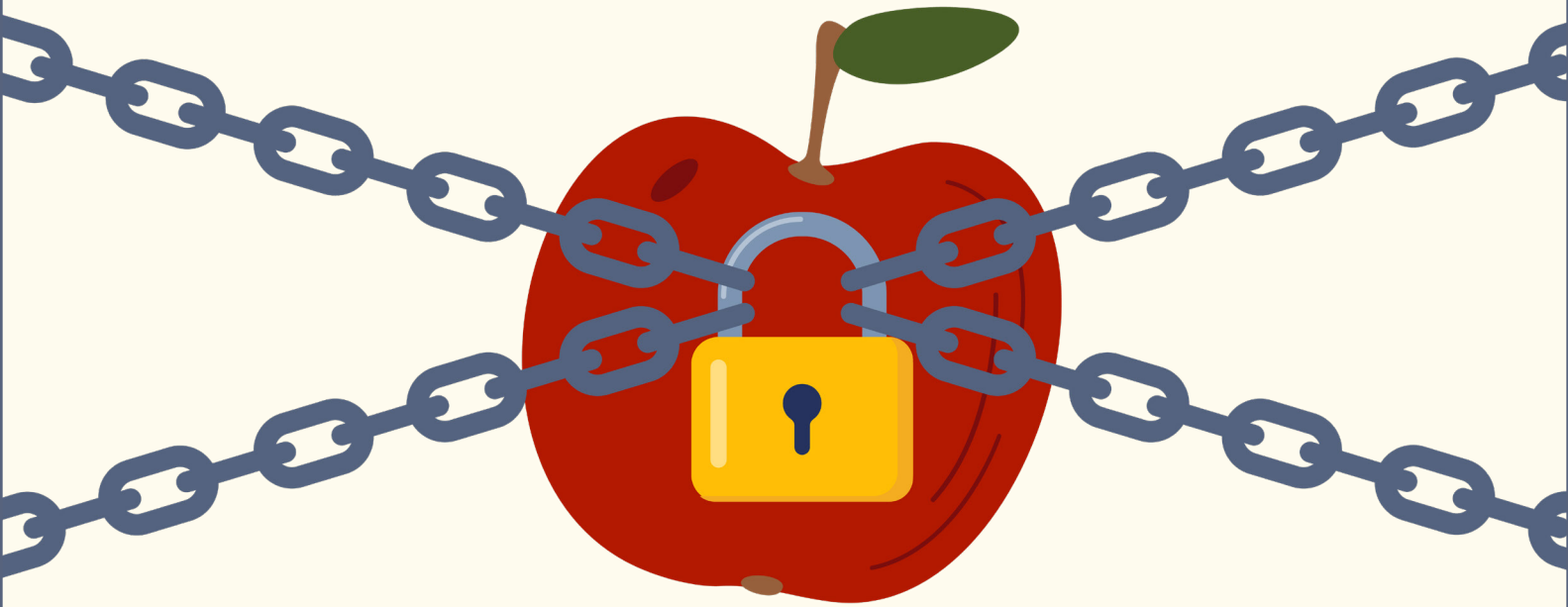




THE PROPOSED FEDERAL “FRESH” ACT AND THE IMPACT OF ITS PREEMPTION PROVISION



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About the Harvard Law School Food Law and Policy Clinic

The Harvard Law School Food Law and Policy Clinic (FLPC) serves partner organizations and communities by providing guidance on cutting-edge food system legal and policy issues, while engaging law students in the practice of food law and policy. FLPC focuses on increasing access to healthy foods; supporting sustainable food production and food systems; and reducing waste of healthy, wholesome food. For more information, visit chlpi.org/flpc.

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In April 2026, Representative Kat Cammack (R-Fla.) released a discussion draft of a bill entitled “FDA Review and Evaluation of Safe, Healthy, and Affordable Foods” or the “FRESH Act.” The Act contains a sweeping preemption provision that could significantly alter the long-standing balance between federal and state authority over food safety regulation, as described in more detail in this report.

States first regulated food through “pure food” laws in the late 19th century, prior to any federal food safety legislation. Later, seminal federal statutes, like the 1906 Pure Food and Drug Act and the 1938 Food, Drug, and Cosmetic Act (FDCA), created national baselines upon which states could and did build. Historically, states have used their traditional “police powers” over health and welfare, bolstered by a federal food safety floor to innovate and fill regulatory gaps as they saw fit. They have been encumbered only by limited federal preemption in areas such as nutrition labeling,

In recent years, states have exercised this authority to fill federal gaps in chemical and food additive oversight. Dozens of states have proposed or enacted laws in a number of areas, including banning specific additives or chemicals, restricting additives or chemicals in school foods, requiring reporting of certain “generally recognized as safe” (GRAS) substances that have not been reviewed by the Food and Drug Administration (FDA), and mandating warning labels on foods with specified chemicals or dyes. In response, industry groups, like Americans for Ingredient Transparency, have pushed for national uniformity and advocated to designate the FDA as the exclusive regulator for ingredients, labeling, and related requirements.

The FRESH Act advances this goal through a sweeping express preemption provision. The draft bill provides that the Act “shall supersede any and all State requirements or prohibitions” relating to the use, labeling, sale, or marketing of food or food additives, or anything that could become a component or affect the characteristics of food. It also preempts state labeling requirements, including “any statement, vignette, or other representation on a label or in labeling” that indicates a risk to health or safety or provides any information beyond a declaration of the ingredient’s presence. As drafted, this language would not only displace recent state additive bans and warning label requirements, it would also preempt and upend many longstanding state laws governing other warning labels, menu sodium and sugar icons, allergen disclosures, alternative protein labeling, and more.

Beyond these obvious targets, the Act’s language threatens to reach deeply into other state food safety and nutrition regulatory domains, including rules regarding chemical and biological contaminants (such as limits on heavy metals in spices, PFAS bans in packaging, or baby food testing requirements), state and local regulation of retail food stores and restaurants (including state food codes, permitting, and lettergrade posting), state law frameworks for “cottage foods” and home kitchens, and state licensing and manufacturing inspection standards. In many of these areas, there is little or no corresponding federal

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regulation, yet the Act does not condition preemption on the existence of federal rules to fill the large gaps that would be created with this novel and expansive federal preemption.

The consequences would be substantial. First, broad preemption without parallel federal standards would create regulatory gaps, leaving some sectors of the food system with no operative safety rules. Second, preempting all state oversight of food retail and food service establishments would necessitate a shift of this oversight to the FDA, dramatically expanding the FDA's workload and funding needs. Without commensurate new resources and authority, food safety oversight could be substantially weakened, or nonexistent. Third, because the FDCA lacks a private right of action, the displacement of "any and all State requirements or prohibitions" will also undermine state consumer protection and tort remedies that currently allow injured consumers and state enforcers to hold companies accountable.

Ultimately, the FRESH Act's expansive preemption scheme risks dismantling more than a century of cooperative federalism in food safety, curtailing states' role as "laboratories of democracy" and significantly encroaching on their longstanding police powers, and replacing a layered, adaptive system with a centralized regime with large regulatory gaps that promises to be less responsive and less protective of public health.

Introduction: the Proposed FRESH Act and the Impact of Its Preemption Provision

In April 2026, Rep. Kat Cammack (R-Fla) published a discussion draft of a bill entitled “FDA Review and Evaluation of Safe, Healthy, and Affordable Foods,” or the “FRESH Act,” aiming to amend the Federal Food, Drug, and Cosmetic Act and establish national standards for food safety and ingredient labeling.¹

The FRESH Act contains a sweeping preemption provision that threatens to upset the longstanding federal-state balance of food safety regulation. This report will consider the implications of the FRESH Act’s preemption provision and discuss the potential it has to preempt critical areas of state public health regulation in six categories of food laws: (1) state regulation of food additives and chemicals, (2) state and local food labeling requirements, (3) state regulation of chemical and biological contaminants in food, (4) state regulation of retail and food service establishments, (5) state regulation of “cottage food” or “home kitchen” producers, and (5) state food manufacturing requirements. This report is not intended to be exhaustive, and additional areas of state laws not described in this document may also be preempted if the FRESH Act were to become law.

Background

The draft FRESH Act responds to a recent increase in states enacting laws to address consumer concerns with the safety of chemical additives in our food supply, as discussed in more detail below.² However, its broad preemption clause threatens to completely overturn the historic balance and cooperation between state and federal regulation of food and consumer safety. This section examines the historical development of food safety regulation in the United States at both the federal and the state levels.

Historical Landscape of Federal Food Safety Statutes

The federal government exercises substantial authority over the national food system, particularly through its power to regulate interstate commerce.³ State governments began regulating the food industry in the late nineteenth century through the early enactment of pure food and pure dairy laws. By 1900 nearly every state had passed some kind of pure food legislation.⁴ Federal regulation of food and consumer safety began with two seminal statutes. In 1906, relying on its authority over goods in interstate commerce under the Commerce Clause, Congress enacted the Pure Food and Drug Act, the first federal law targeting the growing problem of adulterated and mislabeled food, and setting the groundwork for future legislation on food safety.⁵ Under the Pure Food and Drug Act, authority for federal regulation of food safety was granted to the USDA Division of Chemistry, which was renamed the FDA in 1931 and moved out of the USDA in 1940.⁶ This was passed on the same day as the Federal Meat Inspection Act, which created the federal regulatory system for safety and labeling of meat products and assigned oversight of those products to the USDA Food Safety and Inspection Service (later analogous laws were enacted for poultry and egg products).⁷ These federal laws emerged against the backdrop of a national debate over whether food safety was solely a matter of state power, as it had long been treated, or whether the federal government had authority to regulate it as well.⁸ Muckrakers’ accounts of the horrors of the food industry, such as Upton Sinclair’s

book *The Jungle*, and the public outrage they sparked, helped tip the balance for Congress to finally pass these federal laws in the face of dangers in poorly regulated food production.⁹

However, federal regulation still remained insufficient after the passage of the Pure Food and Drug Act, and progressive era reformers and state public health officials pushed for further federal action.¹⁰ In 1938, Congress revamped the 1906 Pure Food and Drug Act, enacting the Food, Drug, and Cosmetic Act (FDCA) to address deficiencies in the existing law and, among other things, more fully empower the FDA as a regulatory agency with increased oversight over the safety and labeling of food, drugs, medical devices and cosmetics.¹¹ The FDCA has been amended numerous times since its passage to address modernizations in the food system.¹² Together, these federal provisions augment state laws and establish a nationwide baseline. However, states have generally also been able to maintain authority over food safety and continue to add their own, more protective requirements, so long as they are consistent with federal law.¹³ And, in areas where federal law has not preempted or where authority is left to the states, like regulation of food establishments and food retail, states have had sole authority to regulate.¹⁴

Historical Landscape of State Food Safety Statutes

State and local governments have long served as key regulators of food and consumer safety.¹⁵ As noted above, state-level food safety laws generally predate federal ones.¹⁶ Prior to the twentieth century, food safety regulations were a matter of state and local concern.¹⁷ Today, states generally retain primary responsibility for regulating in-state food service establishments (such as restaurants and institutional cafeterias) and retail food establishments (such as grocery stores).¹⁸ State and federal regulators share jurisdictional authority in areas like manufacturing and food production, where the federal rules apply to food that will be sold nationally, and states regulate the premises of these large facilities as well as solely regulate the smaller-scale facilities that are exempt from federal regulation.¹⁹ This ongoing role of states in food safety authority is based in part on the Commerce Clause of the U.S. Constitution, which gives the federal government authority only over products in interstate commerce.²⁰ But it is even more importantly grounded in the preservation of state “police power,” or the power to regulate the health and welfare of their residents, under the Constitution’s Tenth Amendment.²¹ The authority to conduct inspections on products like food and enact public health and consumer protection laws has long been included among these traditional police powers.²²

In summary, modern food safety regulation is best understood as an area of concurrent federal/state authority. In some domains, like restaurant and retail food establishments, the federal government operates minimally, if at all, and state and local governments exercise primary regulatory authority.²³ In other areas, like food manufacturing for national sales or packaged food labeling, the federal government plays a major role. And in the case of packaged food labeling, the federal government has enacted preemption in specific limited areas to avoid conflicting state requirements, leaving states free to regulate areas not explicitly preempted.²⁴ Outside of that limited preemption, Congress has considered and ultimately declined to expressly preempt state authority over food regulation on numerous occasions, thereby reinforcing the existing federal-state balance in this area.²⁵ Finally, states have actively used their police power authority to address pressing health concerns in the face of federal regulatory

gaps; for example, California banned ephedra, a harmful dietary supplement ingredient, before any FDA intervention,²⁶ and New York City's and California's early bans on trans fats in 2008 and 2010 were implemented years before FDA followed suit with a federal ban.²⁷

Recent Developments in State Food Additive Regulation

Recently, a number of states have used their authority to enact laws addressing federal regulatory gaps, amid the concern that the federal government has been failing to ensure the safety of chemical additives in our food.²⁸ California, for example, passed the California Food Safety Act in 2023, which bans four different additives from use in foods;²⁹ similarly, West Virginia adopted a statewide ban on certain artificial dyes used in food.³⁰ These recent state bills tend to fall into four key categories: (1) bills aimed at prohibiting food products containing certain specified food additives and colors, (2) bills restricting or banning offerings in school foods with additives of concern, (3) bills requiring companies to report to the state when they use certain GRAS substances, and (4) bills that require warnings labels on foods containing specific additives and artificial dyes.³¹ In 2025, more than 30 states introduced legislation of this type.³² These statutes are still subject to the ordinary constitutional and statutory limitations, and courts have invalidated or enjoined them when they are arbitrary, unclear, or irrational, demonstrating that "checks and balances exist on state powers without the need for broad federal preemption."³³ However, the courts analyzing these claims have agreed that these laws are within the state authority and are not preempted by the federal government currently.³⁴

Industry Actions

The recent passage of various types of additive legislation in multiple states has prompted the food industry to push for federal action to preempt these types of state laws. Americans For Ingredient Transparency (AFIT) is one such industry group pushing for uniform regulatory standards across the United States.³⁵ The AFIT website states this goal: "[t]he Federal Food, Drug, and Cosmetic Act should be amended to establish the U.S. Food and Drug Administration (FDA) as the *sole entity setting the floor and ceiling for regulations on the marketing and sale of foods, beverages, and over-the-counter products in the United States, including safety assessments, ingredient approvals, registrations, reporting requirements, and labeling requirements.*"³⁶ The group has supported the FRESH Act, a bill that would achieve this exact aim: its preemption clause would displace many existing state regulations that govern broad segments of the food system in all 50 states.³⁷

The FRESH Act would likely preempt many areas of state and local food safety law, including:

- state regulation of additives to food
- state and local food labeling and disclosure requirements
- state regulation of chemical and biological contaminants
- state and local regulation of retail food stores and restaurants
- state and local frameworks for "cottage foods" and home kitchen sales
- state licensing and inspection of food manufacturing facilities

Preemption as Proposed Under the FRESH Act

Preemption Generally

Under the Constitution's Supremacy Clause, federal law can supersede, or preempt, conflicting state law,³⁸ so long as the federal government is acting in an area where it has Constitutional authority to Act.³⁹ Even where the federal government would have the authority to preempt, courts are generally reluctant to infer preemption absent clear Congressional intent or an actual conflict between federal and state requirements.⁴⁰ Courts have identified three instances in which federal law preempts state law. The first type is express preemption, in which Congress explicitly states its intention to override state and local laws in the statute's text.⁴¹ The second type is field preemption, which occurs when the federal government's regulation of a specific area is so comprehensive that it leaves no room for state or local government to regulate on their own, thus completely occupying the field.⁴² The last type is conflict preemption, which arises when a state or local law directly conflicts with a federal law.⁴³ The preemption provision in the FRESH Act clearly expresses its intent to preempt state laws in the text of the bill, and thus falls under the express preemption category.

Preemption Proposed by the FRESH Act

The FRESH Act was published as a discussion draft by Rep. Kat Cammack (R-Fla.) on April 22, 2026, and was included in discussion that took place in the House Energy & Commerce Committee legislative hearing on April 29, 2026.⁴⁴ It includes a sweeping express preemption provision, which would add to the Food, Drug, and Cosmetic Act the following text:

The provisions of sections 409, 412, 425, 426, and 721 shall *supersede any and all* State requirements or prohibitions relating to the use, labeling, sale, or marketing, in interstate commerce of – (1) a food, food additive, color additive, dietary ingredient or supplement, food ingredient (including a common food ingredient), substance generally recognized as safe [], or food contact substance.⁴⁵

Along with intentionally-added ingredients covered in the above clause, the FRESH Act also would preempt state requirements related to food contaminants, including “(2) any substance that may be expected, directly or indirectly, to become a component or otherwise affect the characteristics of any food; or (3) any added or naturally occurring substance in food (referred to in this section as a ‘food substance’)[.]”⁴⁶ The language “added or naturally occurring substance in food” can apply to chemical and microbiological contaminants in both food and food packaging.⁴⁷

In addition to the inclusion of labeling and marketing in the list of activities preempted from state action above, the FRESH Act also expressly preempts any state labeling requirements, which includes:

any statement, vignette, or other representation on a label or in labeling... that indicates, directly or by implication, that such food --- (1) presents or may present a risk or hazard to health or safety; (2) presents or may present consequences as a result of consumption; or (3) shall be identified for any reason other than declaration in a list of ingredients...[.]⁴⁸

The FRESH Act is drafted in strikingly broad terms. It does not target a narrow set of laws, but

instead sweepingly applies to a range of state laws that deal with all aspects of food regulation. Ultimately, this bill threatens to preempt state laws and regulation in many aspects of food regulation, including labeling, marketing, ingredients, contaminants, and manufacturing, even when there is no analogous federal law.

State Laws Analyzed Under the FRESH Act's Preemption Provision

Taken together, the breadth of the FRESH Act's preemption clause and the absence of limiting language suggest it will displace laws far beyond the notable recent state additives and warning label laws. The Act threatens to reach deeply into the existing body of state and local food safety and food system regulations that have long been protected as a legitimate exercise of state power.⁴⁹

Because there are some elements of the FRESH Act preemption provision that are unclear, there remain some questions about how courts would interpret its effect on different bodies of state food regulation. This section will first analyze those state and local laws and regulations that would clearly be preempted by the FRESH Act, before turning to those for which preemption is also likely but less certain.

State Laws Clearly Preempted by the FRESH Act

In terms of state laws that would be clearly preempted by the language of the FRESH Act, state food additive regulations and state and local labeling laws are clearly intended to be preempted by this bill. The bill aims to reduce regulations that differ from state to state and thus increase uniformity nationwide.

1: State Food Additive Regulations

According to the bill's sponsor, Representative Cammack, state food additive regulation is a central focus of the bill, given the intent to address the existing "patchwork" of state chemical laws.⁵⁰ These burgeoning state additive bans are certain to be preempted, including, food additive bills like The California Food Safety Act and laws addressing additives like PFAS in food packaging, including Maine's "Toxics in Food Packaging" and Minnesota's "Amara's Law".⁵¹ However, this Act contains no confinement of its reach to these specific laws. Under the FDCA, an "additive" is defined to include essentially any substance that becomes a component of food or otherwise affects its characteristics.⁵² Thus, when the FRESH Act uses "additives" in its express preemption provision in Sec. 402A(a)(1), it will sweep in many long-standing, as well as novel state provisions, that govern ingredients more generally.⁵³ This could include, for example, state laws prescribing or restricting nutrient fortification, such as folic acid requirements or limits,⁵⁴ or statutes addressing novel food or dietary supplement ingredients, such as Kratom.⁵⁵

This broad sweep is also out of character with the historic deference the federal government has afforded states to regulate additives in accordance with their public health needs.⁵⁶ Such

regulation lies at the center of police powers, the long-acknowledged core powers that states hold to make precautionary decisions to protect the health of their residents.

2. State and Local Food Labeling Requirements

Similar to state additive regulations, the second area directly targeted by the FRESH Act's broad preemption language is state labeling laws relating to additives or ingredients, such as recent additive warning-label requirements enacted in Texas and Louisiana.⁵⁷ Food labeling is considered to be any material accompanying the food, including menu requirements, nutrition information, allergen labeling, and more.⁵⁸ Because of the FRESH Act's broad language around labeling, the bill would likely preempt a wide range of state labeling laws including and beyond those intended, such as:

On-package warning labels

On-package warning labels make it easier to identify products with ingredients of concern, and are a clear target of the FRESH Act.⁵⁹ Examples of legislation passed that fit into this category include: Tex. Health & Safety Code § 431.0815 (2025), requiring warning labels on packaged foods sold in Texas that contain certain artificial colors, additives, or chemicals that are banned or not recommended for human consumption by regulators in the E.U., Canada, or Australia (currently enjoined),⁶⁰ and La. Rev. Stat. § 40:661 (as amended), establishing a labeling rule under which food manufacturers in Louisiana must place a specified warning on products containing certain artificial colors, additives, or banned chemicals.⁶¹

One notable exception to the otherwise broad preemption language would be an exception for laws that fall under the FRESH Act's grandfather provision, which exempts from preemption "a state requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997." ⁶² This includes California's Proposition 65, which requires cancer warning labels on consumer products containing certain substances identified by the state that are known to cause cancer or other specific harms, and was passed in November, 1986.⁶³

Menu nutrition and calorie labeling

Menu nutrition and calorie labeling requirements mandate that restaurants or certain other food service establishments highlight specific nutrients of concern, such as sodium, added sugar, or calorie level by displaying clear icons, symbols, or text warnings next to items that exceed defined thresholds (such as the daily recommended limit).⁶⁴ Federally, the FDCA contains mandates for calorie disclosure for establishments with 20 or more locations, but smaller chains are left to the regulation of state and local governments in terms of required calorie disclosures.⁶⁵ Federal law does not contain requirements for any other nutrient labeling at food service but state or local laws do. Example of the types of legislation at risk of preemption are New York City's sodium menu warning rule, which requires chain restaurants to place standardized sodium warning icons and health statements next to items exceeding a regulatory threshold, and New York City's added-sugar menu warning rule requires chain restaurants to place standardized warning icons and an accompanying health statement on menus next to any item that contains above a certain threshold of sugar.⁶⁶

Allergen warnings

Allergen warnings identify the presence of major food allergens (such as milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soy, and sesame) to consumers by mandating standardized disclosures indicating what may be present in a food product. Many state laws require allergen warnings for food offered in restaurants or retail outlets. These are at risk of preemption under the broad FRESH Act language. Example of laws at risk include California's Allergen Disclosure for Dining Experiences Act (SB 68), which requires chain restaurants to provide written disclosure on menus or other specified alternatives of which of the nine major food allergens they know or have reason to know are present in each standard menu item,⁶⁷ and New York's Allergen Labeling Law, which requires full allergen labeling on certain prepackaged items for direct sale.⁶⁸

Alternative protein and plant-based meat labeling requirements

Alternative protein and plant-based meat labeling requirements define how products such as plant-based burgers, cell-cultivated meats, and insect-based proteins can be described on labels and in marketing to ensure consumers are not misled about the product's source or makeup.⁶⁹ Numerous states have enacted requirements on this type of labeling, all of which are at risk of preemption. Examples of laws at risk include Colorado's HB25-1203, which requires qualifying terms like "cell-cultivated" or "lab-grown" to be included on packages to inform consumers of non-conventional meat,⁷⁰ and Utah's HB 138, which requires meat containing a plant or insect-based meat substitute contain a clear label indicating the presence of such substitutes.⁷¹

The numerous categories of state labeling laws at risk, as described above, are at odds with the delicate balance Congress struck in the past by not preempting all state labeling. In enacting the Nutrition Labeling and Education Act of 1990 (NLEA), Congress intentionally preempted only specific types of state labeling requirements, like nutrition labeling and certain health and nutrient-content claims.⁷² Given the presumption against preemption absent explicit congressional intent,⁷³ Congress's choice to use very precise language and a very specific list when it came to labeling preemption in NLEA makes it clear that Congress did not intend to preempt all state labeling laws. With the sprawling preemption of the FRESH Act, the hard work of that earlier Congress in its drafting of the NLEA and the priorities evident from its careful maintenance of the federal-state balance would be lost.

Other State Laws Likely Preempted by the FRESH Act

Beyond the types of laws intended to be preempted by the FRESH Act described above, the broad language sweeps in a number of laws in other categories that might not have been intended. The provision is so broadly drafted that by its plain language many food safety laws, including state regulation of chemical and biological contaminants, regulation of retail food stores and food services establishments, regulation of "cottage food" or "home kitchen" enterprises, and state manufacturing requirements, also likely face preemption by the FRESH Act.

3. State regulation of chemical and biological contaminants

The FRESH Act covers "any and all State requirements or prohibitions relating to the use, labeling, sale, or marketing," including "any substance that may be expected, directly or indirectly, to become a component or otherwise affect the characteristic of any food; or... any added or naturally occurring substance in food."⁷⁴ As a result, state and local laws that

regulate the presence, level, or testing of contaminants would be vulnerable to preemption under the FRESH Act, to the extent that they relate to the “use, labeling, sale, or marketing” of foods. For example, a law may be preempted if it enacts a limit on certain chemical contaminants as a condition of selling the food within the state. Examples of this type of law include New York’s regulations limiting heavy metals in spices,⁷⁵ which impose contamination-based restrictions on products entering the retail market; state laws like those in Minnesota and Maine restricting or banning the use of PFAS in food packaging and food-contact materials;⁷⁶ and California’s law requiring testing of baby food for contaminants.⁷⁷ All of these and similar state laws likely would be swept under the FRESH Act’s broad preemption language.

States also adopt laws requiring specific prevention measures for certain foods, often following model ordinances, like the Grade “A” Pasteurized Milk Ordinance, published by the U.S. Department of Health and Human Services, which provides model standards that states can adopt to require milk sold within the state to be pasteurized.⁷⁸ These state laws provide distinct protections from federal law. For example, FDA regulations only prevent the interstate sale of unpasteurized milk, leaving intra-state sales to be regulated by each individual state.⁷⁹ Thus, only these state laws protect in-state milk sales. Examples of other model food standards that are given effect through state law include the National Shellfish Sanitation Program Model Ordinance⁸⁰ and the Association of American Feed Control Officials Model Regulations for Pet Food.⁸¹ These state laws could be challenged and struck down under the Fresh Act’s preemption language as “requirements or prohibitions relating to the use, labeling, sale, or marketing” of food, leaving these areas unregulated.

4. Regulation of retail food stores and food service establishments

The federal-state balance of food safety regulation has always left the regulation of retail stores and food service establishments—such as restaurants, grocery stores, and institutional cafeterias—to states, under state laws and food safety codes.⁸² The FDA does publish a model ordinance known as the FDA Food Code that contains model safety ordinances for retail and food service. But because the FDA has no direct authority over retail food or restaurants,⁸³ the FDA Food Code has no effect unless adopted by states, and state governments have the choice to adopt all, some, or none of the Food Code, and then use their own inspectors to visit retailers and food service facilities to ensure the state requirements are implemented.⁸⁴ These state laws typically govern how food is prepared and offered for sale, for example, by requiring minimum cooking temperatures, temperature controls, and cross-contamination controls.⁸⁵ States (or localities) may also add additional requirements that do not appear in the FDA’s Model Food Code. An example of such a state or local add-on is the requirement of letter-grade posting in New York City.⁸⁶

Furthermore, retail and food service establishments cannot operate without state permits, another aspect of state regulation.⁸⁷ Such state-level regulations and permitting would likely fall under the FRESH Act’s preemption clause, as the FRESH Act preempts “any and all State requirements or prohibitions relating to the use, labeling, sale, or marketing” of food.⁸⁸ However, the federal government currently has no rules on regulating retail or food service, as this has always been an area of purely state oversight. Federal preemption of such laws

would result in the absence of any laws regulating these entities, and no governmental body responsible to oversee or inspect these entities, absent additional and much more substantial federal action.

5. Regulation of small “cottage food” producers or “home kitchen enterprises”

Small-scale “cottage food” producers, or “home kitchen enterprises,” are individuals and small businesses that prepare pre-made foods or meals in home kitchens for sale on site or at farmers’ markets, roadside stands, or similar venues.⁸⁹ Federal law does not recognize cottage food or home kitchens; however, state laws in all 50 states allow at least some cottage food or home kitchen sales.⁹⁰ This is because, as described above, states have always had the authority to regulate intrastate food sales and to make decisions that modify or exempt certain types of retail or food service from state food safety regulations.⁹¹ Cottage food and home kitchen statutes passed by states typically establish exemptions from certain state licensing and facility requirements.⁹² These conditions, while more lenient, still create “requirements or prohibitions relating to the use, labeling, sale or marketing” of food under the FRESH Act.

Furthermore, the FDA’s model Food Code proposes that no home kitchens be licensed for commercial food production.⁹³ Up until now, states have largely chosen not to incorporate that provision, and have used their traditional authority over food safety to adopt their own cottage food and home kitchen laws and exceptions, as described above. However, if the FRESH Act’s preemption creates a regulatory gap by displacing state regulation of food retail and food service, Congress could adopt the model FDA Food Code as law, which, as written, would end the ability for cottage food or home kitchen enterprises to operate.⁹⁴ If Congress does not adopt the FDA Food Code as law, it will leave a complete regulatory gap for cottage food and home kitchen businesses, which are exempted from federal registration requirements.⁹⁵

6. State manufacturing requirements

The FRESH Act could also disrupt state manufacturing requirements. Under the FDCA and its modifying legislation, like the Food Safety Modernization Act (FSMA), the FDA has authority over food facilities, except for smaller farms and facilities that are exempt from the legislation.⁹⁶ States have the authority to regulate those facilities exempt under FSMA.⁹⁷ States also have the authority to regulate any businesses operating within the state and thus to oversee and license manufacturing facilities in the state, whether they fall under FSMA or are exempt from its provisions.⁹⁸ States have adopted a number of laws in this area, including licensing regimes, product-specific manufacturing controls, and other standards tailored to local concerns.⁹⁹ These requirements could fall under the FRESH Act’s preemption because they are “requirements... relating to the use [and] sale of food.”¹⁰⁰ Examples of these types of state manufacturing laws include California’s Processed Food Registration, which requires a facility that manufactures, packs, or holds processed food to register with the California Department of Public Health,¹⁰¹ and Texas’s food manufacturer license, whose issuance depends on whether the manufacturer meets certain state manufacturing standards.¹⁰²

Implications of the FRESH Act's Broad Preemption Language

The FRESH Act's preemption provision will have consequences beyond the preemption of longstanding state food safety and consumer protection regulations. For example, if these state laws are no longer in effect, the immense burden of regulating every retail food store and food service establishment in the country would fall squarely on the FDA. This shift will be both costly and difficult to navigate, and will have its own consequences for consumers. The preemption would reduce ability for states or consumers to bring consumer protection claims, as they would limit state causes of action.

Regulatory Gaps

First, with the broad preemption proposed by the FRESH Act, there is no requirement that there be a provision of the federal Food, Drug and Cosmetic Act that covers the same issues addressed by a state law in order for preemption to occur.¹⁰³ This is in contrast to earlier express federal preemption such as § 21 U.S.C. 343-1 of the NLEA (national uniform nutrition labeling), where the preempted state laws must be “of the type” covered by specified federal requirements listed explicitly in that section.¹⁰⁴ However, no such language is included in the FRESH Act. Thus, the FRESH Act will preempt even in areas where there is no federal equivalent, meaning many key state laws will be overturned with nothing to replace them.

Burdensome New Costs

Second, by its own estimate, the products overseen by the FDA are valued at \$4.1 trillion and account for about 21 cents of every dollar spent by U.S. consumers.¹⁰⁵ If enacted, the FRESH Act would preempt all state and local food safety regulations, making the FDA solely responsible for regulating all of the retail food and food service establishments currently regulated at the state and local levels. To do so, FDA would need an exponentially larger workforce, budget, and statutory authority.¹⁰⁶ The federal government would either need to directly regulate all of these facilities, or it would need to pay state agencies to regulate the facilities on behalf of FDA. This is because the federal government cannot “commandeer” a state to enact or administer a federal regulatory program.¹⁰⁷ If the FRESH Act displaces state requirements without providing the necessary resources and mechanisms for the FDA to assume these responsibilities or to pay states to do so, the result would be a massive regulatory vacuum over all food retail and food establishments, in which consumers face the brunt of the consequences.¹⁰⁸ This underscores the practical reasons the current federal-state balance of oversight for food safety exists.

Lost Causes of Action

A further consequence of the FRESH Act's preemption scheme is the potential elimination of meaningful private action or state-level enforcement action against bad actors. The FDCA does not create a private right of action for consumers or states to enforce its provisions; only the FDA, FTC, or the DOJ can bring enforcement actions.¹⁰⁹ However, private litigants and states have various causes of action they can use to address unsafe, misleading, or noncompliant products. If the FRESH Act broadly preempts “any and all state requirements or prohibitions,” this language is broad enough to be interpreted similarly to other instances where state tort law causes of action were also preempted.¹¹⁰ This would undercut the existing state-law causes of action that consumers injured by unsafe or deceptively marketed food utilize.¹¹¹ Consumers

would lose a direct cause of action to hold individual companies liable for consumer protection violations, leaving food safety and consumer protection enforcement to the federal government's sole discretion and ability.¹¹²

Conclusion

The FRESH Act would likely preempt hundreds of essential state laws that have long formed the backbone of food safety and consumer protection, from ingredient bans to restaurant regulation, menu labeling, and beyond. Displacing these measures without creating parallel federal mechanisms presents the possibility of placing an immense burden on the FDA, an agency that is ill-equipped to police every food establishment nationwide. It would take away states' ability to regulate more strictly for the public good, a power states have historically been granted under their police powers. This would also eliminate states' ability to make more or less protective decisions for their residents, a key element of the notion of states as "laboratories of democracy" that can choose to regulate differently.¹¹³ The long-standing cooperative federalism model for food safety oversight that has evolved over the past century could be replaced overnight with a single, central regime with large regulatory gaps that is less responsive, less comprehensive, and ultimately, less protective of consumers and public health.

Endnotes

- ¹ *FDA Review and Evaluation for Safe, Healthy and Affordable Foods Act of 2026*, H.R. Discussion Draft, 119th Cong. § 1301 (Discussion Draft of Apr. 22, 2026) <https://democrats-energycommerce.house.gov/sites/evo-subsites/democrats-energycommerce.house.gov/files/evo-media-document/h.r-fda-review-and-evaluation-for-safe-healthy-and-affordable-foods-act-of-2026.pdf> (hereinafter, FRESH Act).
- ² Harvard Law School Food Law & Policy Clinic, *State Regulation of Food Additives and Chemicals: Preemption, the Commerce Clause, and the Breadth of State Authority* (2025), https://chlp.org/wp-content/uploads/2025/12/State-Regulation-of-Food-Additives-and-Chemicals_FINAL_.pdf (“In 2025, more than 30 states introduced nearly 120 pieces of legislation aimed at curtailing the use of additives in foods.”).
- ³ U.S. Const. art. I, § 8, cl. 3 (granting Congress power to regulate interstate commerce) (hereinafter Harvard Law School Food Law and Policy Clinic, *Preemption Report*).
- ⁴ Marc T. Law, *The Origins of State Pure Food Regulation*, 63 J. ECON. HIST. 1103, 1103 (2003), <https://www.jstor.org/stable/3132366>.
- ⁵ *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., (Apr. 24, 2019), <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement>.
- ⁶ *FDA’s Origin*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/fdas-origin> (last visited July 19, 2026) (“Beginning as the Division of Chemistry and then (after July 1901) the Bureau of Chemistry, the modern era of the FDA dates to 1906 with the passage of the Federal Food and Drugs Act . . . The Bureau of Chemistry’s name changed to the Food, Drug, and Insecticide Administration in July 1927. . . in July 1930 the name was shortened to the present version.”).
- ⁷ *FDA-Regulated Meats and Meat Products for Human Consumption*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/meat-guidance-documents-regulatory-information/fda-regulated-meats-and-meat-products-human-consumption> (last visited June 24, 2026); *Federal Meat Inspection Act*, codified at 21 U.S.C. §§ 601-695.; *Poultry Products Inspection Act*, codified at 21 U.S.C. §§ 451-472; *Egg Products Inspection Act*, codified at 21 U.S.C. §§ 1031-1056.
- ⁸ C.C. Regier, *The Struggle for Federal Food and Drugs Legislation*, 1 L. & Contemp. Probs. 4, 3-15 (1933), <https://scholarship.law.duke.edu/lcp/vol1/iss1/2> (explaining that the opposition to the Pure Food and Drug Act included opposition to the federal government extending police power into the states).
- ⁹ *Part I: The 1906 Food and Drugs Act and Its Enforcement*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/changes-science-law-and-regulatory-authorities/part-i-1906-food-and-drugs-act-and-its-enforcement> (describing the impact of muckraking journalists like Upton Sinclair and his nauseating account of the meatpacking industry in *The Jungle* that precipitated federal food and drug law).
- ¹⁰ Laurie J. Beyranevand & Diana Winters, *Retooling American Foodralism*, 44 Am. J.L. & Med. 489, 492 (2018); *Images from the History of the Public Health Service: Pure Food and Drugs*, Nat’l Lib. of Med., https://www.nlm.nih.gov/exhibition/phs_history/foodanddrugs.html (last visited July 2, 2026) (“Gradually a coalition developed, including farmers, food processors, state officials, physicians, women’s club members, and muckraking journalists. Pressure from this powerful lobby... finally pushed Congress to enact, in 1906, both a meat inspection law and the Food and Drugs Act.”).
- ¹¹ Jennifer A. Staman, Cong. Rsch. Serv., R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues* 7 (2018) (“Established under FD&C Act Section 1003, the U.S. Food and Drug Administration (FDA) is the primary agency that administers and enforces the Act.”).
- ¹² See, e.g., Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784 (1958), Drug Amendment of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (commonly referred to as the Kefauver-Harris Amendments), and Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353.
- ¹³ Beyranevand & Winters *supra* note 10 at 493 (“While federal laws and policies largely govern food regulation in the United States, most allow significant room for the states to regulate pursuant to their ability to develop laws and policies to protect the public, health, safety and welfare of their citizens.”). See, e.g., 21 C.F.R § 101.11 (menu labeling) (requiring chain restaurants to display certain calorie information) or 21 U.S.C. § 343(w) (requiring packaged foods to declare major food allergens in a specified way) *contra* Cal Health & Safety Code §114093.5 (requiring chain restaurants to provide written notification of major food allergens for menu items and specifically exempting any packaged foods that are subject to requirements under 21 U.S.C. § 343).
- ¹⁴ *Retail Food Protection*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection> (last visited June 24, 2026) (Stating “more than 3,000 state, local, and tribal agencies have primary responsibility to regulate food and foodservice industries in the United States”) and *Adoption of the FDA Food Code by State and Territorial Agencies Responsible for the Oversight of Restaurants and Retail*, U.S. Food & Drug Admin., <https://www.fda.gov/food/fda-food-code/adoption-fda-food-code-state-and-territorial-agencies-responsible-oversight-restaurants-and-retail> (last visited July 19, 2026) (“The FDA’s Office of Retail Food Protection encourages and monitors adoption of the FDA Food

Code by state and territorial agencies in the United States responsible for regulation of restaurants and/or retail food stores . . . Restaurant and retail food store oversight in the United States is typically handled at the state and local levels, rather than the federal level.”).

- 15 Nat’l Agric. Law Ctr., *Food Safety – An Overview*, <https://nationalaglawcenter.org/overview/food-safety/> (last visited June 19, 2026) (“[S]tate regulatory agencies also play an important role in food safety regulation, especially in enforcement. Most notably, state regulatory agencies are primarily responsible for food sanitation and safe food handling by food retailers, food service providers, and food vending operations.”).
- 16 Dorothy C. Kafka & Wen W. Shen, CONG. RSCH SERV., R48915, *Preemption and the Federal Food, Drug, and Cosmetic Act (FD&C Act)* (2026).
- 17 Nat’l Agric. Law Ctr., *supra* note 15.
- 18 U.S. Const. amend. X, (“Powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or the people.”); *Retail Food Protection*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection> (last visited June 24, 2026) (Stating “more than 3,000 state, local, and tribal agencies have primary responsibility to regulate food and foodservice industries in the United States”).
- 19 For example, Chapter 500 of the Florida Statutes prevents food establishments (“a factory, food outlet, or other facility manufacturing, processing, packing, holding, storing, or preparing food or selling food at wholesale or retail”) from operating without a permit. 500 Fla. Sta. §§ 3 and 12. Fees from permitting go into the Florida Department of Agriculture and Consumer Services (FDACS)’s General Inspection Trust Fund, which helps pay for the state’s inspection program. 570 Fla. Sta. §20. General Inspection Trust Fund; 21 C.F.R. pt. 117 (2024) (Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food) (providing requirements for businesses who manufacture, pack/process, or hold food for consumption in the U.S., while exempting certain smaller facilities).
- 20 U.S. Const. Article I, Section 8, Clause 3.
- 21 The notion that the “police power” belongs to the states has been consistently upheld in judicial interpretations of the Tenth Amendment. *See, e.g.*, U.S. Const. amend. X; *Hamilton v. Kentucky Distilleries* 251 U.S. 156 (1919) (“That the United States lacks the police power, and that this was reserved to the states by the Tenth Amendment, is true.”); Kafka & Wen W. Shen, CONG. RSCH SERV., R48915, *Preemption and the Federal Food, Drug, and Cosmetic Act (FD&C Act)* 2 (2026) (“States have historically regulated many products covered by the FD&C Act based on their general police power to provide for the public health and safety of their residents.”).
- 22 Neal D. Fortin, *Introduction to Food Regulation in the United States* (2016), in *Food Regulation: Law, Science, Policy, and Practice* (2nd ed., 2017) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2885866; *Gibbons v. Ogden*, 22 U.S. 1 (1824) (explaining that inspection laws “form a portion of that immense mass of legislation...all of which can be advantageously be exercised by the states themselves. Inspection laws, quarantine laws, health laws of every description ... are component parts of this mass. No direct general power over these objects is granted to Congress, and, consequently, they remain subject to State legislation.”).
- 23 *Retail Food Protection*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection> (last visited June 24, 2026) (Stating “more than 3,000 state, local, and tribal agencies have primary responsibility to regulate food and foodservice industries in the United States”).
- 24 21 U.S.C. § 343-1(a) (describing that only particular categories of food labeling requirements are preempted, preserving state requirements in other categories).
- 25 *See, e.g.*, *National Uniformity for Food Act* of 2005, H.R. 4167, 109th Cong. (2005) (proposing an amendment to the FDCA that would prohibit states from enacting provisions that are not identical to existing federal provisions for adulterated food, unsafe color and food additives, and several other food safety issues); *National Uniformity for Food Act* of 2006, S. 3128 (proposing national uniformity for food safety warning labels). These proposed bills received considerable opposition from stakeholders and a majority of state attorneys general, who, in 2006 sent a joint letter to Congress explaining that, because “[f]ood safety has been largely a matter of state law and oversight” and “[s]tate and local agencies perform more than 80 per cent of food safety work,” the National Uniformity for Food Act would “undercut[] states’ rights and consumer protection.” *See* Letter from Nat’l Ass’n of Attys Gen. to Members of Congress, Mar. 2, 2006, <https://advocacy.consumerreports.org/wp-content/uploads/2013/05/FoodSafety.pdf>. Congress has, however, enacted laws that expressly preempt certain specific areas of food safety or labeling. *See* Pub. L. 101-535, 104 Stat. 2353, 2362–63 (codified at 21 U.S.C. § 343-1(a)) (enacted in 1990 to preempt state laws on standards of identity and the labeling of food “not identical to” federal standards or requirements); Pub. L. 104-170, 110 Stat. 1489, 1530–31 (codified at 21 U.S.C. § 346(a)(n)(4)) (enacted in 1996 to preclude states from “establish[ing] or enforc[ing] any regulatory limit on a qualifying pesticide chemical residue . . . unless [it] is identical to such qualifying Federal determination”).
- 26 Cal. Health & Safety Code § 110423 (Passed into law on September 27, 2002, through Senate Bill 1884); *Small Entity Compliance Guide: Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk*, U.S. FOOD & DRUG ADMIN., (July 2008), <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/small-entity-compliance-guide-final-rule-declaring-dietary-supplements-containing-ephedrine>.
- 27 The FDA did not issue its final determination that partially hydrogenated oils (primary source of artificial trans fats) were no

longer GRAS until 2015. *Trans Fat*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-additives-petitions/trans-fat> (last visited June 23, 2026). *Contra* Cal. Health & Safety Code § 114377 (2010) (imposing strict mandates to eliminate artificial trans fats in food service in California in 2010) and N.Y.C Dep’t of Health & Mental Hygiene Bd. Of Health, Notice of Adoption of An Amendment (§ 81.08) to Article 81 of the New York City Health Code 1 (Dec. 5, 2006) (eliminating artificial trans fats in food in New York City by 2008).

28 Harvard Law School Food Law and Policy Clinic, *Preemption* Report, *supra* note 2 at 1 (“In 2025, more than 30 states introduced nearly 120 pieces of legislation aimed at curtailing the use of additives in foods.”).

29 California Food Safety Act, ch. 328, 2023 Cal. Stat. (codified at Cal. Health & Safety Code § 109025) (banning brominated vegetable oil, potassium bromate, propylparaben, red dye 3). CA AB2316, 2023-2024 Legis. Sess. (CA 2024) (banning schools from using FD&C Red Dye No. 40, FD&C Yellow Dye No. 5., FD&C Yellow Dye No. 6, FD&C Blue Dye No. 1, FD&C Blue Dye No. 2. FD&C Green Dye No. 3).

30 *Press Release: Governor Patrick Morrisey Signs Food Dye Legislation into Law*, W. VA. OFF. OF THE GOV. (Mar. 24, 2025) <https://governor.wv.gov/article/governor-patrick-morrisey-signs-food-dye-legislation-law>.

31 Harvard Law School Food Law and Policy Clinic, *Preemption* Report, *supra* note 2 at 2-3.

32 *Id.* at 4.

33 *ABA v. Paxton*, 820 F.Supp.3d 494 (W.D. Texas, 2026) (granting a preliminary injunction blocking the enforcement of a food warning label requirement in Texas).

34 *See, e.g. id.* (holding that the warning label requirement was not preempted by existing federal law, while enjoining the warning label requirement on other grounds),

35 Americans for Ingredient Transparency is backed by dozens of huge food and beverage companies. Backers listed on AFIT’s website under the “Backed by these Trusted Brands” section include: The Coca-Cola Company, PepsiCo, Nestlé, Kraft Heinz, Tyson Foods, Sysco, and more. *See* Americans for Ingredient Transparency, Backed by These Trusted Brands, <https://americansforingredienttransparency.com/> (last visited June 19, 2026).

36 Americans for Ingredient Transparency, *Policy Priorities*, <https://americansforingredienttransparency.com/policy-priorities/> (last visited June 19, 2026) (“The FDA Sets the Uniform Standard[.]”) (emphasis added).

37 Americans for Ingredient Transparency, *WHAT THEY ARE SAYING: The FRESH and Affordable Foods Act*, <https://americansforingredienttransparency.com/what-they-are-saying-the-fresh-and-affordable-foods-act/> (last visited Aug., 2, 2026) (“...all agree that the only solution that increases ingredient transparency and keeps grocery prices low is a single uniform national ingredient standard set by Congress through [the FRESH Act]”).

38 U.S. Const. art. VI, cl. 2.

39 U.S. Const. art. X; *La. Pub. Serv. Commn. v. FCC*, 476 U.S. 355, 374 (1986) (“A federal agency may preempt state law only when and if it is acting within the scope of its congressionally delegated authority . . . an agency literally has no power to act, let alone preempt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it.”).

40 *See, e.g., Wyeth v. Levine*, 555 U.S. 555, 565 (2009) (“in all preemption cases, and particularly in those in which congress has ‘legislated . . . in a field which the States have traditionally occupied,’ we ‘start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.” (quoting *Medtronic Inc. v. Loh*, 518 U.S. 470, 485 (1996))).

41 *Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992).

42 *Fidelity Fed. Sav. & Loan Ass’n. v. De la Cuesta*, 458 U.S. 141, 153 (1982) (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U. S., at 230) (“Absent explicit pre-emptive language, Congress’ intent to supersede state law altogether may be inferred because “[the] scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it[.]”).

43 *Pacific Gas & Elec. Co. v. State Energy Resources Conservation and Development Comm’n*, 461 U. S. 190, 204 (1983). Conflict preemption can be further divided into two categories: impossibility conflict, in which it is impossible for one to comply with both regulations simultaneously, and obstacle conflict, in which the state law would act as a direct obstacle to achieving the full purposes and objectives of the law enacted by Congress. Harvard Law School Food Law and Policy Clinic, *Preemption* Report, *supra* note 2 at 5.

44 Hearing on “Healthier America: Legislative Proposals on the Regulation and Oversight of Food,” Subcomm. On Health of the H. Comm. On Energy & Com., 119th Cong. (Apr. 29, 2026), Democrats, Energy & Com. Comm., <https://democrats-energycommerce.house.gov/committee-activity/hearings/hearing-healthier-america-legislative-proposals-regulation-and>.

45 *FRESH Act* *supra* note 1 at § 1301.

46 *Id.*

47 *See United States v. Anderson Seafoods, Inc.*, 447 F. Supp. 1151 (N.D. Fla. 1978) (discussing mercury’s status as an added or naturally occurring substance) and *Continental Seafoods, Inc. v. Schweiker*, 674 F. 2d 38 (D.C. Cir. 1982) (discussing whether salmonella in shrimp is an added or naturally occurring substance); 21 U.S.C. § 348(a) (requiring approval for food contact substances); *Food Chemical Safety*, U.S. Food & Drug Admin., <https://www.fda.gov/food/food-ingredients-packaging/food-chemical-safety> (last updated May 12, 2026) (noting that FDA conducts pre and postmarket evaluations of chemicals in food

packaging, and ensures that industry is minimizing or preventing exposure from unsafe contaminants.

FRESH Act supra note 1 at § 402A(b).

21 U.S.C. § 2104(a)(1) (mandates the Secretary to work with state authorities on activities and programs designed to improve food safety, ultimately requiring cooperation between federal and state government).

Health Hearing: Healthier America: Legislative Proposals on the Regulation and Oversight of Food Before the H. Comm. On Energy & Com., 110th Cong. (2026) <https://energycommerce.house.gov/events/health-hearing> (at 2:21:05) (“Right now we know that there is a patchwork of states that are stepping to fill in the gaps where, honestly, the federal government has fallen short. But the result is a patchwork of differing requirements that create real costs for manufacturers, for retailers, and ultimately, for families.”).

California Food Safety Act, ch. 328, 2023 Cal. Stat. (codified at Cal. Health & Safety Code § 109025); 32 Maine Rev. Stat. § 1733(3B); Minn. Stat. § 116.943.

21 U.S.C. § 21(s) (2024) (“The term “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 otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food[.]).”).

FRESH Act supra note 1 at § 1301.

S.B. 850, Reg. Sess. (Fla. 2026) (proposing a requirement for certain grain products for human consumptions to contain folic acid).

S.B. 220, 86th Leg., Reg. Sess. (W. Va. 2023) (creating the “Kratom Consumer Protection Act” to regulate the preparation, distribution, and sale of kratom products and defining “food” to include food products, food ingredients, dietary ingredients, and dietary supplements).

See *Wyeth v. Levine*, 555 U.S. at 565–73 (demonstrating that in areas “in which Congress has legislated in a field which the States have traditionally occupied,” courts presume “the historic police powers of the States were not to be superseded ... unless that was the clear and manifest purpose of Congress,” and holding that the FDCA does not broadly preempt state law); see generally, California Prop 65.

Tex. Health & Safety Code Ann. § 431.0815 (2025) (requiring warning labels on packaged foods containing any of 44 specified additives or chemicals) and La. Rev. Stat. § 40:661 (2025) (requiring labels on food products containing specific artificial colors, additives, or chemicals to include a QR code and disclaimer linking to FDA chemical-safety information).

21 U.S.C. § 321(m) (“the term ‘labeling’ means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”).

The FDCA contains various labeling requirements for products under the FDA’s authority. If a product does not comply with the requirements imposed by 21 U.S.C. § 343, it will be considered misbranded. The NLEA, which amended 21 U.S.C. § 343, required that no state or political subdivision may establish a requirement that is not identical to certain provisions in 21 U.S.C. § 343-1, but none of the provisions in § 343 or § 343-1 address warning labels on foods other than certain allergen requirements.

Tex. S.B. 25, 89th Leg., R.S. (2025), codified at Tex. Health & Safety Code Ann. § 431.0815 (2025). See *ABA v. Paxton*, 820 F.Supp.3d 494 (W.D. Texas, 2026) (preliminary injunction based on likelihood of the plaintiffs prevailing on a first amendment commercial speech challenge to the warning label).

S.B. 14, 2025 Leg., Reg. Sess. (La. 2025), as amended by S.B. 57, 2026 Leg., Reg. Sess. (La. 2026), codified at La. Rev. Stat. Ann. § 40:661 (2026).

FRESH Act supra note 1 at § 402A(d)(2) (“Exclusion. -- This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.”).

Cal. Health & Safety Code §§ 25249.5-.14 (West 2025) (Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)).

Menu and Vending Machine Labeling, U.S. Food & Drug Admin., <https://www.fda.gov/food/nutrition-food-labeling-and-critical-foods/menu-and-vending-machine-labeling> (last updated Dec. 13, 2023).

21 U.S.C. § 343(q)(5)(H)(i).

N.Y.C. Health Code § 81.49 (Sodium warning) and N.Y.C. Admin. Code § 17-199.18 (“Sweet Truth Act” or added sugar notification).

Cal. Health & Safety Code § 114094.6.

N.Y. Pub. Health Law § 1357 (2025).

These types of warning labels may have a unique complication, as required labeling on foods that include meat or poultry is regulated by the USDA (21 U.S.C. §§ 601-605.), which may implicate cell-cultivated meat laws, and thus may be preempted already by USDA rules.

H.B. 25-1203, 75th Gen. Assemb., 1st Reg. Sess. (Colo. 2025)

H.B. 138, 65th Leg., Gen. Sess. (Utah 2025).

21 U.S.C. § 343-1(a) (lists specific categories of state food-labeling requirements that are preempted).

Wyeth v. Levine, 555 U.S. 555.

FRESH Act supra note 1 at § 1301.

Press Release: Ahead of World Food Safety Day, New York Safe Announces New Action Levels for Heavy Metals in Spices, NEW

YORK STATE DEP'T OF AGRIC. & MKTS., (June 5, 2026) (lowering the New York State's Class II action levels for inorganic arsenic, cadmium, and lead in spices by a factor of almost five times to 0.21 ppm).

See e.g., Minn. Stat. § 325F.075 (2025) (prohibiting the manufacture, sale, or distribution of food packaging containing intentionally added PFAS); Me. Rev. Stat. Ann. tit. 38 § 1614 (2025) (requiring manufacturers of products with intentionally added PFAS to report use to Maine DEP and by 2030, prohibiting sale of more products using intentionally added PFAS unless deemed unavoidable).

Cal. Health & Safety Code §§ 110962-110963.

Grade "A" Pasteurized Milk Ordinance, U.S. Food & Drug Admin., <https://www.fda.gov/media/140394/download> (2019).

21 C.F.R § 1240.61 (2024).

National Shellfish Sanitation Program (NSSP), U.S. Food & Drug Admin., <https://www.fda.gov/food/federal-state-local-tribal-and-territorial-cooperative-human-food-programs/national-shellfish-sanitation-program-nssp> (last visited Aug. 2, 2026).

Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill, Ass'n of Am. Feed Control Officials (Apr. 2023); https://aafco.org/wp-content/uploads/2023/12/20230731_DraftModRegsPFLM_FINAL.pdf.

How to Start a Food Business, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/food-industry/how-start-food-business> (last accessed June 16, 2026) ("Examples of Food businesses NOT regulated by FDA: Retail food establishments (such as grocery stores, restaurants, drive-throughs, cafeterias, and food trucks), which are regulated by state and local government.").

State Retail and Food Service Code and Regulations by State, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/food/fda-food-code/state-retail-and-food-service-codes-and-regulations-state> (last visited June 25, 2026) (listing the different state retail and food service codes by State).

FDA Food Code, U.S. FOOD & DRUG ADMIN., (Dec. 9, 2025), <https://www.fda.gov/food/retail-food-protection/fda-food-code> ("The U. S. Food and Drug Administration (FDA) publishes the Food Code...Local, state, tribal, and federal regulators use the *FDA Food Code* as a model to develop or update their own food safety rules and to be consistent with national food regulatory policy.").

Examples of these types of laws are seen in the Model Food Code; see e.g., Food Code §§ 3-302.11 & 305-11 (requiring food to be protected from cross-contamination through separation, packaging, and certain storage practices and 2022 FDA Food Code § 3-501.16 (requiring certain foods to be maintained at specified temperatures). These examples are part of the FDA Food Code, so states may choose to implement them as they see fit, and are merely provided as an example of laws in this type of category. 24 R.C.N.Y. § 23-07 (covering the posting of letter grades for food establishments).

See generally, N.Y. Agric. & Mkts. Law § 500-b(1); O.C.G.A. § 26-2-371(a); Ark. Code Ann. § 20-57-204(a); S.C. Code Regs. § 61-25 § VII-301(a).

FRESH Act *supra* note 1 at § 130.

Harvard Law School Food Law & Policy Clinic, *Cottage Foods and Home Cooking: Fifty-State Survey of Laws* (2021), <https://chlp.org/wp-content/uploads/2022/04/Cottage-Foods-Final-4.4.pdf> (hereinafter Harvard Law School Food Law & Policy Clinic, *Cottage Foods*).

U.S. Const. amend. X; See *United States v. Lopez*, 514 U.S. 549, 558-59 (1995) (holding that Congress may only regulate wholly local, intrastate economic activities if they in the aggregate "substantially affect" interstate commerce).

Harvard Law School Food Law & Policy Clinic, *Cottage Foods*, *supra* note 89.

Id. at 2 ("As of 2021, all 50 states have expanded upon this exemption in their state laws in various ways to allow for the limited sale of certain foods produced at home.").

U.S. FOOD & DRUG ADMIN., Food Code §1-201.10(B)(3) (explaining the definition of food establishment does *not* include a kitchen in a private home that does not conform to time/temperature controls for safety).

See Nat'l Grocers Ass'n, *The Model Food Code*, <https://www.nationalgrocers.org/news/the-fda-model-food-code-2/> (last visited July 11, 2026) (explaining a longstanding goal of FDA and retailers has been universal adoption of the Food Code by all jurisdictions and thus a possible path federal regulators could take); Harvard Law School Food Law & Policy Clinic, *Cottage Foods*, *supra* note 89 at 2 (Explaining that "entities designated as 'food establishments' must generally meet the regulatory requirements in the Food Code, and home kitchens generally cannot be licensed as food establishments. . .").

21 C.F.R. § 1.227; *How to Start a Food Business*, U.S. Food & Drug Admin., *supra* note 82 ("Examples of Food businesses NOT regulated by FDA: Retail food establishments (such as grocery stores, restaurants...) which are regulated by state and local government" and "Under federal regulations [21 C.F.R. § 1.227], a private residence is not a 'facility' and as a result, is not required to register with FDA.").

See *FDA Food Safety Modernization Act*, Pub. L. No. 111-353, § 103, 124 Stat. 3885, 3889-99 (2011) (codified at 21 U.S.C. §350(g)), including the "qualified facility" exemption, or the Tester-Hagan amendment, 21 U.S.C. §350(g)(l)– (m); 80 Fed. Reg. 55,908 (Sep. 17, 2015) ("Generally, domestic and foreign food facilities that are required to register with section 415 of the Food, Drug, & Cosmetic Act must comply with the requirements for risk-based preventive controls mandated by the FDA Food Safety Modernization Act (FSMA)... (unless an exemption applies)"; 21 C.F.R. § 117.5 (explaining exemptions that may apply to a facility qualifying them for reduced requirements.).

FDA Releases Information for Qualified Facilities Under Preventive Controls Rules, U.S. FOOD & DRUG ADMIN., (Sept. 14, 2018), <https://www.fda.gov/food/hfp-constituent-updates/fda-releases-information-qualified-facilities-under-preventive-controls-rules>

(explaining qualified facilities exempted from federal requirements must still “[comply] with applicable non-federal food safety laws and regulations.”).

- ⁹⁸ See, for example, in Minnesota, the MDA licenses and inspects food and commercial feed manufacturers in Minnesota, and the FSMA created new federal regulations that also apply to food manufacturers, food distributors, and commercial feed processors and distributors in Minnesota. *Food Safety Modernization Act (FSMA)*, Minn. Dept’ of Agric., <https://www.mda.state.mn.us/food-feed/food-safety-modernization-act-fsma> (last visited July 2, 2026).
- ⁹⁹ Committee on the Review of FDA’s Role in Ensuring Safe Food, National Research Council, *Integrating Federal, State, and Local Government Food Safety Programs*, in *Enhancing food Safety: The Role of the Food and Drug Administration* (Robert B. Wallace & Maria Oria eds., Nat’l Acads. Press 2010) <https://www.ncbi.nlm.nih.gov/books/NBK220385/> (explaining the information available from state and local authorities includes data from food safety inspections, disease outbreaks, and product safety investigations).
- ¹⁰⁰ *FRESH Act supra* note 1 at § 1301.
- ¹⁰¹ Cal. Health & Safety Code §10460(a) (2026) (“No person shall engage in the manufacture, packing, or holding of any processed food in this state unless the person has a valid registration from the department...”).
- ¹⁰² Tex. Health & Safety Code Ann. § 431.22 (2026) (requiring a food manufacturer’s license for persons who manufacture or distribute food in Texas).
- ¹⁰³ Bryan L. Adkins et al., CONG. RSCH. SERV., R45825, *Federal Preemption: A Legal Primer* (2023).
- ¹⁰⁴ The NLEA’s careful limitation of preemption to only particular categories would itself become irrelevant were the FRESH Act to become law, as discussed above. See *supra* note 72.
- ¹⁰⁵ Off. of the Comm’r, *FDA at a Glance*, U.S. FOOD & DRUG ADMIN., (2026), <https://www.fda.gov/media/154548/download>.
- ¹⁰⁶ *Retail Food Protection*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/retail-food-protection> (last visited June 24, 2026) (Stating “more than 3,000 state, local, and tribal agencies have primary responsibility to regulate food and foodservice industries in the United States” indicating the huge amount of establishments FDA would have to regulate themselves without state/local assistance).
- ¹⁰⁷ *Printz v. United States* 521 U.S. 898 (1997) (holding that the federal government cannot commandeer state or executive officials to perform a federal regulatory program).
- ¹⁰⁸ Harvard Law School Food Law & Policy Clinic, *Preemption Report supra* note 2 at 1–3, 34–38 (explaining states’ role in filling gaps in FDA oversight).
- ¹⁰⁹ Jennifer A. Staman, CONG. RSCH. SERV., R43609, *Enforcement of the Food, Drug, and Cosmetic Act: Select Legal Issues 2* (2018) (“Because FDA, like most executive agencies, does not have independent litigating authority, it must coordinate with the Department of Justice (DOJ) to pursue criminal or civil remedies...private parties, however, do not have rights to enforce the FD&C through lawsuits.”).
- ¹¹⁰ See, *Employee Retirement Income Security Act of 1974* (ERISA) § 514(a), 29 U.S.C. § 1144(a) (2018) (preempting “any and all State laws insofar as they . . . relate to any employee benefit plan. . .”); *Pilot Life Ins. Co v. Dedeaux* 481 U.S. 41, 43 (holding ERISA preempted respondent’s suit under state common law causes of action for alleged improper processing of claim for benefits); *Federal Food, Drug, and Cosmetic Act* § 521(a), 21 U.S.C. 360k(a) (Medical Device Amendments) (barring states from imposing requirements different from or in addition to federal requirements for certain medical devices); *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008) (holding New York’s common-law tort duties constitute “requirements” within the meaning of § 360k(a) and are therefore preempted).
- ¹¹¹ Dorothy C. Kafka & Wen W. Shen, Cong. Resch. Serv., R48915, *Preemption and the Federal Food, Drug, and Cosmetic Act (FD&C Act)*, (2026) 2 (“State consumer protection and products liability laws provide mechanisms by which consumers allegedly injured by a relevant product may challenges the product’s promotion, manufacture, design, and/or warning, on the grounds that the defendant manufacturers should have taken a different course of action with respect to those activities...[.]”).
- ¹¹² U.S. Gov’t Accountability Off., GAO-08-597, *FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* 13 (2008), <https://www.gao.gov/assets/gao-08-597.pdf> (“FDA’s use of oversight and enforcement tools has not kept pace with the growing number of food firms. As a result, FDA has limited assurance that companies in the food industry are in compliance with food labeling requirements, such as those prohibiting false or misleading labeling.”); U.S. Gen. Accounting Off., GAO/RCED-00-156, *Food Safety: Improvements Needed in Overseeing the Safety Dietary Supplements and “Functional Foods,”* (2000) <https://www.gao.gov/assets/rced-00-156.pdf> (explaining that in response to health related claims “according to an FDA official, the agency has chosen to use its limited resources on regulating product safety rather than on taking enforcement actions against problematic label claims.”).
- ¹¹³ See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) (“It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”).



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THE PROPOSED FEDERAL “FRESH” ACT AND THE IMPACT OF ITS PREEMPTION PROVISION

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