

# **The REAL Food Act**

## **A Policy Proposal to Prohibit Cell-Cultured Food Products and Known Carcinogens, and to Require Independent Safety Review of Bioengineered Foods, in the United States Food Supply**

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### **Abstract**

This proposal addresses a structural gap in United States federal food regulation and recommends a differentiated legislative remedy. For bioengineered (genetically engineered) crops, already integrated into the conventional American agricultural economy and grown by farmers nationwide, this proposal recommends a mandatory independent long-term safety review requirement in place of the current voluntary and self-certified pathways. For cell-cultured (“lab-grown”) animal-based food products, a novel, non-agricultural substitute for traditionally raised meat that threatens the economic viability of domestic ranching, and for known human carcinogens used as intentional food or animal-feed ingredients, this proposal recommends an outright statutory prohibition with no conditional review-and-approval pathway. These recommendations are embodied in the accompanying REAL Food Act (Regulating Engineered and Altered-food for Life Act), which requires independent long-term review before bioengineered foods may remain on the market, permanently prohibits the sale of cell-cultured food products for human consumption, permanently prohibits known carcinogens from the human food and animal feed supply, closes the self-affirmation loophole for shelf-life additives, requires plain-language disclosure of insect-derived ingredients, and establishes premarket safeguards for pharmaceutical-producing food crops before such technology reaches commercial scale.

### **The REAL Food Act: A Policy Proposal**

#### **Introduction and Statement of the Problem**

The average American consumer operates under a reasonable but frequently mistaken assumption: that a food product available for retail sale in the United States has been independently and rigorously tested for long-term safety by a federal regulatory agency prior to reaching the market, and that a food ingredient shown to cause cancer is removed from the food supply as a matter of course. For a substantial and growing share of the U.S. food supply, neither assumption reflects how the regulatory system actually functions.

Three categories of food technology, bioengineered (genetically engineered) crops, cell-cultured animal-based food products, and novel shelf-life-extending additives, have entered commercial distribution over the past three decades through regulatory pathways that either explicitly permit company self-certification of safety or rely on short-term (typically 90-day) toxicological data in lieu of chronic, multi-year safety review. A fourth category, known human carcinogens used as intentional food or feed ingredients, has in specific historical instances remained legally marketable for decades after credible evidence of harm existed, absent any statutory mechanism requiring automatic removal. This proposal documents the scope of these gaps, traces their regulatory origins, and recommends a legislative remedy calibrated to the nature of each category: independent review where a technology is already embedded in American agriculture, and outright prohibition where a technology is a novel substitute for real food or is affirmatively known to cause cancer.

#### **Background: The Regulatory Architecture**

Congress established the National Bioengineered Food Disclosure Standard through the 2016 amendments to the Agricultural Marketing Act of 1946 (Pub. L. No. 114-216, 130 Stat. 834, 2016), codified at 7 U.S.C. §§ 1639-1639i. The statute directed the Secretary of Agriculture to establish a mandatory disclosure standard, which USDA's Agricultural Marketing Service implemented through regulations at 7 C.F.R. part 66 (USDA, 2018). The standard

requires covered entities to disclose that a food is or contains a bioengineered ingredient, but, critically, does not require identification of which specific ingredient is bioengineered, and until recently exempted highly refined foods (such as refined sugar and oil) in which modified genetic material is not detectable in the finished product.

That refined-food exemption was substantially narrowed by the U.S. Court of Appeals for the Ninth Circuit in *Natural Grocers v. Rollins*, No. 22-16770 (9th Cir. Oct. 31, 2025), which held that USDA committed legal error in equating non-detectability of modified genetic material with the legal conclusion that a food does not contain bioengineered material. The court further directed vacatur of regulations permitting standalone electronic-link and text-message disclosure formats and remanded the matter to the agency for further rulemaking. The exemption at issue had applied to an estimated 70 percent of foods containing bioengineered ingredients prior to the ruling (Covington & Burling LLP, 2025).

A structurally similar gap exists under the Federal Food, Drug, and Cosmetic Act's ("FDCA") "Generally Recognized as Safe" (GRAS) provision. Under 21 U.S.C. § 321(s) and its implementing regulations at 21 C.F.R. §§ 170.30 and 170.35, a manufacturer may determine independently that a food substance is GRAS and market it without ever submitting the underlying safety data to FDA for review, a pathway known as "self-affirmation." FDA "strongly encourages but does not require" notification (Epstein Becker Green, 2025). This is the pathway through which shelf-life-extending produce coatings, including those marketed under the Apeel and Organipeel brand names, entered the U.S. market, and it is also the pathway through which a food additive later confirmed to cause cancer in animal testing, discussed in Gap Six below, remained in the food supply for thirty-five years after that evidence emerged.

Cell-cultured ("cultivated") meat and seafood are jointly regulated by FDA and USDA's Food Safety and Inspection Service (FSIS) pursuant to a Formal Agreement executed March 7, 2019, under which FDA oversees cell collection, cell banking, and cell growth and differentiation, with jurisdiction transferring to FSIS at the point of harvest for products derived from species amenable to the Federal Meat Inspection Act (21 U.S.C. § 601 et seq.) and the Poultry Products Inspection Act (21 U.S.C. § 451 et seq.) (USDA, 2019). FDA issued its first premarket "no questions" letter for a cell-cultured product in November 2022, and USDA-FSIS issued the first grants of inspection in June 2023 (Food Safety News, 2023), in neither case following any chronic or multi-generational feeding study of the product.

## **The Current State of the Market**

This section documents products and categories currently in commercial distribution or under active regulatory review, organized by technology type.

### **Bioengineered Crops.**

USDA's official List of Bioengineered Foods, maintained under 7 C.F.R. § 66.6, currently identifies fourteen crops: alfalfa, apple (Arctic varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon, soybean, squash (summer, virus-resistant varieties), sugar beet, and sugarcane (Bt insect-resistant varieties) (USDA, 2018). These are, with few exceptions, crops grown by American farmers as part of the conventional agricultural economy, which is the basis for this proposal's recommendation that they be subject to mandatory review rather than outright prohibition.

### **Cell-Cultured Meat and Seafood.**

Companies with full FDA and USDA-FSIS clearance to sell cell-cultured products for human consumption in the United States include UPSIDE Foods and GOOD Meat/Eat Just (cultivated chicken, cleared 2022-2023), Wildtype (cultivated salmon, cleared 2025), Mission Barns (cultivated pork fat), and Believer Meats (cultivated meat generally, the first foreign company cleared for U.S. sale in 2025). Under this proposal, each of these existing clearances would be revoked and the affected products withdrawn from the market on the timeline described in the accompanying legislation.

## **Cell-Cultured Cocoa and Related Confectionery Investment.**

California Cultured, in partnership with Puratos, is targeting a U.S. commercial rollout of cultured cocoa butter in late 2026. Celleste Bio (Israel) has partnered with Mondelēz International, the parent company of Cadbury, Oreo, Toblerone, and Milka, targeting a 2027 rollout of cultured cocoa butter. Major confectioners with disclosed financial stakes in cocoa cell-culture research and development include The Hershey Company (approximately \$20 million), Lindt & Sprüngli (approximately \$5.6 million, via Food Brewer), Nestlé (approximately \$44 million), and Ferrero (approximately \$15 million); Mars has disclosed multi-year strategic investment without a specified figure. These investments illustrate that the substitution of cell-cultured for conventionally sourced ingredients is not limited to meat and is actively advancing across the food industry.

## **Fermentation-Produced Enzymes: The Regulatory Origin Point.**

The precedent underlying the modern self-affirmation and substantial-equivalence framework was established in March 1990, when FDA approved fermentation-produced chymosin (FPC), a genetically engineered enzyme used to curdle milk in cheesemaking, without requiring source disclosure on the finished product. FPC is estimated to be used in approximately 90 percent of commercial cheese produced in North America [1].

## **Shelf-Life-Extending Additives.**

Apeel and Organipeel, produce coatings composed primarily of purified mono- and diglycerides, reached market through the self-affirmed GRAS pathway described above. No independent, peer-reviewed, long-term human safety study of these coatings as ingested products currently exists in the published literature [2]. Apeel's own GRAS submission disclosed trace residues including ethyl acetate, heptane, palladium, arsenic, lead, cadmium, and mercury, each reported below FDA-permitted limits.

## **Insect-Derived Ingredients.**

Insect protein, most commonly cricket-derived, remains a niche ingredient category in the U.S. market as of 2026, supplied by firms including Aspire Food Group, Entomo Farms, and All Things Bugs, among others. No major national brand currently markets a mainstream product containing insect protein, though at least one major manufacturer has reportedly tested cricket flour in product formulation without commercial launch. Where insect-derived ingredients are disclosed, they are frequently identified only by scientific or taxonomic nomenclature (e.g., *Acheta domesticus*) rather than plain-language terms, limiting consumer comprehension.

## **Emerging Research: Pharmaceutical-Producing Food Crops.**

A National Science Foundation-funded project conducted by researchers at the University of California, Riverside, in partnership with the University of California, San Diego, and Carnegie Mellon University, has explored whether messenger RNA vaccine constructs could be produced within edible plants such as lettuce and spinach [3]. University officials have stated this approach has not been demonstrated at commercial or agricultural scale. The U.S. House of Representatives has separately voted to restrict federal funding for this line of research, and public health communications organizations have documented and corrected false public claims that such technology is already deployed in the commercial food supply (Public Health Communications Collaborative, 2024).

## **Identified Regulatory Gaps**

### **Gap One: Absence of Mandatory Long-Term Safety Testing for Bioengineered Foods.**

No federal statute or regulation currently requires long-term (multi-year or multi-generational) independent safety testing of any bioengineered food prior to market approval. The standard toxicological package for a trait such as the CP4 EPSPS protein (which confers glyphosate tolerance in Roundup Ready crops) consists of acute toxicity studies, digestibility and allergenicity screening, and subchronic feeding trials of approximately ninety days (Harrison et al., 1996). The single published attempt at a genuine two-year feeding study on a related glyphosate-tolerant maize variety (Séralini et al., 2014) remains scientifically contested and was retracted by its original publisher before

republishing elsewhere; its central relevance to this proposal is not its disputed findings but the fact that it remains, a decade later, essentially the only attempt at genuine chronic testing for this category of trait.

### **Gap Two: The Refined-Food Detectability Loophole.**

Prior to Natural Grocers, USDA permitted highly refined bioengineered ingredients, including refined sugar derived from Roundup Ready sugar beets, to be exempted from disclosure where the modified genetic material was not detectable in the finished product, notwithstanding that the crop itself was engineered and grown under materially different agronomic conditions (heavier herbicide application). This is illustrated by common retail products such as Carnation Sweetened Condensed Milk, whose only two ingredients, milk and sugar, include a bioengineered-source disclosure attributable to the sugar rather than the milk.

### **Gap Three: The Animal-Feed Exemption.**

Under 7 U.S.C. § 1639b(b)(2)(A), USDA regulations must prohibit a food derived from an animal from being considered "bioengineered" solely because the animal consumed bioengineered feed. This means milk, meat, and eggs from an animal fed exclusively bioengineered corn and alfalfa for its entire life are categorically exempt from disclosure, regardless of feed composition.

### **Gap Four: The Self-Affirmation Pathway.**

As described above, a manufacturer may market a novel food-contact substance as GRAS without ever submitting supporting data to FDA. While pending legislation (S. 3122, H.R. 4958) would impose a mandatory notification requirement, notification alone does not guarantee that the underlying safety data reflects long-term, independent testing rather than manufacturer-funded short-term studies.

### **Gap Five: No Premarket Framework for Pharmaceutical-Producing Food Crops.**

No existing statute specifically addresses the scenario in which a food crop is engineered to express a pharmaceutical or biologic substance for direct human consumption. Although this technology remains in early, non-commercial research stages, its convergence of food-safety and drug-approval regulatory frameworks, and the informed-consent implications of a vaccine delivered via an ordinary grocery item, warrant a dedicated statutory framework before, rather than after, such a product approaches market readiness.

### **Gap Six: No Mechanism for Automatic Removal of Known Carcinogens from the Food Supply.**

Current law imposes no automatic requirement that a substance be removed from the food or animal feed supply once it is affirmatively classified as a known human carcinogen. FD&C Red No. 3 was barred from use in cosmetics in 1990 after being shown to cause cancer in male rat testing, yet remained legally marketable in food, candy, and children's medicine for a further thirty-five years until FDA revoked its food authorization on January 15, 2025, under the mandatory Delaney Clause, with compliance deadlines extending as late as January 2028 for ingested drugs. Brominated Vegetable Oil (BVO) was removed from FDA's GRAS list in 1970 over toxicity concerns yet remained legally permitted in small amounts in the U.S. market for a further fifty-four years, until a full ban took effect July 2, 2024, long after the United Kingdom (1970), the European Union (2008), and Japan (2010) had each already prohibited it. In both cases, removal required an affirmative agency rulemaking action rather than occurring automatically upon classification, and in both cases that action took decades.

## **Rationale for Differentiated Treatment**

This proposal treats bioengineered crops, cell-cultured food products, and known carcinogens differently, and that distinction is deliberate rather than inconsistent.

Bioengineered crops are already integrated into the conventional American agricultural economy: the fourteen crops on USDA's bioengineered list are grown by American farmers at commercial scale, and an outright, unconditional

ban would disrupt the livelihoods of the very farmers this proposal is intended to protect. Accordingly, this proposal recommends mandatory independent review, not prohibition, for this category: bioengineered crops may remain on the market, but only upon completion of the long-term safety testing that current law does not require.

Cell-cultured food products stand on different ground. They are not a crop grown by American farmers; they are a laboratory-manufactured substitute for the meat, poultry, and seafood that American ranchers and fishermen already produce, brought to market without any chronic feeding study and without the land stewardship, herd management, or regulatory burden borne by conventional livestock producers. A prohibition on cell-cultured products protects, rather than disrupts, the domestic agricultural base. For this reason, this proposal recommends outright prohibition rather than a conditional review pathway.

Known carcinogens are treated as an outright prohibition for a simpler reason: once a substance is affirmatively classified, by the International Agency for Research on Cancer or the National Toxicology Program, as carcinogenic to humans, no further review is owed to a manufacturer before that substance is removed from the food or feed supply. A conditional review-and-approval process is appropriate where the safety question is open; it is not appropriate where a competent scientific body has already answered it.

## Policy Recommendations

This proposal recommends the following reforms, each embodied in a corresponding section of the accompanying REAL Food Act:

1. Require an independent long-term safety review, defined as a chronic study of not less than two years conducted by, or with no financial relationship to, the reviewing agency, before a bioengineered food may remain on the market (REAL Food Act, Sec. 4).
2. Prohibit outright the sale of cell-cultured animal-based food products for human consumption, with no review-and-approval exception, and revoke all existing premarket clearances and grants of inspection for such products (REAL Food Act, Sec. 5).
3. Prohibit outright the use of any substance classified as a known human carcinogen by the International Agency for Research on Cancer or the National Toxicology Program as an intentionally added ingredient in food or in animal feed intended for animals raised for human food production (REAL Food Act, Sec. 6).
4. Amend 21 U.S.C. § 321(s) to eliminate self-affirmed GRAS status for novel food-contact additives absent FDA notification and review (REAL Food Act, Sec. 7).
5. Establish a public, quarterly updated federal registry of approved and pending bioengineered and novel-additive products, and of documented cell-cultured and carcinogen violations (REAL Food Act, Sec. 8).
6. Apply all prohibitions and review requirements equally to imported products, through FDA's import-refusal authority (21 U.S.C. § 381) and USDA's foreign-inspection-system equivalence determinations (21 U.S.C. §§ 620, 466) (REAL Food Act, Sec. 11).
7. Clarify that the existing disclosure standard's preemption provision (7 U.S.C. § 1639i) governs labeling format only and does not limit state authority to adopt independent, more protective market restrictions (REAL Food Act, Sec. 12).
8. Establish a dedicated premarket framework for pharmaceutical-producing food crops, requiring independent long-term review, new-drug approval under 21 U.S.C. § 355, and explicit opt-in consumer consent distinct from ordinary food labeling (REAL Food Act, Sec. 13).
9. Require plain-language disclosure of insect-derived ingredients alongside any scientific or taxonomic nomenclature used on an ingredient label, as a transparency measure rather than a market restriction (REAL Food Act, Sec. 15).

## Anticipated Counterarguments and Responses

Proponents of the current regulatory framework, and of continued biotechnology investment generally, raise several substantive objections that this proposal does not dismiss.[4]

First, it is argued that bioengineered and cell-cultured technologies may be necessary to meet future global food demand and to reduce agricultural inputs such as pesticide use and land conversion. This is a legitimate empirical claim, and this proposal does not take a position on its ultimate merit for bioengineered crops, which remain reviewable and marketable under this proposal upon completion of long-term testing. As to cell-cultured products specifically, this proposal's position is that a speculative future benefit does not justify permitting an untested substitute to displace a proven, domestically produced food source in the present.

Second, it is argued that the acute, digestibility, allergenicity, and 90-day subchronic testing already performed on bioengineered crops constitutes adequate safety review, and that no credible peer-reviewed evidence demonstrates harm from any currently marketed bioengineered product. This proposal does not dispute the second half of this claim; it argues that the absence of evidence of harm from short-term testing is not equivalent to evidence of long-term safety, and that this is a testable, closeable gap, which is precisely why this proposal recommends review rather than prohibition for this category.

Third, it may be argued that prohibiting cell-cultured food products outright, rather than subjecting them to the same review-and-approval process recommended for bioengineered crops, is economically protectionist rather than safety-driven, since it forecloses market entry regardless of testing outcome. This proposal accepts that economic protection of domestic ranching and livestock agriculture is, in fact, part of its stated purpose, and does not disguise that purpose as a purely safety-based rationale. The proposal's position is that Congress may legitimately protect a functioning, proven domestic food-production base from displacement by an untested, non-agricultural substitute, and that this is a permissible and disclosed policy judgment rather than a scientific claim in need of further review.

Fourth, it may be argued that an outright, no-exception prohibition on known carcinogens is unnecessary given that FDA already possesses authority to revoke GRAS status or food-additive approvals once evidence of carcinogenicity emerges. The regulatory history documented in Gap Six demonstrates that this existing authority has, in practice, taken decades to exercise even after credible classification, thirty-five years in the case of Red Dye No. 3, fifty-four years in the case of Brominated Vegetable Oil. This proposal's response is that an automatic statutory prohibition tied to an existing, externally maintained classification (IARC Group 1 or the NTP Report on Carcinogens) removes the multi-decade discretionary delay inherent in the current case-by-case rulemaking approach.

## Conclusion

The regulatory gap documented in this proposal did not originate with any single company or product; it originated with a 1990 enzyme approval and has been extended, through consistent regulatory logic, across three subsequent decades of food biotechnology. Closing that gap for bioengineered crops does not require rejecting the underlying science or disrupting the farmers who grow them; it requires only that the same standard already applied to new pharmaceuticals, independent, long-term, publicly reviewable safety data, be extended to those crops before, rather than after, they remain indefinitely on the American dinner table. Closing it for cell-cultured food products and for known carcinogens requires a different and more direct remedy: keeping untested laboratory substitutes out of a food supply that American agriculture already fills, and keeping substances affirmatively known to cause cancer out of that supply altogether.

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## Notes

[1] The 90 percent figure has been repeated across industry and food-science trade sources for over a decade and reflects the widespread adoption of fermentation-produced chymosin following its 1990 FDA clearance; a precise, independently audited current figure was not identified for this proposal and should be treated as a reasonable industry estimate rather than an agency-verified statistic.

[2] This statement reflects the absence of published long-term ingestion studies as of this proposal's drafting; it is not a claim that such coatings have been shown to be unsafe.

[3] The project received approximately \$500,000 in National Science Foundation funding; a university spokesperson confirmed to press inquiries that the technology has not been demonstrated at commercial or agricultural scale.

[4] This section is included consistent with standard policy-analysis practice of engaging the strongest available counterarguments rather than only the weakest.