ALLIANCE FOR NATURAL HEALTH MEDIA KIT

- REFORMING GRAS -

FOOD SAFETY WITHOUT SACRIFICE

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ENDORSEMENTS

The National Foundation for Integrative Medicine appreciates and supports the Alliance for Natural Health (ANH) in its efforts to retain the self-GRAS program established under the Food Additive Amendment of 1958 as launched as the FDA's GRAS program in 1998. NFIM does so recognizing the current program's flaws, such as the need to prioritize removal of unsafe ingredients, to provide a public transparency registry, to implement a tiered risk/benefit assessment schema, to establish consistent safety standards for safe harbor pathways for long known and trusted ingredients, and for warnings for GRAS ingredients. We endorse the proposed reforms put forward by the ANH—to enhance safety, speed healthy products to market, and in aligning with our mission of advancing 3rd Generation (integrative) Medicine. We applaud the well-reasoned and balanced proposals of the ANH, ensuring natural therapies remain available and safe for the public.

— **Peter Demitry, M.D., M.P.H., Chairman, National Foundation for Integrative Medicine**

We at the Global Wellness Forum applaud ANH's bold yet balanced proposal to reform the GRAS pathway. Rather than a blunt abolition of Self-GRAS — which risks collateral damage to the integrative health movement — ANH's roadmap offers a pragmatic solution: remove high-risk additives while protecting time-honored, beneficial compounds. Their call for transparency, proportionality, and scientific rigor is exactly the kind of middle way the MAHA movement needs to safeguard public health without stifling innovation or access. We're proud to stand in solidarity on this crucial reform.

— **Sayer Ji, Co-Founder, Global Wellness Forum**

Corporations have long abused the FDA's GRAS process to evade the rigorous, scientific reviews required under Congress's 1958 food additives law. This is how the products of genetic modification, nanotechnology, synthetic biology, and lab engineering have been slipped into our food without safety testing. We applaud Sec. Kennedy for being the first Health & Human Services Secretary to turn this around and the Alliance for Natural Health for stepping up to help him accomplish this worthy goal.

— **Alexis Baden-Mayer, Esq., Political Director, Organic Consumers Association**

PRESS RELEASE

Health Groups Urge FDA:
Target Toxins, Preserve Safe Food Ingredients

White Paper Calls for Reform of 10,000+
Self-GRAS Food Ingredients

ALEXANDRIA, VA, April 10, 2025: Today, the Alliance for Natural Health (ANH) USA released a comprehensive white paper entitled GRAS Reform: Food Safety Without Sacrifice. The paper was developed in response to HHS Secretary Robert F. Kennedy, Jr.'s March 10 directive to the FDA to explore eliminating the "self-affirmed" Generally Recognized as Safe (GRAS) pathway, which allows companies to determine food ingredient safety without FDA review.

The white paper advocates for an alternative to the total elimination of the 'Self-GRAS' pathway, focusing instead on eliminating the most hazardous chemicals while preserving access to safe, beneficial ingredients. The paper and further background materials can be found here.

ANH's white paper has been endorsed by a range of groups including the Global Wellness Forum, the Organic Consumers Association, and the National Foundation for Integrative Medicine. It was also sent to RFK, Jr. and various members of relevant FDA and HHS committees, encouraging them to incorporate this common-sense plan into GRAS reform.

"**We support Secretary Kennedy's intention to remove the most toxic substances from our food supply,**" said Jonathan Emord, J.D., ANH General Counsel and co-author of the white paper. **"However, the government should avoid complete elimination of Self-GRAS, which would create a massive regulatory bottleneck, potentially removing thousands of safe ingredients from the market along with those that are unsafe."**

The authors emphasize that their targeted approach is particularly well-suited to the current reality of reduced resources at the Department of Health and Human Services. **"By focusing regulatory scrutiny on the small subset of ingredients with demonstrated safety concerns rather than attempting to review all 10,000+ self-affirmed ingredients, this strategy allows the FDA to efficiently protect public health even with limited staff and resources**," the white paper explains.

The GRAS designation was established under the Food Additive Amendment of 1958 to exempt well-established, demonstrably safe food ingredients from FDA's rigorous pre-market approval process. Unfortunately, unscrupulous companies have used this pathway to introduce ingredients of dubious safety into the food supply, including colors, preservatives, technological additives, and chemicals—most of which have not been thoroughly reviewed for safety or reassessed after decades of use. While these concerns are valid, the Self-GRAS pathway remains vital for introducing safe, innovative products without unnecessary regulatory burdens.

ANH's proposed reforms draw important contrasts with the European regulatory approach to food additives, where only about 400 ingredients are currently permitted. The paper argues this may be overly cautious, potentially depriving consumers of healthy options.

"**Our white paper defines a strategy for balanced GRAS reform while avoiding the EU model of extensive regulatory overreach in favor of freedom of choice**," said Robert Verkerk, Ph.D., ANH's Executive & Scientific Director and white paper co-author.

The white paper proposes several key reforms:

1. **Targeted Approach to Unsafe Ingredients**: Prioritize the removal of specific unsafe ingredients rather than requiring re-evaluation of all 10,000+ self-affirmed GRAS substances. The paper identifies potassium bromate, propylparaben, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), sodium benzoate, and brominated vegetable oil (BVO) as examples of additives that may be injurious due to their chronic toxicity.

2. **Public Transparency Register**: Create a comprehensive online database of all GRAS determinations, enhancing accountability and consumer information. This would complement the FDA's recently announced Chemical Contaminants Transparency Tool.

3. **Tiered Risk/Benefit Assessment**: Implement a four-tier system that calibrates evidence requirements based on an ingredient's history of use and safety profile. Substances with at least 30 years of safe use would face minimal requirements, while those with evidence of potential toxicity would require more robust safety data.

4. **"Safe Harbor" for Time-Tested Ingredients**: Create a pathway for ingredients with a documented history of safe use for over 60 years, predating the 1958 Food Additive Amendment. These would be officially recognized by the FDA as "historically safe."

5. **Appropriate Warning Requirements**: When specific populations may be vulnerable to otherwise safe ingredients, warnings rather than outright bans

should be required. The FDA would recognize such warnings as creating a presumption of safety for the ingredient.

# # #

About Alliance for Natural Health USA (www.anh-usa.org): Established in 1992, the Alliance for Natural Health USA is the largest advocacy organization in the United States promoting natural, preventative, and regenerative approaches to health. ANH has 670,000 followers across the U.S. plus international reach through its sister organization, ANH International. As a 501(c)(4) organization, ANH-USA's mission is to protect the right of all Americans to choose natural and regenerative healthcare options for optimal health.

BACKGROUNDER: REFORMING THE GRAS PROCESS

What is GRAS?

GRAS stands for "Generally Recognized as Safe," a designation under U.S. law for substances intentionally added to food that experts consider safe under their intended conditions of use. GRAS substances are exempt from FDA premarket approval if their safety is widely recognized among qualified experts. While GRAS status can be achieved through FDA notification, many companies instead determine GRAS status independently, a practice known as Self-GRAS.

A Brief History of the GRAS System

- The GRAS provision was created through the 1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act. That year, the FDA published its first list of GRAS substances.
- After 1958, companies could also petition the FDA for GRAS affirmation, submitting scientific evidence—typically supported by a panel of "qualified experts"—demonstrating the safety of a substance. The FDA would review these petitions, then either affirm, reject, or request more data. The affirmation petition process involved formal rulemaking procedures, making it labor and resource intensive.
- In 1997, to streamline the process, the FDA proposed replacing the GRAS affirmation petition system with a GRAS notification procedure. Under this system, companies may notify the FDA of their GRAS determinations. The FDA may then agree with the determination, request additional data, or issue an objection. Importantly, companies are not required to submit these notifications, meaning many Self-GRAS substances remain unreviewed and invisible to both the FDA and the public.

Today, more than 10,000 Self-GRAS substances are in use, some of which may pose risks while others contribute significantly to wellness and nutrition.

Why Reform Is Needed Now

The Self-GRAS pathway has played a pivotal role in supporting innovation across the wellness, dietary supplement, functional food, and natural health product sectors. It has enabled thousands of beneficial ingredients to enter the market—many of which pose no risk to public health and have a long history of safe use.

However, the same system has also allowed potentially hazardous substances to enter the food supply without public scrutiny or independent FDA review. In response, calls for reform have intensified, with some stakeholders advocating for the complete abolition of the Self-GRAS pathway.

While well-intentioned, such a sweeping change could have serious unintended consequences, including:

- Disrupting the wellness and supplement sectors, which rely heavily on the Self-GRAS pathway to introduce health-promoting products into the marketplace.
- Overloading the FDA, which, even when fully staffed, lacks the capacity and expertise to assess over 10,000 Self-GRAS ingredients.

Rather than eliminating the Self-GRAS process altogether, a more nuanced, pragmatic reform strategy is needed—one that enhances transparency, prioritizes removal of high-risk additives, and preserves access to safe and beneficial substances.

Striking the Right Balance: Avoiding Extremes

While concerns about dangerous chemicals in the food supply are valid—and in many cases, long overdue—some advocacy efforts risk swinging the pendulum too far in the opposite direction. Adopting overly stringent risk/benefit assessments, like those used in the European Union, can lead to unnecessary and disproportionate restrictions on safe, beneficial ingredients. These systems often demand exhaustive safety data, even for substances with a long history of safe use, effectively penalizing natural or traditional ingredients simply for lacking modern documentation. Onus data requirements also favor large corporations with deep resources, while providing a barrier to market entry for smaller companies that have often been at the vanguard of natural health product innovation.

In short, reform should guard against both extremes: unchecked use of unsafe substances and over-regulation that restricts consumer choice and innovation.

ANH's Proposal: A Balanced, Transparent Reform Path

In response, the Alliance for Natural Health (ANH) has released a white paper offering a rational, science- and law-informed strategy for GRAS reform. The plan outlines a middle-ground approach that preserves beneficial innovation while closing regulatory loopholes.

Key proposals include:

- Creating a GRAS Transparency Register to make all GRAS determinations publicly visible and open to independent scrutiny.
- Empowering the FDA to focus enforcement on a small group of high-risk additives rather than spreading resources thin across all ingredients.
- Implementing a tiered risk assessment system for GRAS ingredients moving forward based on the adulteration standard in U.S. law, tailored to each ingredient's risk profile.
- Avoiding burdensome EU-style regulation and risk assessment for low-risk ingredients, which could unnecessarily restrict consumer choice and innovation.

Looking Ahead

This reform proposal has been shared with federal leaders, including Robert F. Kennedy, Jr.'s team, and complements ongoing efforts at the Department of Health and Human Services like the Chemical Contaminants Transparency Tool launched on March 20, 2025.

ANH urges all stakeholders—including MAHA-aligned organizations and health freedom advocates—to rally behind this unified, practical, and common-sense solution to safeguard public health without stifling innovation or freedom of choice.

ALLIANCE FOR NATURAL HEALTH WHITE PAPER

Reforming GRAS: Food Safety Without Sacrifice

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Executive Summary

Concerns have arisen over the "self-affirmed" Generally Recognized as Safe (GRAS) pathway for food additives, which allows companies to declare ingredients safe without FDA review. In response, on March 10, 2025, Health and Human Services Secretary Robert F. Kennedy, Jr. directed the FDA to consider eliminating this pathway, leaving only the formal FDA GRAS notification process.

Established under the Food Additive Amendment of 1958 to the federal Food, Drug, and Cosmetic Act (FDCA), the purpose of the GRAS designation was to prevent unnecessary regulatory burdens on ingredients that had a well-established safety record, thus ensuring food safety while promoting industry efficiency and innovation.

Since the inception of the FDA's GRAS program in 1998, the agency has received and filed over 1,200 GRAS notices through the formal notification process. Estimates suggest, however, that as many as 10,000 or more ingredients have been self-affirmed as GRAS ('Self-GRAS'). Precise numbers, however, are unavailable because under Self-GRAS, companies are not required to inform FDA.

Self-GRAS has enabled unscrupulous companies to place ingredients of dubious safety in the food supply. In fact, the current Self-GRAS process is likely responsible for significant public exposure to harmful chemicals. However, Self-GRAS remains a vital pathway for food and supplement companies to introduce safe, innovative, and health-promoting products without unnecessary regulatory burdens.

Self-GRAS raises previously unaddressed concerns about conflicts of interest, bias, lack of transparency, and insufficient scientific rigor. Self-GRAS has contributed to less healthy American diets compared to those in European countries. In Europe, only about 400 food additives or ingredients are currently permitted. In contrast, the U.S. allows more than 25 times this number, including colors, preservatives, technological additives, and chemicals used to produce additives—most of which have not been thoroughly reviewed for safety or reassessed after decades of use.

Ensuring food safety is paramount, but disproportionate application of the precautionary principle[1] is not appropriate and contravenes the intended purpose of the GRAS program. Elimination of Self-GRAS entirely without grandfathering the use of substances with well-established safety records and narrowing the scope of Self-GRAS disallowance to substances known to cause injury at dose levels in foods would likely have the unintended consequence of depriving consumers of safe alternatives and healthy options in the food market and stifling innovation.

Moreover, the entire elimination of Self-GRAS would create a massive regulatory bottleneck as thousands of substances, for which there is a reasonable basis for safe use, would clog FDA GRAS notification channels, along with those lacking such reasonable basis. The agency would thus labor for years, perhaps even decades, to discern which ones meet the new approval standards.

There is also concern that the entire elimination of Self-GRAS would jeopardize public health, as safe foods under Self-GRAS would be removed from the market along with the unsafe. This is of particular concern as U.S. diets have become increasingly less diverse, more processed, and less natural, given the increased use of chemical additives.

This White Paper proposes reforming GRAS to keep safe products on the market while targeting and ensuring evaluation only of those for which sound scientific evidence

[1] The roots of the precautionary principle can be traced to statements by Aldo Leopold (1949) and Sir Austin Bradford Hill (1965), and it is also addressed in Principle 15 of the Rio Declaration on Environment and Development of 1992: "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." In the food context, the precautionary principle has been employed to justify prohibiting ingredients on the basis that at some dose level injury occurs, albeit without proof that any particular product contains an ingredient at that dose level. The principle thus restricts consumer choice without scientific justification when employed in this manner. By contrast, the Paracelsian principle, which undergirds the adulteration provisions of the Food Drug and Cosmetic Act, stands for the proposition that dose determines toxicity and that banning an ingredient's use must only occur at the precise dose level and above at which injury occurs.

suggests a significant or unreasonable risk of illness or injury. The solutions proposed include:

1. **Prioritizing the Removal of Unsafe Ingredients**

   Using adverse event reporting data together with peer-reviewed toxicity data, the FDA should prioritize and target the subset of GRAS ingredients for which there is proof of a significant or unreasonable risk of illness or injury. Federal regulators should then notify companies using ingredients in this subset of the scientific basis for questioning those ingredients, explain, the precise safety concerns, and require the ingredients not be used thereafter unless and until notices seeking FDA GRAS have been accepted without objection.

   Examples of Self-GRAS additives on the U.S. market that may be injurious given their chronic toxicity, including carcinogenic potential, include potassium bromate, propylparaben, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), sodium benzoate, and brominated vegetable oil (BVO).

2. **Creating a Public Transparency Register**

   The FDA should publish online a complete listing of agency GRAS evaluations and require all companies that have Self-GRAS determinations to supply the agency with those determinations to also post online. This initiative would work alongside the FDA's existing contaminants register, the Chemical Contaminants Transparency Tool.

3. **Implementing a Tiered Risk/Benefit Assessment System**

   In instances where there is published, peer-reviewed scientific evidence revealing a lack of safety and a potential for mutagenicity, carcinogenicity, or other significant or unreasonable risk of illness or injury, the FDA should demand more robust evidence of safety at dose levels intended for foods before future acceptance of GRAS by the agency.

4. **Establishing a Consistent Safety Standard in Accordance with the Dietary Ingredient Provisions of the Food Drug and Cosmetic Act (FDCA), 21 USC 342**

   In assessing the safety of a food additive, whether through Self-GRAS determinations or FDA allowance of GRAS following notification, the agency should adhere to the FDCA adulteration standard for dietary

ingredients. FDA should assess whether a preponderance of reliable and reproducible scientific evidence supports the conclusion that an ingredient presents a "significant or unreasonable risk of illness or injury" at the dose level recommended for ingestion in food. If so, then the agency should withhold GRAS allowance and prohibit use of the additive in foods. A zero-risk tolerance approach is inadvisable because every dietary ingredient and food results in some adverse effect at some dose level, and nearly every one results in an adverse effect to a sensitive subpopulation, such as those who may suffer an allergic reaction to the particular dietary ingredient or food.

5. Creating a "Safe Harbor" Pathway for Ingredients with a Long History of Safe Use

Ingredients with a documented history of safe use in food for over 60 years, predating the 1958 Food Additive Amendment, should be officially recognized by the FDA as "historically safe"—provided they are added in food without chemical alteration, maintaining the same chemical identity as the long-used source.

6. Requiring Warnings for GRAS Food Ingredients

When a subset of the population is vulnerable to adverse effects from an otherwise safe substance, such as allergic reactions or minor risks, the company using the food additive should identify the risks and warn the public. This enables the affected subpopulation to avoid ingestion and related harm. The FDA should then recognize such warnings as creating a presumption of safety in favor of the ingredient.

These reforms would significantly improve food safety, enhance public confidence in the food supply, and maintain efficiency without stifling innovation.

1. Introduction

On March 10, 2025, Secretary Robert F. Kennedy, Jr. directed the FDA to explore eliminating the self-affirmed GRAS ("Self-GRAS") pathway.[2] Concerns about Self-GRAS—where companies declare food ingredients safe without FDA notice—have sparked debate over the Self-GRAS system's effectiveness in safeguarding the public from unsafe food additives.

Secretary Kennedy's action has brought renewed attention to the GRAS system, but calls for reform are not without precedent. Bills to eliminate the self-affirmed GRAS pathway were introduced in both chambers of Congress in 2023-2024.[3]

Established in 1958 with the enactment of the Food Additive Amendment, the GRAS designation aimed to simplify regulatory oversight by identifying substances with proven safety histories, allowing them to bypass the formal FDA approval process required for new food additives.

Mounting concerns about this system are rooted in the potential misuse of GRAS by unscrupulous companies adding ingredients to food without adequate evidence of safety. On the other hand, GRAS remains an important pathway for food and supplement companies to bring safe, innovative, health-promoting products to the market free of unnecessary regulatory encumbrance.

Ensuring the safety of the food supply is paramount, but an overly rigid application of the precautionary principle will not only stifle innovation and exceed strictures necessary to protect public health but may also result in a net loss of public health. This is because demonstrably safe additives and dietary ingredients could be swept up and removed along with those that are clearly unsafe.

The precautionary principle has been defined as:

> *When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.*[4]

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[2] Dept HHS, "HHS Secretary Kennedy Directs FDA to Explore Rulemaking to Eliminate Pathway for Companies to Self-Affirm Food Ingredients Are Safe", March 10, 2025: *https://www.hhs.gov/about/news/2025/03/10/hhs-secretary-kennedy-directs-fda-explore-rulemaking-eliminate-pathway-companies-self-affirm-food-ingredients-safe.html.*

[3] See S.3387, the Ensuring Safe and Toxic-Free Foods Act of 2023, and H.R.9817, the Toxic Free Food Act of 2024.

[4] See "Wingspread Statement on the Precautionary Principle," Science and Environmental Health Network, *http://www.sehn.org/wing.html.*

This principle has been widely used to address concerns about environmental degradation and exposure to chemicals, exposure to which confer no direct benefits to humans, only the potential risk of harm. Food additives may include substances intentionally added to provide health benefits to consumers, as well as those included for other purposes, such as cost reduction, enhancing the product's physical appearance, or achieving specific technical or sensory effects. This means that when the precautionary principle is triggered and results in the prohibition of substances that bear only a potential for harm (a characteristic of all substances, water included), the mere presence of scientific uncertainty leads to a loss of consumer choice, the potential for harm due to lack of access, as well as a loss of innovation and growth in the food sector.

Who wouldn't want total certainty about food safety? In actuality, however, absolute safety is an impossible standard in science and regulation. No ingredient, food, or even everyday activity can ever be deemed "completely safe" in all circumstances. Demanding absolute certainty would lead to the unnecessary removal of food ingredients that are safe and beneficial at dose levels commonly consumed, simply because higher dose levels are associated with a risk of illness or injury or because long-term safety data is unavailable, less than complete, or evolving. It could also create a chilling effect on innovation, making it more difficult for companies to introduce new, health-promoting ingredients or reformulate products in response to consumer demand. It can also result in the loss of ingredients with a long history of safe use with few ill effects by the vast majority of consumers because a discrete subset experiences ill effects (e.g., those who are peculiarly allergic to the ingredients).

A well-calibrated approach to GRAS reform must be rational, focusing on whether the ingredient at the dose levels ordinarily consumed results in a significant or unreasonable risk of illness or injury. While it is essential to prevent bad actors from exploiting the system, reforms should not create unnecessary barriers to demonstrably safe products—especially those that align with Secretary Kennedy's advocacy for healthier food options. The challenge lies in ensuring rational protection for consumer safety while avoiding excessive regulation that could hinder scientific progress and consumer access to beneficial ingredients.

This White Paper makes the case for that rational approach to GRAS reform by looking at the current GRAS system, its shortcomings, and targeting solutions to ensure a safer food supply without inviting regulatory overreach.

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> *The precautionary principle, for all its rhetorical appeal, is deeply incoherent. It is of course true that we should take precautions against some speculative dangers. But there are always risks on both sides of a decision; inaction can bring danger, but so can action. Precautions, in other words, themselves create risks—and hence the principle bans what it simultaneously requires.*[5]
>
> — **Cass Sunstein, former administrator of the Office of Information and Regulatory Affairs**

> *The truly fatal flaw of the precautionary principle, ignored by almost all the commentators, is the unsupported presumption that an action aimed at public health protection cannot possibly have negative effects on public health.*[6]
>
> — **Frank Cross, University of Texas professor of law**

[5] Cass R. Sunstein, "Throwing Precaution to the Wind: Why the 'Safe' Choice Can Be Dangerous," *Boston Globe*, July 13, 2008.
[6] Frank B. Cross, Paradoxical Perils of the Precautionary Principle. *Washington and Lee Law Review*, 1996; 53(3): 860.

2. The Current GRAS System: Benefits and Defects

2.1 What is GRAS?

The GRAS designation, established in 1958, exempts certain food ingredients from the FDA's notification process for food additives.[7] This exemption is granted when an ingredient is recognized by qualified experts as having been adequately shown to be safe for its intended use.[8]

There are two primary pathways for establishing GRAS status: 1) through scientific procedures, or 2) through experience based on common use before January 1, 1958 (the "common use" pathway).

2.1.1 Scientific Procedures

Establishing an ingredient as GRAS through "scientific procedures" requires the same level of evidence as obtaining approval for a food additive: that is, a "reasonable certainty" among scientists that the substance is not harmful under the conditions of its intended use.[9,10] While the approval of food additives can be based on proprietary data, GRAS status must be established through publicly available scientific data.[11] We recommend uniform adoption of the dietary ingredient adulteration standard, which is itself based on the Paracelsian principle,[12] not the precautionary principle.[13] Under the Paracelsian principle, a dietary ingredient is only presumed unsafe when it presents a significant or unreasonable risk of illness or injury under recommended or common conditions of use, including recommended or common dosing. The principle encapsulates the concept that any substance can be toxic at a high enough dose.

The principle has already been employed in the newly launched FDA register for contaminants, the Chemical Contaminants Transparency Tool,[14] which deems foods

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[7] See 21 CFR 170.3 and 21 CFR 170.30.

[8] 21 CFR 170.30(a)(2): "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 under the conditions of its intended use."

[9] 21 CFR 170.30(b).

[10] 21 CFR 170.3(i).

[11] 21 CFR 170.30(b).

[12] Gantenbein UL. Chapter 1 - Poison and Its Dose: Paracelsus on Toxicology. In: *Philip Wexler, History of Toxicology and Environmental Health, Toxicology in the Middle Ages and Renaissance*. Academic Press,2017: pp. 1-10 .The Swiss physician and alchemist Paracelsus (1493–1541) advocated "the dose makes the poison" (Latin: "Sola dosis facit venenum") around 450 years ago.

[13] Bschir K. Risk, Uncertainty and Precaution in Science: The Threshold of the Toxicological Concern Approach in Food Toxicology. *Sci Eng Ethics*. 2017;23(2):489-508.

[14] FDA Chemical Contaminants Transparency Tool: *https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=contaminant-levels*.

safe to consumers when contaminants are below specified action levels, and potentially harmful when above these levels.

2.1.2 Common Use

To establish an ingredient as GRAS through experience based on common use in food before January 1, 1958, a company must demonstrate "a substantial history of consumption for food use by a significant number of consumers."[15] Companies must also be able to show that the product and its use, such as the levels of use of the substance, are equivalent to pre-1958 versions.[16] With technological and manufacturing advances since 1958—advances that allow companies to more efficiently isolate and extract ingredients, for example—it is exceedingly difficult for companies to satisfy these criteria. Indeed, the FDA's own website states this "common use" pathway is rarely used.[17]

Currently there are two options for companies to document the GRAS status of an ingredient:

- **Self-Affirmation**: Companies can self-affirm an ingredient as GRAS based on their own safety testing, without notifying the FDA (i.e., "Self-GRAS").

- **FDA Notification**: Companies can voluntarily submit GRAS notifications to the FDA for review. The agency can respond in one of three ways: 1) a "no questions" letter when there are no concerns about the safety of the substance; 2) an "insufficient basis" letter when the agency believes that the criteria for a GRAS determination have not been met; and 3) a "cease to evaluate" letter if the notifier requests that FDA stop evaluating the substance.

2.2 Impact on Dietary Supplements

It is important to note that reforms to the GRAS system will have significant consequences for the dietary supplement industry and consumer access to an array of healthy products because ingredients determined to be GRAS, as well as those regarded as old dietary ingredients (ODIs) i.e., supplements sold before October 15, 1994), may be used as ingredients in dietary supplements without notification to the FDA.

For dietary supplement companies, the GRAS system is often a more attractive option for introducing new products that contain new ingredients that would otherwise be

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[15] 21 CFR 170.3 (f).

[16] 81 FR 54960, see Response 22.

[17] FDA, "How U.S. FDA's GRAS Notification Program Works", Jan 2005/Feb 2006: *https://www.fda.gov/food/generally-recognized-safe-gras/how-us-fdas-gras-notification-program-works*

prohibited as new dietary ingredients under the Dietary Supplement Health & Education Act of 1994.[18]

The law requires those who wish to market a supplement containing a "new dietary ingredient" (NDI)—that is, an ingredient that was not marketed as a supplement in the United States before October 14, 1994—to prepare and submit a notification to the FDA showing, among other things, that the ingredient is safe.[19]

There is an exemption to submitting an NDIN on a new dietary ingredient if the ingredient is GRAS, has been used in the food supply, and is to be used as a dietary ingredient without chemical alteration.[20] Companies can, therefore, proclaim GRAS status for a substance, use it in a food, and then market the ingredient in a supplement without the need for a NDIN.

Why would companies use the GRAS route for supplements? There are data indicating that FDA has a more favorable view of GRAS notices compared to NDINs, potentially due to a higher level of familiarity with GRAS procedures and standards, which have been in use since 1958, compared to NDIN standards which are still in development. One analysis found the FDA deemed approximately 30 percent of NDIN submissions as favorable, whereas the agency viewed 75 percent of GRAS notifications as favorable.[21]

To ensure the application of a uniform standard, we recommend the use of the dietary ingredient adulteration standard in 21 USC 342 discussed above. This standard ensures consumer protection while eliminating the many years of intensive assessment work that would be required to evaluate formal notifications of the many thousands of existing Self-GRAS ingredients. By contrast, application of the afore-mentioned adulteration standard would mean GRAS determinations are applied appropriately only to those substances that do not present a significant or unreasonable risk of illness or injury.

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[18] FDA, "New Dietary Ingredient (NDI) Notification Process", April 3, 2024: *https://www.fda.gov/food/dietary-supplements/new-dietary-ingredient-ndi-notification-process.*

[19] 21 USC 342 (f)(1)(B), i.e., that the ingredient "doesn't present a significant or unreasonable risk of illness or injury."

[20] FDA, "Dietary Supplements: New Dietary Ingredient Notifications and Related Issues: Guidance for Industry: Draft Guidance", April 2024: *https://www.fda.gov/media/99538/download* (See IV.B.2).

[21] Robert S. McQuate, Richard C. Krasta. "GRAS vs. NDI", *Nutritional Outlook*, June 13, 2013: *https://www.nutritionaloutlook.com/view/gras-vs-ndi.*

2.3 Current GRAS System: Advantages and Defects

Advantages and defects in the current GRAS system are summarized in the table below.

Advantages of the GRAS System	Defects of the GRAS System
• **Encourages Innovation**: The system enables the swift introduction of new ingredients, particularly through self-affirmation. • **Optional FDA Oversight**: Companies can seek FDA review for added credibility, though it is not required. • **Increased Efficiency**: The GRAS system, particularly self-affirmation, allows the FDA to ensure a safe food supply while being able to focus its attention and resources on other, more pressing priorities. This may be of particular relevance as the current administration prepares to substantially reduce the Department of Health and Human Services' workforce.[22]	• **Lack of Transparency**: The public has no access to the safety evidence supporting self-affirmed GRAS determinations. There is also insufficient transparency to identify potential conflicts of interest within the FDA regarding its response to GRAS notifications. • **Conflict of Interest**: GRAS determinations can be made by company-employed experts who may be biased or conflicted. • **High Rates of Self-Affirmation**: Since 2000, nearly 99% of new chemicals in food were self-affirmed GRAS without FDA review.[23] • **Withdrawal Loophole**: Companies can withdraw GRAS notifications if the FDA raises concerns yet still use the ingredient in food products via Self-GRAS. • **Common Use Pathway Untenable**: Given technological and manufacturing advances since 1958 and the elapse of time, the exemption for pre-1958 ingredients is no longer a valid option.

[22] Politico, "HHS braces for a reorganization", March 13, 2025: *https://www.politico.com/news/2025/03/13/hhs-reorganization-00230113?utm_source=substack&utm_medium=email.*

[23] EWG, "EWG analysis: Almost all new food chemicals greenlighted by industry, not the FDA", April 13, 2022: *https://www.ewg.org/news-insights/news/2022/04/ewg-analysis-almost-all-new-food-chemicals-greenlighted-industry-not-fda.*

3. Proposed Solutions for GRAS Reform

To address current concerns while maintaining GRAS as a pathway for safe ingredients, we have developed, with extensive consultation, including experience from other regulatory systems, an approach designed to yield the greatest benefits for consumers, while avoiding undue restraint on the food industry. A summary of the advantages, disadvantages, and proposals is given in the Appendix (pp. 19-20).

The key elements of the proposal are explained in Sections 3.1 through 3.6 below.

3.1 For Existing GRAS Ingredients (Self-GRAS and GRAS Notices to FDA): Prioritize Market Removal of Unsafe Food Additives and Ingredients

- A thorough, scientific review of adverse event data and peer-reviewed literature should be conducted by FDA to identify previously marketed GRAS ingredients for which there is a preponderance of sound scientific evidence in the public, peer reviewed literature that those ingredients present a significant or unreasonable risk of illness or injury at dose levels commonly consumed.
- Once ingredients have been identified as presenting a significant or unreasonable risk of illness or injury, FDA should serve notice to food manufacturers of its findings together with a demand that companies cease use of the ingredients or show cause at a hearing why the ingredient at dose levels commonly consumed does not present a significant or unreasonable risk of illness or injury. The revised GRAS program will prevent companies from using the ingredients, whether GRAS status was achieved through Self-GRAS or FDA notification, in newly manufactured products unless and until either the FDA or a court of competent jurisdiction holds the FDA's findings arbitrary and capricious or contrary to law.
- In all instances where previously marketed GRAS ingredients have not been the subject of adverse event reports and are not identified in the public, peer reviewed scientific literature as presenting a significant or unreasonable risk of illness or injury at dose levels commonly consumed, the agency would take no further action.
- In all instances in which a previously marketed GRAS ingredient had a long history of safe use preceding the Food Additive Amendment of 1958, the FDA would presume the ingredients safe and would take no further action.

This targeted approach ensures that the focus remains on removing genuinely hazardous chemicals, such as potassium bromate, propylparaben, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), titanium dioxide, Red 40, Yellow 5, Yellow 6, Blue 1, Blue 2, Green 3, azodicarbonamide (ADA), sodium benzoate, brominated vegetable oil (BVO), while safeguarding access to a plethora of

safe and beneficial ingredients presently in use through Self-GRAS (e.g., Vitamin E tocotrienols, sulforaphane, beta-glucan, tagatose, and allulose).

A major advantage of this policy is that it prevents a flood of GRAS petitions requiring FDA review and allows regulators to take a targeted approach, prioritizing demonstrably unsafe ingredients for removal from the food supply.

While the onus to show that specific additives or ingredients pose a significant or unreasonable risk of illness or injury should rest fully with the FDA, the agency's task can be fulfilled through private contracting with independent laboratories commissioned to evaluate all publicly available scientific evidence and adverse event reports to recommend to the agency a subset of ingredients for which there is evidence of a significant or unreasonable risk of illness or injury.

It must be recognized that the process of retrospectively determining which of the probable 10,000 plus Self-GRAS substances pose significant or unreasonable risks of illness or injury is a very substantial scientific undertaking. The FDA lacks sufficient expertise or resources to adequately undertake this retrospective appraisal. Accordingly, private contracting with unbiased, science-based institutions and individuals can facilitate the process of prioritizing the flagging of substances that are likely to pose significant or unreasonable risk of illness or injury. There must be no conflict-of-interest waivers to ensure true independence by individual contracting entities and individuals.

The private contracting parties' recommendations would be evaluated by the FDA. The Agency's determination would then trigger issuance of notice to manufacturers of findings that ingredients are unsafe, also triggering a right to a show cause hearing if a manufacturer wished to protest the determination. Manufacturers will be able to respond to the FDA's decisions in ways that are unchanged, namely by participating in show cause hearings, submitting revised GRAS Notifications, requesting informal meetings with the FDA for consultation, or challenging FDA decisions in federal court.

3.2 Implement a GRAS Transparency Register

The FDA should require all companies with Self-GRAS determinations, as well as those with FDA-accepted GRAS notifications, to enter relevant data into a central, publicly accessible, FDA-maintained GRAS Transparency Register. This data should include the ingredients covered by these determinations, the foods they are added to, and any associated warnings. The FDA should also use this Register to publish notices to manufacturers regarding scientific determinations that certain ingredients pose a significant or unreasonable risk of illness or injury. Additionally, the FDA should require manufacturers to cease using such ingredients and provide the agency's reasons for the decision or a link to the official correspondence sent to the manufacturers.

Currently, no public register or centralized database lists all ingredients—estimated at approximately 10,000—that manufacturers in the United States have determined to be Self-GRAS. The only existing register covers ingredients designated as GRAS through formal FDA notification, totaling around 1,200 items, which are listed in the GRAS (SCOGS) Database. Merging the SCOGS Database with Self-GRAS ingredients into a publicly accessible Transparency Register would close a critical gap in the GRAS system's transparency. This register should include all Self-GRAS ingredients currently in use, as well as those proposed for future use, and provide detailed identifying information, including (as applicable): the food company's details, recommended usage levels, foods in which the additives are incorporated, any label warnings, chemical name, CAS Registry Number, empirical and structural formulas, quantitative composition, manufacturing method, botanical parts (for botanicals), source or origin (for naturally derived ingredients), genus and species (for ingredients derived from living organisms), contaminants, microbiological data, and any specifications relevant to food-grade materials.

The GRAS Transparency Register would be another invaluable resource that would complement the existing register of chemical contaminants, the Chemical Contaminants Transparency Tool.[24]

3.3 Establishing a Consistent Safety Standard for Risk Assessment

When assessing the safety of a food additive—whether through Self-GRAS determinations or via formal FDA notification—the agency should apply the same standard established in the Food, Drug, and Cosmetic Act (FDCA) for dietary ingredients, as outlined in 21 USC 342. Toxicological testing should demonstrate that the food additive does not present a "significant or unreasonable risk of illness or injury" at the dose intended for ingestion in food. A zero-risk tolerance approach is inadvisable, as every dietary ingredient and food causes some adverse effect at a certain level of ingestion.

For a consistent standard to be proportionately applied to substances according to their duration of historical use and potential for risk to health, a tiered system of risk/benefit assessment is recommended (Section 3.4).

3.4 New GRAS Notifications to FDA: Establish a Tiered Risk/Benefit Assessment System

A tiered risk/benefit assessment system for new GRAS notifications to FDA represents a pragmatic approach that aligns evidence requirements with the duration of historical

[24] FDA Chemical Contaminants Transparency Tool: *https://www.hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=contaminant-levels*.

use and with the totality of available evidence on real-world safety risks. It also recognizes the extent to which risks to susceptible population groups can be managed—for example, through warning labels or limiting concentrations of specific chemical components—so that the majority can derive benefits.

A four-tier assessment system is proposed for GRAS Notifications to the FDA as follows:

- **Tier 1**: Notifications under this tier may be submitted for ingredients with credible evidence of long-term safety, based on 30 years or more of use in the food supply. Such evidence will need to demonstrate that prescribed uses do not present a significant or unreasonable risk or illness or injury. No further toxicological evidence is required. Petitions may include no restriction on maximum levels (*quantum satis*) or with specified maximum levels (of the substance itself or of a designated marker substance within the substance). Substances used pre-1958 (i.e., over 60 years) should be categorized by the FDA as "historically safe" (see Section 3.5). The petitioner may challenge FDA determinations in the usual manner, and the FDA may require a safety assessment at a higher tier.

- **Tier 2**: Notifications for ingredients with less than 30 years and more than 20 years of claimed safe use will be carried out in the same manner as Tier 1, although it will be evident that substances under this tier have had shorter durations of exposure which will necessitate provision of additional evidence of safety from market surveillance, health authorities (including outside the USA), and in the published scientific literature.

- **Tier 3**: Notifications for ingredients that have not been associated with historic dietary exposure (Tiers 1 and 2) and have less than 20 years of use, will require submission of basic toxicological data on acute and chronic toxicity, as well as data from human studies. Evidence confirming lack of delayed toxicity (mutagenicity, carcinogenicity or teratogenicity) will also be required. Maximum levels will be stipulated where there is a significant or unreasonable risk of illness or injury at specific thresholds of exposure.

- **Tier 4**: Notifications for ingredients with evidence of potential delayed toxicity (mutagenicity, carcinogenicity or teratogenicity) will be assessed under this tier and data requirements will be substantial, requiring the full complement of studies required under the provisions of the Food Additive Amendment of 1958, including studies of short-term and subchronic toxicity, chronic toxicity and carcinogenicity, genotoxicity and mutagenicity, reproductive and developmental toxicity, neurotoxicity and immunotoxicity, metabolism and pharmacokinetics. Conditions of limited use will also be determined.

3.5 New Limited Self-GRAS: The "Common Use" Pathway

- Update the 1958 cutoff to include ingredients with at least 30 years of safe use in any jurisdiction (see Tier 1 risk/benefit assessment; Section 3.4).
- Permit grandfathering of specific ingredients used in traditional preparations based on presumption of safety (i.e., evidence of long-term, safe history of use, and no evidence of significant or unreasonable risk of illness or injury to consumers from intended use).
- Grandfathering of ingredients in non-traditional formats will be permitted only when there is no change in the chemical identity of the ingredient and no significant change to the exposure profile of the ingredient if it would present a significant or unreasonable risk of illness or injury at dose levels commonly consumed.
- Where ingredients have a long history of over 60 years safe use pre-dating the Food Additive Amendment of 1958 and are added to food without change in their chemical identities, FDA should define such ingredients as "historically safe" and grant official acceptance of them predicated on a Self-GRAS determination and proof of the historic use.

Updating the 1958 cutoff and allowing substances with at least 30 years of safe use to qualify prevents outdated regulatory hurdles from hindering innovation. The grandfathering approach proposed ensures that traditional and well-understood ingredients remain accessible while maintaining safety through exposure-based criteria.

Overall, these reforms provide a science-driven, flexible framework that protects public health while fostering innovation and market accessibility.

3.6 Require Warnings for GRAS Food Ingredients, as Evidence Justifies

In instances where a subset of the population is vulnerable to an adverse effect arising from an otherwise safe substance, such as in the case of allergic reactions or effects that do not rise to the level of significant or unreasonable risks of illness or injury, the company responsible for the use of the food additive should be required to identify these risks and warn the public. Such warnings ensure that those in the subpopulation are able to avoid ingestion and the related risk peculiar to that subpopulation.

In turn, employment of such warnings should be recognized by the FDA as creating a presumption against a lack of safety and in favor of the company concerning the particular adverse reactions identified.

4. Conclusion

The GRAS system was originally intended to streamline the introduction of safe food ingredients, but loopholes that exclude any FDA or independent oversight have allowed bad actors to exploit it. It is also clear that the FDA does not currently have sufficient resources or expertise to retrospectively evaluate the many thousands of food additives that are on the U.S. market and flag those that may present significant and unreasonable risks to health. Nor does the FDA apply a uniform standard to its assessments.

The proposed reforms presented in this White Paper aim to close these gaps by enhancing transparency, strengthening oversight, ensuring rigor, and prioritizing public health without stifling responsible innovation or inadvertently harming public health as a result of regulatory overreach. By holding companies accountable and ensuring that safety assessments are made under a single, updated adulteration standard, these changes will not only protect and benefit consumers and their health but will also restore confidence in the U.S. food regulatory system.

APPENDIX

Alliance for Natural Health Summary Assessment of the Existing GRAS (Generally Recognized as Safe) System, with Outline Proposals for Reform

Attribute	Advantages	Disadvantages	Proposals for Reform
Self-Affirmation of GRAS Status (21 CFR 170.205)	- Enables rapid innovation and market entry without FDA pre-market approval.	- Lack of transparency; public cannot review the safety evidence. - Potential conflicts of interest (GRAS determinations can be made by company-employed experts). - No independent verification.	- FDA, supported by an independent committee of toxicological experts, should retrospectively flag and remove from the market Self-GRAS substances that pose a significant risk to health. - Establish public (transparency) register for Self-GRAS substances. -Self-GRAS remains as the most appropriate pathway for substances that have long histories of safe use.
FDA Notification (Optional) (21 CFR Part 170 Subpart E)	- Provides an avenue for FDA acknowledgment, adding credibility to a GRAS determination. - GRAS notices to FDA are publicly available.	- FDA's conclusions cannot be challenged. - Insufficient transparency to identify potential conflicts of interest within the FDA.	- Optional notification may be more suitable for more novel food additives which have limited evidence of historical use and may pose a greater risk to health
Safety Data Requirements (GRAS demonstration through scientific procedures) (21 CFR 170.30(b))	- Requires the same standard as food additives: "reasonable certainty of no harm" under intended use. - Safety data must be publicly available and recognized by qualified experts.	- No standardized threshold for "sufficient" safety data. - Some safe substances may be excluded due to high-dose concerns.	- Establish 4-tiered risk/benefit assessment system for new : Tier 1: Substances with 30+ years of safe use require no further toxicological data, relying on historical safety evidence. Pre-1958 substances (60+ years) should be classified as "historically safe." Tier 2: Substances with 20–30 years of safe use undergo enhanced scrutiny through market surveillance, health authority data, and scientific literature. Tier 3: Substances with less than 20 years of use require basic toxicological data (acute, chronic, and human studies) and evidence of no delayed toxicity.

Attribute	Advantages	Disadvantages	Proposals for Reform
			Tier 4: Substances with potential delayed toxicity face full toxicological testing, including chronic, genotoxic, reproductive, and neurotoxicity studies.
Grandfathering of Traditional Ingredients (Common Use Pathway) (21 CFR 170.30(a)(2))	- Allows pre-1958 ingredients to remain on the market without costly evaluations. - Can be based on common use in food outside the U.S. - Requires "substantial history of consumption for food use by a significant number of consumers."	- Unclear which substances qualify, leading to potential arbitrary exclusions. - The 1958 cutoff date makes this pathway nearly impossible to use given technological advances.	- Grandfathering creates 'safe harbors' for substances with long histories of safe use. - Update the 1958 cutoff to include substances with more recent long-term safe use. - Grandfathering of substances in non-traditional formats should be permitted only when there is no significant change to the exposure profile of substances that would otherwise present a safety concern at higher levels of exposure.
Interplay with FDA's New Dietary Ingredient Notification (NDIN) Guidance	- The GRAS system is often a more attractive option for companies than NDIN, allowing for easier market entry and better supplement choices. - FDA tends to have a more favorable view of GRAS notices compared to NDINs.	- Same potential for abuse and conflicts of interest as self-affirmed GRAS.	- Reform involving the proposed GRAS Transparency Register that allows public oversight as well as by independent scientists overcomes the potential risks for abuse and conflicts in the GRAS process.

SELECTION OF FOOD ADDITIVES USED IN USA WITH KNOWN SAFETY CONCERNS

NOTE: All of the following additives are FDA-approved, despite significant safety concerns. This is indicative of the need for re-evaluation of all food additives using an updated, tiered risk assessment approach, with independent scientific scrutiny, as proposed in the ANH white paper.

Synthetic Food Dyes

Commonly used to enhance the appearance of food, especially in processed snacks, candies, and beverages.

1. Red 40 (Allura Red AC)
    - Concern: Linked to hyperactivity in children, potential cancer risk in animal studies.
    - Used in: Candy, cereals, snacks, sodas.
    - Banned in: Several European countries require warning labels.
2. Yellow 5 (Tartrazine)
    - Concern: Hyperactivity, allergic reactions, especially in asthmatics.
    - Used in: Cereals, sodas, processed foods.
3. Yellow 6 (Sunset Yellow)
    - Concern: Tumors in animals, possible allergic reactions.
    - Used in: Baked goods, cereals, gelatin desserts.
4. Blue 1 and Blue 2
    - Concern: Linked to brain tumors in animal studies (Blue 2); allergic reactions.
    - Used in: Candy, drinks, ice cream.

Preservatives

Use to extend shelf life but can have potential toxic effects.

5. BHA (Butylated hydroxyanisole)
    - Concern: Classified as a possible human carcinogen by IARC.
    - Used in: Chips, cereal, gum, butter.

6. BHT (Butylated hydroxytoluene)
    - Concern: Similar concerns to BHA, endocrine disruptor potential.
    - Used in: Snack foods, chewing gum, meats.
7. Propyl Gallate
    - Concern: Potential endocrine disruption and estrogenic activity.
    - Used in: Fats, oils, and meat products.
8. Sodium Nitrite/Nitrate
    - Concern: Can form nitrosamines (carcinogenic compounds), linked to colorectal cancer.
    - Used in: Cured meats like bacon, ham, sausages.

Sweeteners

Some sugar substitutes are controversial despite being FDA-approved.

9. Aspartame
    - Concern: Linked to headaches, seizures, potential cancer risks (especially in rodents).
    - Used in: Diet sodas, sugar-free products.
10. Acesulfame Potassium (Ace-K)
    - Concern: Cancer concerns in animal studies.
    - Used in: Baked goods, chewing gum, diet drinks.
11. Sucralose (Splenda)
    - Concern: Possible gut microbiome disruption, chlorinated compound.
    - Used in: Diet foods and drinks.

Flavor Enhancers

These improve taste but may affect the nervous system or metabolism.

12. Monosodium Glutamate (MSG)
    - Concern: “Chinese Restaurant Syndrome,” neurotoxicity concerns in sensitive individuals.
    - Used in: Packaged soups, snacks, seasoning blends.
13. Artificial and “Natural” Flavors
    - Concern: Proprietary, undisclosed chemical mixtures that may include potentially harmful compounds.
    - Used in: Nearly all processed food.

Emulsifiers & Thickeners

Used for texture and consistency but may cause inflammation or gut disruption.

14. Carrageenan
    - Concern: Inflammatory and potentially carcinogenic in degraded form.
    - Used in: Dairy alternatives, processed meats.
15. Polysorbate 80
    - Concern: Linked to gut inflammation, fertility issues in animal studies.
    - Used in: Ice cream, salad dressings.
16. Carboxymethylcellulose (CMC)
    - Concern: May disrupt gut microbiota, promote inflammation.
    - Used in: Ice cream, baked goods, dressings.

Other Additives of Concern

17. Titanium Dioxide
    - Concern: Potential carcinogen, banned in the EU for food use.
    - Used in: Candy coatings, chewing gum, coffee creamers.
18. Brominated Vegetable Oil (BVO)
    - Concern: Banned in Europe and Japan, accumulates in body fat and may affect thyroid and nervous system.
    - Used in: Citrus-flavored sodas (e.g., Mountain Dew).
19. Potassium Bromate
    - Concern: Known carcinogen in animal studies, banned in many countries.
    - Used in: Bread and baked goods.

SELECTION OF PROBABLE* ‘SELF-GRAS’ NATURAL AND BIOSYNTHETIC INGREDIENTS

(*based on wide usage in marketplace, absence in the SCOGS database of FDA-notified additives or ingredients, and absence in the list of ‘old dietary ingredients’ compiled by the Council for Responsible Nutrition in 1998)

Class	Name
Flavonoids	Quercetin
	Epigallocatechin Gallate
	Epicatechin
	Epicatechin Gallate
	Epigallocatechin
	Cyanidin
	Delphinidin
	Genistein
	Luteolin
	Pelargonidin
	Peonidin
	Petunidin
	Malvidin
	Hesperidin
	Rutin
Proanthocyanidins	Vitis vinifera Grape Skin & Seed Extracts
	Vitis rotundifolia Grape Skin & Seed Extracts
	Pycnogenol
Other Polyphenols (incl. Stilbenes)	Resveratrol (and other Salvestrols)
	Pterostilbene
	Curcumin
	Ellagic Acid
Carotenoids	Lutein
	Zeaxanthin
	Lycopene
	Astaxanthin
	B-Cryptoxanthin
	Fucoxanthin
	Canthaxanthin

	Bixin
	Peridinin
	Violaxanthin
	Neoxanthin
Glucosinolates	Sulforaphane
	Indole-3-Carbinol
	Glucoraphanin
	Sinigrin
	Glucobrassicin
	Gluconasturtiin
	Glucotropaeolin
Saponins	Soyasaponins
	Ginsenosides
	Protopanaxadiol
	Protopanaxatriol
	Oleanolic Acid
	Ocotillol
Lignans	Secoisolariciresinol
	Matairesinol
	Sesamol
	Pinoresinol
	Sinol
	Enterodiol
	Lariciresinol
Triterpenes	Betulinic Acid
	Ursolic Acid
	Lupeol
	Ursolic Acid
	Oleanolic Acid
	Asiaticoside
	Astragaloside IV
Diterpenoids	Trans-geranylgeraniol
Alkaloids	Berberine
	Theobromine
	Solanine
	Theophylline
	Tomatine
	Capsaicin
Phytosterols	Beta-Sitosterol
	Campesterol
	Stigmasterol

	Sitostanol
Phytoestrogens	Genistein
	Daidzein
Omega Fatty Acids	Re-esterified Triglycerides (rTG) (EPA and DHA)
	Algal-derived EPA and DHA
Essential Oils	Thymol
	Eugenol
	Limonene
Resins and Gums	Boswellia serrata Extract (Boswellic Acids)
	Commiphora
	Gum Arabic
	Xanthan Gum
Bitter Compounds	Gentian Root Extract
	Artichoke Extract
	Grapefruit Seed Extract
Chlorophyll	Chlorophyllin
Mushroom Extracts	Ganoderma Lucidum
	Hericium Erinaceus
	Cordyceps
Natural Sweeteners	Allulose
	Steviol rebaudiosides
	Tagatose
Plant Extracts	Green Tea Extract
	Turmeric Extract (curcuminoids)
	Mesembryanthemum tortuosum (kanna) extract
	Forskolin
Seaweed Extracts	Fucoxanthin
Amino acids	Acetyl-L-Carnitine
	L-Carnitine L-Tartrate
	N-Acetyl-Cysteine
	Gamma-Amino Butyric Acid (GABA)
Nitrogenous bases/nucleotides	Uridine
	Thymidine
	Adenine
	2'-Deoxyadenosine
	2'-Deoxyguanosine
	2'-Deoxycytidine
Metabolic cofactors	Betaine
Miscellaneous	Ubiquinol (reduced coenzyme Q10)
	Methylsulfonylmethane

ABOUT THE ALLIANCE FOR NATURAL HEALTH

USA: *www.anh-usa.org*
International: *www.anhinternational.org*
Europe: *www.anheurope.org*

The Alliance for Natural Health is an international non-profit organization dedicated to promoting natural, sustainable healthcare through good science and good law. ANH protects the right of natural health practitioners to practice and the right of consumers to choose the healthcare options and treatment modalities they prefer, including complementary and alternative medicine. ANH unites consumers, practitioners, and the natural health industry to speak with a common voice, having worked since 1992 to help shift the medical paradigm from its primary focus on drugs and surgery to an "integrative" approach that seeks to optimize dietary health and lifestyle, while minimizing exposure to harmful chemicals.

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