Date of Hearing: April 14, 2026

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Damon Connolly, Chair
AB 2034 (Addis) – As Introduced February 17, 2026

SUBJECT: Food safety: unsafe additives and ingredient disclosures

SUMMARY: Deems a food additive or dietary ingredient in food unsafe unless it meets any of several specified conditions, including that it is used in compliance with notice, public listing, and licensing requirements established under AB 2034, or has successfully gone through the federal Food and Drug Administration (FDA)'s voluntary "Generally Recognized as Safe" (GRAS) Notification Program; requires individuals intending to use a food additive or dietary ingredient in food to submit a notice containing specified information to the California Department of Public Health (CDPH); requires CDPH to post these notices in a publicly available database; requires CDPH to issue licenses for food additives and uses, as specified; requires CDPH to assess, and reassess every three years, the safety of specified substances, including food and color additives and dietary ingredients; requires manufacturers to submit to CDPH a list of its food products that do not individually list each of the product's ingredients, and to identify each ingredient not individually named on the ingredient list, as specified; requires CDPH to post this ingredient information on a publicly available database, as specified.

1) Makes multiple findings and declarations, including that:

   a) There is growing public concern regarding the impact of harmful ultraprocessed foods (UPFs) on health and safety;

   b) Food additives, color additives, and flavors are often used in UPFs without FDA knowledge or agency review to ensure safety; and,

   c) Congress intended new chemicals to undergo premarket review with the passage of the Food Additive Amendment of 1958, but food companies circumvent such review through the GRAS loophole.

2) Adds to the state's existing "food additive" definition—which differs from the federal definition in that the federal, but not state definition, exempts GRAS substances from the definition of "food additive" and, as a result, associated requirements for food additives—a cross-reference to another provision in existing state law that authorizes CDPH to, by regulation, "prescribe conditions under which a food additive may be used…whether or not these conditions are in accordance with regulations adopted pursuant to" the federal Food, Drug, and Cosmetics Act (FD&C).

3) Deems a food additive unsafe if it is found to induce cancer when ingested by a human or animal, or if it is found, after tests that are appropriate for the evaluation of the safety of food substance, to induce cancer in a human or animal.

Provision of notice and licensing requirements

4) Deems a food additive unsafe in food intended for humans with respect to its intended use unless the substance and its intended use meet any of the following conditions:

a) Were widely used in the United States (U.S.) prior to January 1, 1958, without known detrimental effects, and subject only to conventional processing and intended uses as practiced prior to January 1, 1958, and for which no known safety hazard exists;

b) Are subject to a regulation prescribing a tolerance, including, but not limited to, a zero tolerance, for a poisonous or deleterious substance or food additive;

c) Are recognized in federal regulations as prior sanctioned or GRAS for use in human food or food contact materials;

d) Are a food contact substance or use subject to an effective premarket notification demonstrating safety for its intended use;

e) Are subject to a new dietary ingredient notification and received a current letter of acknowledgment from the FDA without objection that the substance is safe under the notification's intended conditions of use;

f) Are subject to a GRAS notice submitted to the FDA (via the FDA's voluntary GRAS Notification Program) and a current letter stating that the FDA has no questions regarding the conclusion that the substance is GRAS under its intended conditions of use; or,

g) Were introduced after January 1, 1958, and are used in accordance with the notice, public listing, and licensing requirements created by this bill.

5) Requires, on or before July 1, 2027, CDPH to publish on its internet website a database for notices submitted to comply with bullet (4)(g) above.

6) Authorizes CDPH to issue a license to an individual who intends to use a food additive or dietary ingredient to comply with bullet (4)(g) above; authorizes the license to limit the quantity and the use or intended use of a food additive; and authorizes CDPH to require manufacturers to guarantee that foods they market in the state comply with this tolerance.

7) Requires, commencing July 1, 2027, an individual who intends to use a food additive or dietary ingredient pursuant to AB 2034's licensing requirements, to submit a notice to CDPH that includes the same information that would be required, under federal regulations, for submission of a notice to the FDA's voluntary GRAS Notification Program.

8) Requires CDPH to do the following in issuing a license:

a) For food additives and uses introduced on or before July 1, 2027, issue a license following publishing of a notice described in bullet (5) above; and,

b) For food additives and uses introduced on or after July 1, 2027, do all of the following:

i) Allow 45 days for any filing of an objection by any member of the public presenting reasonable questions of safety for the conditions of use described in the notice;

ii) Determine whether to issue a license for the conditions of use described in the notice within 15 days from the close of the objection period described above; and,

iii) Review the notice and issue a license only if CDPH finds that no reasonable safety questions or concerns have been raised regarding the conditions of intended use of the substance.

9) Requires CDPH, within 60 days of receiving a notice, to verify that the notice contains the information required for the FDA's voluntary GRAS Notification Program and do either of the following:

   a) Publish the notice in the public database; or,

   b) Issue a rejection letter detailing missing information needed to complete the notice.

10) Requires CDPH, for the notice database established pursuant to this bill, to do all of the following:

   a) Prior to publishing information in the database, redact information that has been designated by the submitter of that information as a trade secret; prohibits the redaction of data needed to establish safety;

   b) Ensure that members of the public are able to search the database and download and print notices (including all submitted safety information and CDPH responses); and,

   c) Ensure that the database includes any licenses, safety information, and supporting information related to each notice and accommodates reasonably anticipated and actual public use.

11) Requires CDPH to provide an interim progress report with specified information to the Legislature, Governor, and on its internet website concerning efforts to develop and implement the notice database, including a projected completion date, a description of obstacles to the development and implementation of the database system, and an estimate of the costs to complete implementation of the database system.

12) Authorizes CDPH, when considering whether to issue a license, to consider and use evidence not contained in the submitted notice; requires CDPH to consult with the Office of Environmental Health Hazard Assessment and the Department of Toxic Substances Control.

13) States that licenses established by the bill are transferable, providing that any party intending to use the license other than the original submitter notifies CDPH prior to engaging in use.

14) Requires CDPH, if CDPH determines not to issue a license, to publish a letter summarizing the reasonable safety questions or concerns with the conditions of intended use of the substance.

15) Specifies that this bill does not limit CDPH in issuing regulations pursuant to existing law or otherwise limit its authority to regulate the use of a food additive.

16) Exempts small businesses from the licensure requirements of this bill; defines a "small business" as a business that is independently owned and operated, and employs 100 or fewer persons.

17) Authorizes a food facility, food service establishment, food relief organization, supermarket, grocery store, specialty food store, a farmers' market, or any other vendor that, in the regular course of business, sells food at retail directly to the public on premises located in the state, to sell, deliver, distribute, hold, offer or expose for sale any food or food product acquired for sale in the state before July 1, 2027, and for which the sale would otherwise be prohibited by this article, until the expiration date, "best by" date, or "sell by" date printed on the packaging of the food or food product by the manufacturer or producer, but no later than July 1, 2030.

Safety assessments

18) Requires, on or before July 1, 2030 and every three years thereafter, CDPH to systemically reassess the safety, including the safety of conditions of use, of at least ten of the following substances, or classes thereof:

    a) Food additives;

    b) Color additives;

    c) Prior-sanctioned substances; and,

    d) Dietary ingredients.

19) Authorizes CDPH, when determining which substances should be reassessed and in conducting the reassessments under this section, to require any person that manufactures, introduces, delivers for introduction, or receives a food substance in the state to conduct, and submit to CDPH, safety evaluations of the substance; requires the safety evaluation to include, with respect to the substance, the updated information described in bullet (20).

20) Requires CDPH to consider, but not be limited to considering, all of the following information when assessing the safety of a food additive for purposes of regulating a food additive or reassessing the safety of a food additive:

    a) Factors specified in existing law established by AB 1264 (Gabriel, Chapter 467, Statutes of 2025);

    b) Whether the food additive is subject to a Proposition 65 warning;

    c) Estimates of dietary exposure among California and the U.S. population;

    d) The cumulative effects of the substance and chemically and pharmacologically related substances;

    e) Hazard, dose response, and exposure;

    f) The application of adequately protective safety factors to ensure an appropriate margin of safety to take into account uncertainties in hazard identification, dose response, exposure, and sensitivities;

    g) Whether the weight of the evidence shows that the substance has not been found to be carcinogenic;

h) Whether the weight of the evidence shows that the substance has not been found to induce reproductive toxicity or developmental toxicity in humans or animals, including through an endocrine mode of action; and,

i) Other information that CDPH specifies in regulation.

21) Authorizes CDPH to revoke a previously issued license if CDPH determines that a concern about the safety of a substance, or the intended use of the substance, exists; requires CDPH to post the revocation in the notice database.

22) Authorizes CDPH to create and update user fees for notices, assessments, and reassessments.

Ingredient disclosures

23) Requires, on or before July 1, 2027, the manufacturer of any packaged food product subject to regulation by the FDA that is sold in this state to provide CDPH with a complete and accurate list of its food products that, as of the date of the submission, are sold in the state and do not individually list each of the product's ingredients in the ingredient list; establishes the following provisions with respect to the submission of this information:

a) Requires this submission to be on a schedule and in electronic or other format, as determined by CDPH;

b) Requires, for every product submitted, the manufacturer to identify each ingredient not individually named in the ingredient list by its common or usual name, and other relevant identifiers, including the Chemical Abstracts Service number, Flavor and Extract Manufacturers Association of the U.S. number, or license number established by this bill; requires the manufacturer to specify whether the ingredient is a natural flavor, artificial flavor, artificial color, or spice as those terms are defined in federal regulations; specifies that manufacturers are not required to disclose the weight, amount, or manner in which the ingredient is formulated.

c) Requires the manufacturer of a product subject to this bill to submit to CDPH information reflecting changes made to its ingredients, if any of the following occur:

i) Ingredients are added, modified, or removed from the product; or,

ii) Product labeling is modified to individually list each ingredient.

d) Exempts manufacturers, distributors, or retailers of food products with annual aggregate sales of food products, both within and outside of California, of less than $1,000,000, based on the party's most recent tax year filing.

e) Specifies that this bill does not require any changes to the packaging or labeling of products with regards to state or federal requirements.

24) Requires CDPH, on or before July 1, 2027, to develop and make operational a consumer-friendly, public internet website that creates an ingredient database for the information described in bullet (23); requires the following with respect to this database:

a) The database to be searchable to accommodate a wide range of users, including users with limited technical and scientific literacy; and,

b) The website to be designed to be easily navigable, to enable users to compare and contrast products and reportable ingredients, and to include hypertext links to other educational and informational internet websites to enhance consumer understanding.

EXISTING LAW:

State law

1) Establishes the Sherman Law, which provides for the regulation of the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements, under the administration and enforcement of CDPH. (Health and Safety Code (HSC) § 109875, *et seq.*)

2) Defines food additive to mean any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in the substance becoming a component of the food or otherwise affecting characteristics of the food; specifies that this definition includes any substance or radiation source intended for use in producing, manufacturing, packing, treating, packaging, transporting, or holding any food; exempts from the definition of "food additive" all of the following:

   a) A pesticide chemical in or on a raw agricultural commodity;

   b) A pesticide chemical that is used, or intended for use, in the production, storage, or transportation of any raw agricultural commodity;

   c) A color additive; and,

   d) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, the Poultry Products Inspection Act, the Meat Inspection Act of March 4, 1907, or the Food and Agricultural Code of this state. (HSC § 109940)

3) Deems any added poisonous or deleterious substance, or any food additive, pesticide chemical, preservative, or color additive, unsafe for use with respect to any food unless there is in effect a regulation adopted, as specified, that limits the quantity and the use, or intended use, of the substance to the terms prescribed by the regulation. (HSC § 110445)

4) Authorizes CDPH to adopt regulations (upon its own motion, or upon the petition of any interested party) that prescribe tolerances, included but not limited to zero tolerances, for poisonous or deleterious substances, food additives, pesticide chemicals, or color additives whenever public health or other considerations in this state require; authorizes CDPH to prescribe the conditions under which a food additive or a color additive may be safely used and to grant exemptions for a food additive or color additive when it is to be used solely for investigational or experimental purposes. (HSC § 110070)

5) Requires CDPH, when establishing a tolerance, to consider several factors that the petitioner is required to furnish, including, among other things, the name and all pertinent information

concerning the substance, including its chemical identity and composition; its proposed use, including directions, recommendations, and suggestions; its proposed labeling and all other relevant data bearing on its physical or other technical effect, and the quantity required to produce that effect; the probable composition of any substance formed in or on a food, drug, device, or cosmetic resulting from the use of the substance; the probable consumption and effect of the substance in the diet of man or any other animal; and facts supporting the contention that the use of the substance will serve a useful purpose. (HSC § 110075)

6) Provides that all food additive regulations and any amendments to regulations adopted pursuant to the FD&C in effect on November 23, 1970, or adopted on or after that date, are the food additive regulations of California; authorizes CDPH to, by regulation, prescribe conditions under which a food additive may be used in this state, whether or not these conditions are in accordance with regulations adopted pursuant to the FD&C. (HSC § 110085)

7) Makes all color additive regulations and any amendments to the regulations adopted pursuant to the FD&C the color additive regulations of this state; authorizes CDPH, by regulation, to prescribe conditions under which a color additive may be used in this state, whether or not these conditions are in accordance with the regulations adopted pursuant to the FD&C. (HSC § 110090)

8) Deems a food adulterated if it contains any food additive or color additive that is unsafe, as specified. (HSC § 110555; HSC § 110595)

9) Makes it unlawful for any person to adulterate any food or manufacture, sell, deliver, hold, offer for sale, receive in commerce, or deliver any food that is adulterated. (HSC § 110620-110630)

10) Deems any food additive, color additive, or an added poisonous or deleterious substance as unsafe for use with respect to any food unless there is in effect a regulation that limits the quantity and the use, or intended use of the substance, as specified. (HSC § 110445)

11) Authorizes CDPH—in any case where CDPH has adopted a regulation prescribing a tolerance, including, but not limited to, a zero tolerance, for a poisonous or deleterious substance, food additive, pesticide chemical, or color additive in processed foods—to require manufacturers to guarantee that foods they market in the state comply with the tolerance; authorizes CDPH to require a guarantee periodically, but in no case more often than once each calendar quarter. (HSC § 110285)

12) Requires manufacturers of any cosmetic product, sold into California and subject to regulation by the FDA, to provide CDPH with a complete and accurate list of cosmetic products that contain any ingredient that is a carcinogen or reproductive toxicant; requires CDPH to maintain a consumer-friendly, searchable online database that contains product information collected by CDPH. (HSC § 111791, *et seq.*)

13) Requires, under statute established by AB 1264 (Gabriel, Chapter 467, Statutes of 2025), CDPH to adopt regulations, on or before June 1, 2028, to define "ultraprocessed foods (UPFs) of concern" and "restricted school foods," as specified, and requires CDPH, when defining UPFs of concern and restricted school foods, to consider all of the following factors:

a) Whether the products include or require a warning label in another state, federal, or international jurisdictions due to concerns about adverse health consequences;

b) Whether, based on reputable peer-reviewed scientific evidence, a substance or group of substances are linked to health harms or adverse health consequences, including, but not limited to, cancer, cardiovascular disease, metabolic disease, developmental or behavioral issues, reproductive harm, obesity, Type 2 diabetes, or other health harms associated with UPF consumption;

c) Whether, based on reputable peer-reviewed scientific evidence, a substance or group of substances may be hyperpalatable, or may contribute to food addiction;

d) Whether the food has been modified to be high in saturated fat, added sugar, or salt;

e) Whether the food meets the requirements of FDA's final rule issued on December 27, 2024, entitled "Food Labeling: Nutrient Content Claims; Definition of Term 'Healthy'" that defines nutrient contents that are deemed to be a part of a nutritious diet; and,

f) Whether the substance is a common natural additive. (HSC § 104662)

14) Defines, for the purposes of statute established under AB 1264 (Gabriel, Chapter 467, Statutes of 2025):

a) "Food" to mean all food and beverages intended for sale or to be served to school pupils on campus during the schoolday; and,

b) "Ultraprocessed food" or "UPF" to mean any food or beverage that contains any of several specified substances and either high amounts of saturated fat, sodium, or added sugar, as specified, or a nonnutritive sweetener or other substance, as specified.

Federal law

1) Establishes the FD&C, which provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics, including dietary supplements, enforced by the FDA. (21 United States Code (U.S.C.) § 301, *et seq.*)

2) Defines "food additive" to mean 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; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; specifies that "food additive" does not include:

a) A pesticide chemical residue in or on a raw agricultural commodity or processed food;

b) A pesticide chemical;

c) A color additive;

d) Any substance used in accordance with a sanction or approval granted prior to September 6, 1958, as specified;

e) A new animal drug; or,

f) A dietary supplement, or intended for use in, a dietary supplement. (21 U.S.C. § 321)

3) Authorizes a person to notify the FDA of a view that a substance is not subject to the premarket approval requirements of the FD&C based on that person's conclusion that the substance is GRAS under the conditions of its intended use. (21 Code of Federal Regulations (CFR) § 170.205)

4) Specifies that general recognition of safety is to be based only on the views of experts qualified by scientific training and experience to evaluate the safety of substances directly or indirectly added to food. Authorizes the basis of such views to be either:

a) Scientific procedures; or,

b) In the case of a substance used in food prior to January 1, 1958, through experience based on common use in food. (21 CFR § 570.30)

5) Specifies that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful to either the target animal or to humans consuming human food derived from food-producing animals under the conditions of its intended use. Requires general recognition of safety based upon scientific procedures to require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. (21 CFR § 570.30)

6) Defines "natural flavor" to mean the essential oil, oleoresin (natural extracts containing both resin and essential oil), essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. (21 CFR § 101.22)

7) Defines "artificial flavor" to mean any substance, the function of which is to impart flavor, which is not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products, or fermentation products thereof. (21 CFR § 101.22)

8) Defines "artificial color" to mean any "color additive," which is any material which is not otherwise exempted by federal law, that is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source and that, when added or applied to a food, drug, or cosmetic or to the human body or

any part thereof, is capable (alone or through reaction with another substance) of imparting a color thereto. (21 CFR § 101.22; 21 CFR § 70.3(f))

9) Defines "spice" as any aromatic vegetable substance in the whole, broken, or ground form, except for those substances which have been traditionally regarded as foods, such as onions, garlic and celery; whose significant function in food is seasoning rather than nutritional; that is true to name; and from which no portion of any volatile oil or other flavoring principle has been removed. (21 CFR § 101.22)

10) Establishes the requirements for information to be included in the voluntary GRAS notice, which includes scientific data and information that identifies the notified substance, a description of the method of manufacture with sufficient detail to evaluate the safety of the notified substance as manufactured, an estimate of the amount of dietary exposure, data and information on self-limiting levels of use if applicable, evidence of substantial history of use by a significant number of consumers prior to 1958 if the basis for the manufacturer's conclusion of GRAS status is based on common use in food, a narrative explaining the basis of the manufacturer's conclusion of GRAS status, as specified. (21 CFR § 170.225-170.255)

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: According to the author:

> "The food industry has turned what was a limited and reasonable exemption into a loophole that is abused at the expense of the consumer. By using the GRAS exemption to go around FDA safety inspections, new, untested chemicals are entering our food supply, sometimes in complete secrecy. Furthermore, we have seen additives that were previously considered GRAS get banned due to their harmful effects coming to light, which shows that we cannot trust companies to put the proper amount of effort towards research and self-regulation. Consumers deserve to know what goes into their food and that what they are eating is safe and tested. We can no longer allow these companies to self-regulate because they have a financial interest in avoiding these necessary safety precautions."

Regulation of food additives under the federal FD&C: The FD&C defines different types of food ingredients based on how they are intended to be used and the FDA's authorities related to them. The FD&C defines a "food additive" as any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in it becoming a component or otherwise affecting the characteristics of any food.

The FDA administers separate programs for uses of ingredients that are food additives versus GRAS (described below). For food additives, a manufacturer or other sponsor must first seek approval from the FDA by submitting a petition to market a new direct food additive, or before using a direct food additive in a different way than how the FDA has currently approved it. The FDA consults with the U.S. Department of Agriculture during the review process for food additives that are proposed for use in meat and poultry products. This process provides for "pre-market review" of the substance, in that food additive petitions must provide scientific evidence that the substance is safe for the ways in which it will be used, including the foods it will be used in and the intended levels of use. The FDA publishes a notice of the petitions under FDA review

in the public Federal Register. The FDA evaluates the petition, and other available data and information to determine if the evidence demonstrates that the food additive is safe.

The GRAS exemption: Substances that are generally recognized among qualified experts as having been adequately shown to be safe under the conditions of its intended use are exempt from the federal definition—and associated federal requirements—for food additives. These substances do not have to undergo premarket review by the FDA. The use of a food substance may be GRAS either through scientific procedures or, for a substance used in food before 1958, through experience based on common use in food.

Any person, typically a food or ingredient manufacturer, that has concluded that the use of an ingredient can meet the standard for GRAS may notify the FDA through the FDA's voluntary GRAS Notification Program. According to the FDA, this program was established to help ensure that GRAS ingredients are safe for the ways in which they will be used, and to help industry meet its responsibility for ensuring the GRAS status of ingredients they intend to use in food.

When the FDA evaluates a GRAS Notice, the agency considers whether the notice demonstrates that the ingredient is safe under the conditions of its intended use and whether the criteria for general recognition are satisfied. Following this evaluation, within 30 days, the FDA responds to the manufacturer with a letter describing whether it questions the basis for the manufacturer's GRAS conclusion. The FDA manages and maintains a public database where all GRAS notices are posted, along with supporting data and the FDA's final response letters to manufacturers.

According to the FDA's website, manufacturers that choose not to go through the FDA's voluntary GRAS Notification Program are still responsible for ensuring that their products comply with federal law. In other words, participation in this program is not mandatory, but companies that choose to "self-affirm" that their substances are GRAS must still ensure that they have investigated the substance's safety; however, under this "self-affirmation" pathway, manufacturers are not required to publicly disclose their safety information or scientific evidence for the substances they have classified as GRAS.

Serious safety and transparency concerns pertaining to the GRAS exemption: Some food additives that were deemed GRAS were later banned. For example, in May 2024, the FDA announced that it would ban the unapproved food additive tara flour. The ingredient was used in some food products as a protein source, until it was identified as an ingredient of interest in an outbreak associated with Daily Harvest plant-based crumbles. In June 2024, the Center for Science in the Public Interest (CSPI, the sponsor of AB 2034) released a blog post entitled, "FDA declares tara flour unsafe—two years after outbreak." In the post, CSPI reports that in June 2022, 393 people were sickened and 133 hospitalized, some with permanent organ damage, after eating the Daily Harvest product. In the wake of this incident, CSPI raised concerns about the GRAS exemption, stating: "Currently, manufacturers have the ability to introduce chemicals and ingredients into our food supply without FDA oversight, and when those ingredients are unsafe, the FDA is forced to play catch-up and react to harm after it occurs. This is simply unacceptable. If official premarket approval had been required before new food chemicals and ingredients could be used, tara flour would not have been approved, and consumers would have been protected."

A 2018 policy statement on food additives and children's health from the American Academy of Pediatrics, published in the journal *Pediatrics,* states the following regarding GRAS safety concerns:

> "Regulation and oversight of many food additives is inadequate because of several key problems in the Federal Food, Drug, and Cosmetic Act. Current requirements for a GRAS designation are insufficient to ensure the safety of food additives and do not contain sufficient protections against conflict of interest. Additionally, the FDA does not have adequate authority to acquire data on chemicals on the market or reassess their safety for human health. These are critical weaknesses in the current regulatory system for food additives. Data about health effects of food additives on infants and children are limited or missing; however, in general, infants and children are more vulnerable to chemical exposures. Substantial improvements to the food additives regulatory system are urgently needed, including greatly strengthening or replacing the GRAS determination process, updating the scientific foundation of the FDA's safety assessment program, retesting all previously approved chemicals, and labeling direct additives with limited or no toxicity data."

Federal moves on GRAS: On March 10, 2025, Health and Human Services Secretary Robert F. Kennedy, Jr. directed the FDA to take steps to explore potential rulemaking that would revise GRAS regulations and related guidance to eliminate the self-affirmed GRAS pathway, to enhance the FDA's oversight of ingredients considered to be GRAS and improve transparency for American consumers. This proposed rule, if finalized, would amend GRAS regulations to require the mandatory submission of GRAS notices for the use of human and animal food substances that are purported to be GRAS. Food substances that are listed or affirmed as GRAS for the intended use by regulation, or for which FDA has already issued a "no questions" letter on its GRAS notice inventory, would be exempted. Under the proposed rule, the FDA would maintain and update the public-facing GRAS notice inventory for all substances that are the subject of mandatory GRAS notice. The proposed rule would also clarify the process under which FDA would determine that a substance is not GRAS.

This proposed rule is still under review by the federal Office of Management and Budget, and the estimated completion date is unknown at the time of this analysis' publication.

Actions in other states to address the GRAS loophole: A bill pending in the New York State Assembly would ban the sale and use of any self-affirmed GRAS substance in New York unless a report has been submitted to the Commissioner of the Department of Agriculture and Markets and has been included in a public database. The required report must include a significant amount of information, similar to the information required for FDA consideration of a GRAS petition. The bill provides that data establishing GRAS status must be publicly available in a searchable database. The bill authorizes the Commissioner to enforce the law through investigations, fines, and other actions, and bans three specific food additives: FD&C Red No. 3 (a synthetic red dye), potassium bromate (a flour treatment agent), and propylparaben (a preservative).

AB 2034 implementation concerns raised by CDPH: As noted in the Assembly Health Committee analysis for AB 2034, CDPH raises several concerns regarding the implementation of AB 2034. In particular, CDPH states that it does not have the expertise or resources to conduct the detailed scientific assessments for food additives proposed in AB 2034, including

assessments for carcinogenic potential, as well as reproductive or developmental toxicity. According to CDPH, this process would be resource intensive and require staff classifications that are not part of CDPH's workforce, such as toxicologists. CDPH also states that it does not have the legal authority to ensure that firms outside of California comply with the requirement to submit food additives for review.

CDPH also contends that the FDA has the resources and expertise to conduct the evaluations proposed in AB 2034 under its existing programs. By requiring CDPH to review substances for safety and issue licenses, AB 2034 may unintentionally lead to situations in which both CDPH and FDA end up examining the same substances, which may result in confusion within the regulated community if FDA and CDPH arrive at different conclusions.

Author's amendments: To help address CDPH's implementation concerns, particularly with respect to the licensing and scientific assessment provisions in the bill, the author of AB 2034 wishes to amend the bill to refine and narrow its scope, and accomplish the following:

1) Reduce burdens on CDPH by striking out provisions that would have established state licensing and scientific assessment requirements;

2) Focus the bill on transparency, by retaining requirements for companies to share, and CDPH to make publicly available using databases, the following information: 1) safety information for substances that companies self-affirmed as "generally recognized as safe," and 2) chemical names for ingredients that are currently hidden behind generic terms like "artificial flavor"; and,

3) Further the bill's aims of transparency and safety, by deeming a new substance introduced to the market after January 1, 2027 as unsafe, unless it has gone through the FDA's voluntary GRAS Notification Program or meets any of several other specified exemptions in the bill, including designation as a "food additive."

This bill: Under current federal law and regulations, GRAS substances are not required to undergo premarket review before they are used in food products. Instead, the FD&C authorizes companies to either "self-affirm" that their substances are GRAS, or go through the FDA's voluntary GRAS Notification Program, in which companies submit safety and scientific information for a substance to the FDA. The latter option provides for transparency because the FDA posts these notices into a publicly available database, whereas self-affirmation allows for substances to be added to foods without disclosure to either the FDA or the public. One of the core aims of AB 2034 is to provide for public transparency by requiring self-affirmed GRAS substances to be reported to CDPH, and by requiring companies to report products to CDPH that use generic terms like "artificial flavor."

To accomplish these aims, AB 2034 has multiple components, making it a fairly large and complex bill, which, as noted above, has raised some implementation concerns. To address these concerns, the author has proposed amendments to significantly narrow the scope of the bill, while retaining AB 2034's focus on promoting public transparency and food safety.

Arguments in support: According to a coalition of environmental, environmental justice, and health organizations:

"Congress designed a premarket FDA-approval process for new food additives, but a loophole in that law allows food companies or their paid experts to declare that a substance is "generally recognized as safe," or GRAS, for use in food and bypass that premarket approval process. FDA maintains a voluntary GRAS notice process, which some companies choose to use. However, some companies can—and do—introduce new chemicals into the food supply in complete secrecy due to the voluntary nature of the federal GRAS notification process. Some companies have exploited this loophole to market poorly tested or clearly unsafe chemicals, including animal carcinogens, for use in food…

Federal regulations allow food companies to use vague terms like "natural flavor," "artificial flavor," "spices," and "artificial color" on packaged food ingredient labels instead of listing all ingredients by name. This combined with the GRAS loophole creates a situation in which not even FDA knows which substances have been added to our foods and if those chemicals are safe. The only entities with that information are food and chemical companies, which is a clear and troubling conflict of interest and contrary to commonsense consumer protection policy. Some consumers need to avoid certain ingredients due to food allergies or religious or ethical reasons…

Industry abuse of the GRAS loophole harms consumers. In 2022, an outbreak associated with a product sold by Daily Harvest resulted in nearly 400 people being sickened, including 133 hospitalized, some with severe liver toxicity. The company identified the likely cause to be the ingredient tara flour. Investigations revealed that tara flour was not an approved food additive and that there were no GRAS notices filed with the FDA for it, meaning the only way it could legally have come to market was via a secret GRAS determination. Nearly two years after the outbreak began, FDA concluded there was no evidence that tara flour was safe for use in food.

Industry also uses the GRAS loophole to market food chemicals that are clearly unsafe. A recent report by the Center for Science in the Public Interest found eleven substances deemed GRAS by the flavor industry that have been banned or restricted in the European Union [EU] due to safety concerns. Ten of those substances were banned in the EU over concern that they could cause genotoxicity (DNA damage), and the eleventh substance, 2,4-hexadienal, was shown to cause cancer in animal studies completed by the U.S. National Toxicology Program. Congress expressly prohibited the use of food additives shown to cause cancer in humans or animals via a provision of the 1958 Food Additive Amendment known as the Delaney Clause. However, because GRAS substances are considered distinct from food additives under federal law, courts have found that the Delaney Clause does not apply to GRAS substances. Effectively, industry can exploit the GRAS loophole to market food chemicals known to cause cancer…

Consumers are increasingly worried about the lack of transparency caused by the GRAS loophole. Although FDA has recently expressed intent to revise its approach to GRAS, submitting a proposal of unknown content to the Office of Management and Budget, initial indications suggest that the agency will not require premarket safety reviews for new GRAS substances, meaning the agency has no intent to address the fundamental concern with GRAS: that chemicals enter the food supply without independent safety review by FDA."

Arguments in opposition: According to a coalition of organizations representing the industry, business, and agricultural sectors:

"While we share the author's stated goal of improving public health and ensuring the safety and transparency of food ingredients, AB 2034 establishes a broad and duplicative regulatory framework that overlaps substantially with existing law, creates significant new administrative burdens, and would impose substantial costs on both the State of California and the food supply chain without clear evidence of improved public health outcomes…

Just last year, the Legislature enacted the Real Food, Healthy Kids Act AB 1264 (Gabriel), which already establishes a comprehensive framework for evaluating and regulating food ingredients, as ultraprocessed foods, many of which are subject to this legislation.

AB 1264 requires the California Department of Public Health (CDPH) to:

- Review all food ingredients that could be used in a school lunch program and identify "Ultraprocessed Food."
- Adopt regulations defining "ultraprocessed foods of concern" and "restricted school foods" by June 1, 2028.
- Conduct scientific evaluations of food ingredients and substances associated with adverse health outcomes.
- Consult with multiple state agencies and scientific experts, including the Office of Environmental Health Hazard Assessment (OEHHA), the California Department of Education, the California Department of Food and Agriculture, and University of California researchers.
- Develop a vendor reporting system requiring food manufacturers and suppliers to submit product ingredient, nutrition, and classification information.
- Maintain a regulatory process to update definitions and evaluate emerging scientific evidence.
- Submit ongoing reports to the Legislature regarding implementation and outcomes.

AB 2034 proposes to create a separate statewide additive licensing and review system administered by CDPH that would evaluate many of the same ingredients and substances already subject to review under the AB 1264 framework.

As a result, AB 2034 would establish a parallel regulatory structure addressing substantially the same scientific questions and policy objectives.

Rather than allowing the AB 1264 framework to be implemented and evaluated, AB 2034 creates a duplicative system that risks regulatory confusion, inconsistent determinations, and unnecessary administrative complexity…

California's Proposition 65 is a well-established review and warning statute for any food ingredients that pose a risk through carcinogenicity or reproductive toxicity. This program, managed by the [Office of Environmental Health Hazard Assessment] is a scientifically rigorous review. AB 2034 would duplicate this review process at CDPH, creating another

duplicative food ingredient review process in an unrelated department housed in another administrative agency.

In addition to duplicating elements of AB 1264, AB 2034 would require the creation of an entirely new and costly licensing, reporting, and enforcement program for food additives used in products sold in California…

At a time when the State is facing ongoing fiscal pressures, establishing a second major regulatory system addressing similar policy questions raises serious concerns regarding the efficient use of public resources…

Creating a unique state level licensing regime for food additives could introduce significant regulatory uncertainty for manufacturers and suppliers that operate across multiple states. Duplicative regulatory frameworks, particularly when layered on top of newly enacted state programs, can lead to increased compliance costs, supply chain disruptions, reduced product availability, and increased costs for consumers."

Related legislation:

1) AB 2244 (Gabriel). Requires CDPH, no later than June 1, 2028, to create a "California Certified" seal that indicates a product is not a UPF, UPF of concern, or restricted school food, as defined in AB 1264 (see below); authorizes companies to apply for this seal; requires a food facility to prominently display at least three or more "California Certified" products if the food facility offers for sale more than 25 certified items; authorizes, if a food facility fails to meet these requirements, a court of competent jurisdiction to enjoin the food facility through action of CDPH, the Attorney General, county counsel, city attorney, consumer, business entity, or nonprofit organization, as specified. AB 2244 is pending before the Assembly Health Committee.

2) AB 1264 (Gabriel, Chapter 467, Statutes of 2025). Establishes, among other things, a definition for "ultraprocessed food"; requires CDPH, on or before June 1, 2028, to adopt regulations to define UPFs of concern and restricted school foods, as specified; requires CDPH to update these definitions every five years, as needed; requires schools, by July 1, 2029, to begin to phase out restricted school foods and UPFs of concern; prohibits a vendor, beginning on July 1, 2032, from offering restricted school foods or UPFs of concern to a school; and, requires vendors, on or before February 1, 2028, and annually thereafter through February 1, 2032, to report specified information, including ingredient lists and whether a food product is a UPF, UPF of concern, or a restricted school food, to CDPH.

3) AB 2316 (Gabriel, Chapter 914, Statutes of 2024). Prohibits, commencing December 31, 2027, food containing six specified food dye additives (Blue 1, Blue 2, Green 3, Red 40, Yellow 5, and Yellow 6) from being sold to students by school districts, county offices of education, charter schools, and state special schools.

4) AB 418 (Gabriel, Chapter 328, Statutes of 2023). Prohibits a person or entity, commencing January 1, 2027, from manufacturing, selling, delivering, distributing, holding, or offering for sale in commerce a food product for human consumption that contains any of the following substances: brominated vegetable oil, potassium bromate, propylparaben, and red dye 3.

REGISTERED SUPPORT / OPPOSITION:

Support

Center for Science in the Public Interest (sponsor)
A Voice for Choice Advocacy
Allergy & Asthma Network
Alpha-Gal Alliance Action Fund
Bay Area Community Resources
Breast Cancer Prevention Partners
California Farmer Justice Collaborative
California Public Interest Research Group
Ceres Community Project
Clean Water Action
Cleanearth4kids.org
Consumer Federation of America
Consumer Reports
Courage California
Cured NFP
Elijah-Alavi Foundation
Facts Families Advocating for Chemical and Toxics Safety
Feed Black Futures
Food and Water Watch
FPIES Foundation
Harvard Law School Food Law and Policy Clinic
Healthy Food America
Mamavation - Non-toxic Products for Healthy Families
National Consumers League
Pesticide Action and Agroecology Network
Rising Communities
San Francisco Bay Physicians for Social Responsibility
Sierra Harvest
Strategic Training Initiative for the Prevention of Eating Disorders
United Parents and Students

Opposition

Agricultural Council of California
American Beverage Association
American Chemistry Council
CalAsian Chamber of Commerce
California Chamber of Commerce
California Grain & Feed Association
California Grocers Association
California Hispanic Chambers of Commerce
California League of Food Producers
California Manufacturers & Technology Association
California Manufacturers and Technology Association
California Restaurant Association
California Retailers Association
California Seed Association

California Warehouse Association
Can Manufacturers Institute
Chemical Industry Council of California
Civil Justice Association of California
Consumer Brands Association
Consumer Healthcare Products Association
Council for Responsible Nutrition
Dairy Institute of California
Food Ingredient Safety Coalition
International Dairy Foods Association
National Confectioners Association

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