- **1938 FD&C Act (Federal Food, Drugs and Cosmetic Act)**
  - Legally enforceable food standards of identity, quality
  - Provided for safe tolerances to be set for "unavoidable" poisonous substances

1940 – FDA (DHHS)

- **USDA FSIS** maintains jurisdiction over commercial meat, poultry, and eggs
- **1949 First FDA guidance to industry** Procedures for the Appraisal of the Toxicity of Chemicals in Food
- **Amendments to FFDCA**

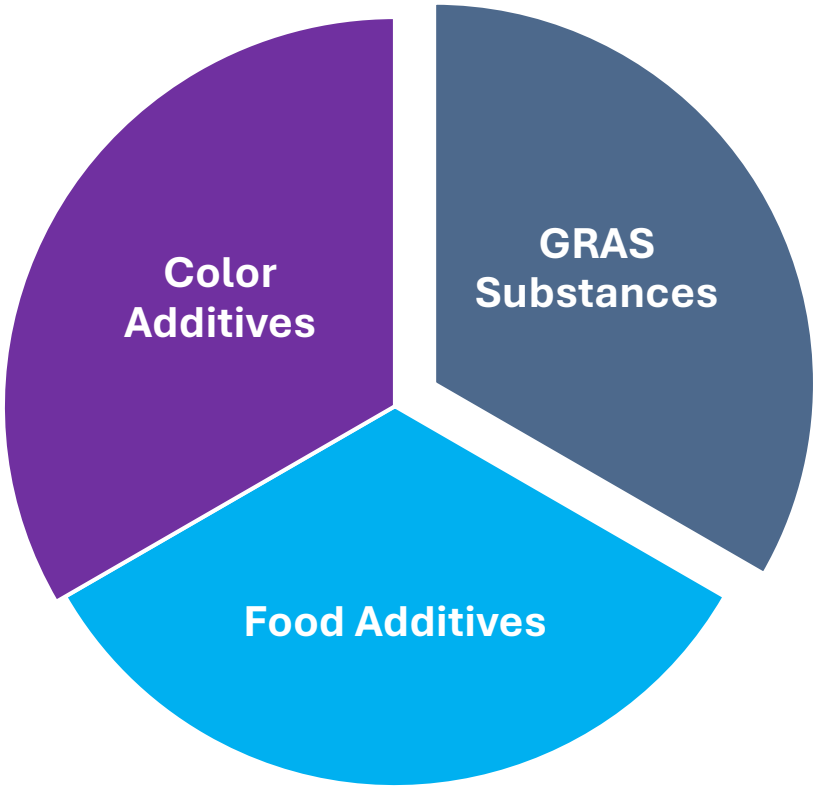
1950 – Congress

- **Food Additives Amendment 1958** requires industry to establish safety of new food additives
- **Delaney Clause** prohibits the approval of any food additive shown to induce cancer in humans or animals
- **Established GRAS** list contained over 370 food substances

FOOD ADDITIVES - US

- **Food Additive** - A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not GRAS or sanctioned prior to 1958 or otherwise excluded from the definition of food additives.
- **Color Additive** - A color additive is a dye, pigment or other substance, which is capable of imparting color when added or applied to a food, drug, cosmetic, or to the human body. The legal definition can be found in Section 201(t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides exclusions as well. Color additives for use in food, drugs, and cosmetics require premarket approval.
- **GRAS** - "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise exempted from the definition of a food additive. GRAS substances are distinguished from food additives by the type of information that supports the GRAS conclusion, that it is publicly available and generally accepted by the scientific community, but should be the same quantity and quality of information that would support the safety of a food additive.
- **Food ingredients** must meet the same safety standard regardless of whether they are naturally or artificially derived.
- **Prior Sanctioned Food Ingredients**
  - 21 CFR § 181.5 - A prior sanction shall exist only for a specific use(s) of a substance in food, i.e., the level(s), condition(s), product(s), etc., for which there was explicit approval by the Food and Drug Administration or the United States Department of Agriculture prior to September 6, 1958
  - 21 CFR § 181.1 - Based upon scientific data or information that shows that use of a prior-sanctioned food ingredient may be injurious to health, and thus in violation of section 402 of the Act, the Commissioner will establish or amend an applicable prior sanction regulation to impose whatever limitations or conditions are necessary for the safe use of the ingredient, or to prohibit use of the ingredient

US FOOD INGREDIENT CATEGORIES



Direct	Secondary Direct	Indirect

32

US Food Additive Categories

Examples

Direct Food Additive	Secondary Direct Food Additive	Indirect Food Additive
Sucralose may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect [21 CFR §172.210].	***Candida lipolytica*** may be safely used as the organism for fermentation production of citric acid in accordance with the conditions of 21 CFR §173.165.	**Acrylate ester copolymer coating** may safely be used as a food-contact surface of articles intended for packaging and holding food, including heating of prepared food [21 CFR §175.210].

33

FOOD REGULATIONS - US

Federal Food, Drug, and Cosmetic Act (FD&C Act)

(Title 21 Chapter 9 of the United States Code)

- ‘‘**food**’’ means (1) articles **used for food or drink for man or other animals**, (2) chewing gum, and (3) articles used…
- ‘‘**dietary supplement**’’ - (1) means a product (other than tobacco) **intended to supplement the diet** that bears or contains one or more of the following dietary ingredients: (A) a vitamin; (B) a mineral; (C) an herb or other botanical; (D) an amino acid; (E) a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or (F) a concentrate, metabolite, constituent, extract, or combination of any ingredient described…”
- **"cosmetic"** means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise **applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance**, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.
- ‘‘**drug**’’ means (A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; (B) **articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals**; and (D) articles intended for use as a component of any articles specified in clause for components of any such article…

SAFETY STANDARDS - US

Food & Dietary Supplements

"Safe or *safety* means that there is 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." (21 CFR 170.3 - https://www.fda.gov/CFR=170.3) – (**Risk only**)

Pharmaceuticals

Benefit-Risk Framework – "FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients." (Benefit-Risk Assessment in Drug Regulatory Decision-Making, Draft PDUFA VI Implementation Plan (FY 2018-2022) (https://www.fda.gov/Benefit-Risk in Drugs) – (**Benefit/Risk**)

PRODUCT SAFETY AND REGULATION

- Product safety begins with its design including ingredients/components
- The use of an ingredient/component defines the safety and regulatory requirements
- Risk equation for products
  - Risk = Hazard *f(x)* Exposure
  - Risk ≠ Hazard
- Results in the same ingredient used in many types of products
  - Consumers concerned and confused how a chemical can be used in foods and consumer products

Food, Dietary Supplement, Cosmetic, or Pharmaceutical?

Food, Dietary Supplement, Cosmetic, or Pharmaceutical? or PESTICIDE?

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

READ THIS LABEL: Read this entire label and follow all use directions and use precautions.

IMPORTANT: Do not expose children, pets, or other nontarget animals to rodenticides. To help to prevent accidents

1. Store product not in use in a location out of reach of children and pets.
2. Apply bait in locations out of reach of children, pets, domestic animals and nontarget wildlife, or in tamper-resistant bait stations. These stations must be resistant to destruction by dogs and by children under six years of age, and must be used in a manner that prevents such children from reaching into bait compartments and obtaining bait. If bait can be shaken from bait stations when they are lifted, units must be secured or otherwise immobilized. Even stronger bait stations are needed in areas open to hoofed livestock, raccoons, bears or other potentially destructive animals, or in areas prone to vandalism.
3. Dispose of product container and unused, spoiled, and unconsumed bait as specified on this label.

USE RESTRICTIONS: For control of Norway rats, roof rats and house mice in and around homes, industrial, commercial and agricultural buildings, and similar man-made structures. This product may also be used inside transport vehicles (ships, trains, aircraft) and in related port or terminal buildings.

SELECTION OF TREATMENT AREAS: Determine areas where rats and mice will most likely find and consume the bait. Generally, these are along walls, by gnawed openings, in or beside burrows, in corners and concealed places, between floors and walls, or in locations where rodents or their signs have been seen. Protect bait from rain or snow. Remove as much alternative food as possible.

WARRANTY: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk of use and/or handling of this material when such use and/or handling is contrary to label instructions.

QUINTOX®

RAT & MOUSE BAIT

KILLS RATS AND MICE

ACTIVE INGREDIENT: Cholecalciferol 0.075%
INERT INGREDIENTS 99.925%
TOTAL 100.000%

KEEP OUT OF REACH OF CHILDREN

CAUTION

(See right side panel for additional precautionary statements.)

For 24-hour emergency medical advice, call 1-877-854-2494

NET WEIGHT: 5.5 lbs. (2.5 Kg)

Manufactured by

Bell Laboratories, Inc.
Madison, WI 53704

EPA EST. NO. 12455-WI-1 EPA REG. NO. 12455-19

APPLICATION DIRECTIONS

RATS: Apply 2 to 8 ounces of bait per placement. Space placements at intervals of 15 to 30 feet. Maintain an uninterrupted supply of fresh bait for at least 15 days or until signs of rat activity cease.

MICE: Apply 1/4 to 1/2 oz (1-2 level tablespoons) of bait at each placement location. Space placements at 8- to 12- foot intervals. Larger placements (up to 1 ounce) may be needed at points of very high mouse activity. Maintain an uninterrupted supply of fresh bait for at least 10 days or until signs of mouse activity cease.

RATS AND MICE: Replace contaminated or spoiled bait immediately. Collect and dispose of all dead animals and leftover bait properly. To prevent reinfestation, limit sources of rodent food, water and harborage as much as possible. If reinfestation does occur, repeat treatment. Where a continuous source of infestation is present, establish permanent bait stations and replenish as needed.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Keep away from humans, domestic animals, and pets.

STATEMENT OF PRACTICAL TREATMENT

If swallowed, drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Avoid use of all oils.

NOTICE TO PHYSICIAN: If serum calcium levels are elevated, treatment with Calcitonin is effective in reducing calcium to normal levels. Continue monitoring serum calcium and treat as necessary for hypercalcemia (Reference, AMA Drug Evaluations, Third Edition (1977), Chapter 16, pp. 248-251).

ENVIRONMENTAL HAZARDS: Keep out of lakes, streams or ponds.

STORAGE AND DISPOSAL

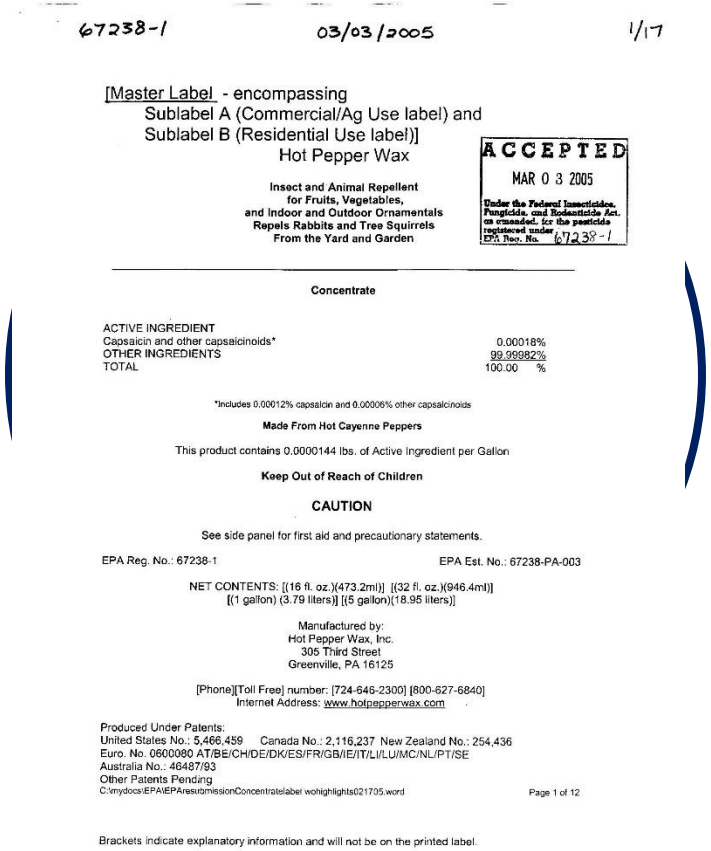
Do not contaminate water, food or feed by storage or disposal.

STORAGE: Store only in original container in a dry area inaccessible to children and pets.

PESTICIDE DISPOSAL: Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Completely empty pail. Then dispose of empty pail in a sanitary landfill or by incineration or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

QUINTOX is a registered trademark of Bell Laboratories, Inc.



67238-1 03/03/2005 1/17

[Master Label - encompassing
Sublabel A (Commercial/Ag Use label) and
Sublabel B (Residential Use label)]
Hot Pepper Wax

ACCEPTED
MAR 0 3 2005
Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 67238-1

**Insect and Animal Repellent
for Fruits, Vegetables,
and Indoor and Outdoor Ornamentals
Repels Rabbits and Tree Squirrels
From the Yard and Garden**

Concentrate

ACTIVE INGREDIENT	
Capsaicin and other capsaicinoids*	0.00018%
OTHER INGREDIENTS	99.99982%
TOTAL	100.00 %

*Includes 0.00012% capsaicin and 0.00006% other capsaicinoids

Made From Hot Cayenne Peppers

This product contains 0.0000144 lbs. of Active Ingredient per Gallon

Keep Out of Reach of Children

CAUTION

See side panel for first aid and precautionary statements.

EPA Reg. No.: 67238-1 EPA Est. No.: 67238-PA-003

NET CONTENTS: [(16 fl. oz.)(473.2ml)] [(32 fl. oz.)(946.4ml)]
[(1 gallon) (3.79 liters)] [(5 gallon)(18.95 liters)]

Manufactured by:
Hot Pepper Wax, Inc.
305 Third Street
Greenville, PA 16125

[Phone][Toll Free] number: [724-646-2300] [800-627-6840]
Internet Address: www.hotpepperwax.com

Produced Under Patents:
United States No.: 5,466,459 Canada No.: 2,116,237 New Zealand No.: 254,436
Euro. No. 0600080 AT/BE/CH/DE/DK/ES/FR/GB/IE/IT/LI/LU/MC/NL/PT/SE
Australia No.: 46487/93
Other Patents Pending
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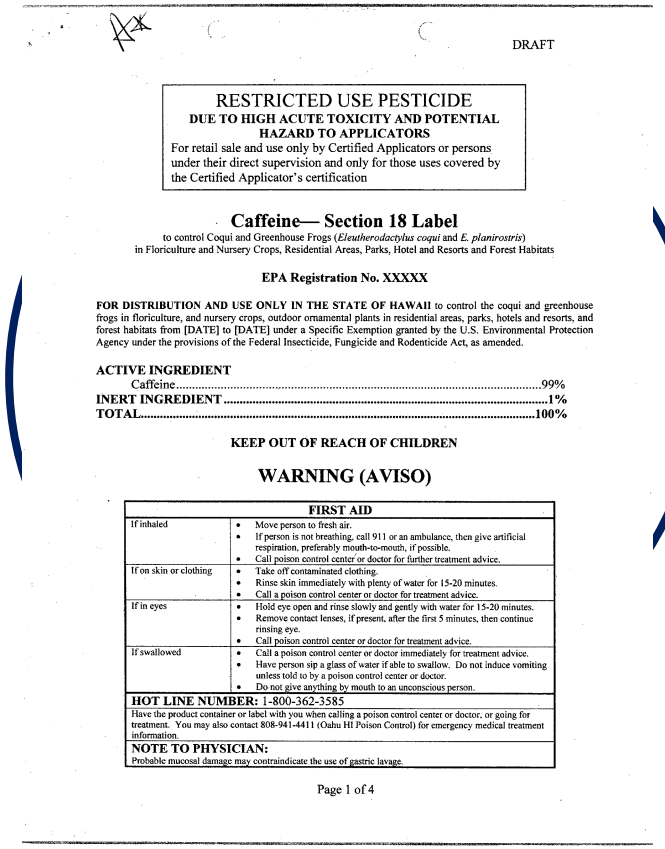
Brackets indicate explanatory information and will not be on the printed label.



DRAFT

RESTRICTED USE PESTICIDE
DUE TO HIGH ACUTE TOXICITY AND POTENTIAL HAZARD TO APPLICATORS
For retail sale and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification

Caffeine— Section 18 Label
to control Coqui and Greenhouse Frogs (*Eleutherodactylus coqui* and *E. planirostris*)
in Floriculture and Nursery Crops, Residential Areas, Parks, Hotel and Resorts and Forest Habitats

EPA Registration No. XXXXX

FOR DISTRIBUTION AND USE ONLY IN THE STATE OF HAWAII to control the coqui and greenhouse frogs in floriculture, and nursery crops, outdoor ornamental plants in residential areas, parks, hotels and resorts, and forest habitats from [DATE] to [DATE] under a Specific Exemption granted by the U.S. Environmental Protection Agency under the provisions of the Federal Insecticide, Fungicide and Rodenticide Act, as amended.

ACTIVE INGREDIENT
Caffeine.....99%
INERT INGREDIENT.....**1%**
TOTAL.....**100%**

KEEP OUT OF REACH OF CHILDREN

WARNING (AVISO)

FIRST AID	
If inhaled	• Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. • Call poison control center or doctor for further treatment advice.
If on skin or clothing	• Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
If in eyes	• Hold eye open and rinse slowly and gently with water for 15-20 minutes. • Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call poison control center or doctor for treatment advice.
If swallowed	• Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
HOT LINE NUMBER: 1-800-362-3585 Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 808-941-4411 (Oahu HI Poison Control) for emergency medical treatment information.	
NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.	

Page 1 of 4

SCIENTIFIC EVIDENCE AND ACTION- CASE STUDIES

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US – TRANS FAT

- **FDA - Revocation of Uses of Partially Hydrogenated Oils in Foods; Companion Document to Direct Final Rule** 2023-16724 (88 FR 53827) https://www.federalregister.gov/documents/2023/08/09/2023-16724/revocation-of-uses-of-partially-hydrogenated-oils-in-foods-companion-document-to-direct-final-rule
  - In June 2015, FDA published a declaratory order (Order) setting forth our final determination, based on the available scientific evidence and the findings of expert scientific panels, that there is no longer a consensus among qualified experts that PHOs, which are the primary dietary source of industrially produced *trans* fatty acids, are GRAS for any use in human food.
  - Also proposing to revoke prior sanctions (*i.e.,* pre-1958 authorization of certain uses) for the use of PHOs in margarine, shortening, and bread, rolls, and buns based on our conclusion that these uses of PHOs may be injurious to health.
  - Determined that this body of evidence established the health risks associated with the consumption of *trans* fat
- **Epidemiological evidence cited**
  - Meta-analysis of prospective studies of trans fatty acids and risk of coronary heart disease. A 2% increase in the energy intake from trans fatty acids was associated with a 23% increase in the incidence of coronary heart disease (pooled relative risk 1.23; 95% confidence interval 1.11 to 1.37). (Mozaffarian D, Katan ME, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. N Engl J Med 2006;354: 1601-13)
  - In the United States, artificial trans fat in food was estimated in 2006 to cause one in five (up to 250,000) heart attacks and 50,000 deaths a year. – (Mozaffarian D, Katan ME, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. N Engl J Med 2006;354: 1601-13)
  - Association ≠ Causation
  - Associations with relative risks below 3 are considered moderate or weak – (Wynder E. L. Workshop on Guidelines to the Epidemiology of Weak Associations: Introduction. Prev. Med. 1987;16:139–141. doi: 10.1016/0091-7435(87)90078-8)
  - Epidemiology, therefore, faces the challenge of identifying the weak causal associations that require large study populations and taking special care to exclude bias and confounding, and it is not surprising that the evidence on which these associations are based is often challenged. – (Paola Boffetta Causation in the Presence of Weak Associations. Crit Rev Food Science Nutr. 2010 Dec4;50(s1):13-16. doi:10.1080/10408398.2010.526842)

EU – AZO FOOD COLORS

- **Publication** - McCann et al. (2007) concluded exposure to two mixtures of 4 synthetic colours plus a sodium benzoate preservative in the diet resulted in increased hyperactivity in 3-year old and 8- to 9-year old children in the general population (Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community:a randomized, double-blinded, placebo-controlled trial. November 03, 2007. The Lancet Vol 370, Issue 9598, P1560-1567)
- European Food Safety Authority (EFSA)
  - Scientific Opinion (14 March 2008) - Limited evidence that the mixtures of additives tested had a small effect on the activity and attention of some children (The EFSA Journal (2008) 660, 1-54)
- **Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives** - https://eur-lex.europa.eu/eli/reg/2008/1333/oj
  - Amended in July 2008 to add Annex V
  - List of the food colours referred to in Article 24 for which the labelling of foods shall include additional information

Foods containing one or more of the following food colours	Information
Sunset yellow (E 110) (*1)	'name or E number of the colour(s)': may have an adverse effect on activity and attention in children.
Quinoline yellow (E 104) (*1)	
Carmoisine (E 122) (*1)	
Allura red (E 129) (*1)	
Tartrazine (E 102) (*1)	
Ponceau 4R (E 124) (*1)	

SUMMARY

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Summary

- Virtually all food is processed prior to consumption
- Virtually all food is composed of numerous chemical ingredients
- Numerous definitions for Ultra-processed foods exist
- Scientific evidence for UPF concerns – Association not Causation
- Food Safety and Regulation (US and EU) similar but not identical resulting in different approaches and decisions
- Intended use of a substance determines its regulatory framework – substances can be regulated under multiple regulatory frameworks
- Varying levels of scientific evidence can result in regulatory/legislative actions on foods

THANK YOU!

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QUESTIONS?

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