

When a Trace Becomes an Ingredient

The FDA's 2026 Threshold-of-Regulation Proposal and the Scientific Limits of Exposure-Based Food Authorisation

A comparative analysis of direct food uses, toxicological screening, cumulative exposure and regulatory design in the United States, European Union and United Kingdom.

José M. López, R+D+I Director

Abstract

An August 2026 U.S. Food and Drug Administration proposal, brought into renewed public debate on 10 October, would extend the Threshold of Regulation (TOR) exemption from substances migrating out of food-contact materials to substances added directly to food. It would also replace a diet-wide concentration benchmark with a body-weight-adjusted exposure threshold. The change is embedded within a separate proposal to require notifications for uses claimed to be generally recognised as safe (GRAS). These measures are neither final nor equivalent to unrestricted ingredient approval. Yet their interaction raises an important question: can an exposure-based exemption designed for incidental migration be applied coherently to intentional technological use? This article distinguishes the proposed legal mechanism from claims made in public debate, examines the toxicological limitations of generic thresholds, compares EU and British positive-list authorisation systems, and develops a proposed Exposure–Function Evidence Matrix. The research agenda focuses on cumulative exposure, susceptible populations, analytical verification and the boundary between risk-based prioritisation and market permission.

Keywords: Threshold of Regulation; GRAS; food additives; dietary exposure; toxicological thresholds; cumulative risk; comparative food law; regulatory science

Knowledge Center category: Regulatory Affairs | Food Safety | Functional Ingredients | Emerging Research

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Meta description: FDA's proposed food-additive threshold raises a key question: can trace-exposure exemptions safely govern ingredients deliberately added to food products?

Internal tags: Regulatory Affairs; Food Additives; GRAS; Toxicology; Exposure Assessment; Food Safety; EU–US Comparison; Emerging Research

Editorial Position and Evidence Classification

Established: the existing U.S. TOR food-contact route, the published August 2026 proposed text, the EU/GB authorisation frameworks, and EFSA's TTC and mixture guidance. **Emerging:** the public debate following 10 October reporting and the potential effect of direct-use expansion if enacted. **Expert interpretation:** implications for the adequacy of exposure models and international compliance. **Hypotheses and research agenda:** the Exposure–Function Evidence Matrix and the function–hazard prioritisation study. No proposed exemption is represented here as current law or as a demonstrated safety finding.

1 | The overlooked clause in a highly visible reform

On 11 August 2026, the U.S. Food and Drug Administration (FDA) published a proposed rule entitled **Substances Generally Recognized as Safe** in the Federal Register (91 FR 51834–51881; docket FDA-2025-N-3262). The publicly emphasised reform was a proposed **mandatory notification system** for uses of substances claimed to be generally recognised as safe (GRAS). A second change, located in the same 48-page proposal, deserves at least as much technical scrutiny, when FDA proposes to amend 21 CFR §170.39 so that the Threshold of Regulation (TOR) exemption would no longer be confined to substances migrating from food-contact articles. It could also cover substances **intentionally added to food**. [1]

The distinction came into sharper public view on 10 October 2026, when investigative reporting highlighted concerns that a route created for negligible migration from packaging could be extended to direct food uses. That report supplies the immediate editorial trigger, so the primary evidence for this article is the proposed regulatory text itself, rather than the interpretation of any campaigner or commentator. [2]

This is a question about **regulatory architecture**, not simply whether one particular chemical is safe. A risk-based exemption can be legitimate when exposure is demonstrably negligible and hazard screening is adequate. The problem is determining whether the assumptions supporting such an exemption survive a change in the **purpose**, **route**, **distribution** and **frequency** of exposure. A molecule migrating incidentally from packaging and a molecule deliberately used to achieve a technological effect may be chemically identical but belong to different regulatory situations.

2 | What the FDA actually proposes - and what it does not

Under the existing TOR regulation, a manufacturer may request exemption for a food-contact substance that migrates, or may be expected to migrate, into food under specified conditions. The current principal low-exposure criterion is a dietary concentration at or below 0.5 parts per billion, with additional conditions, including screening for carcinogenicity and other safety concerns. FDA evaluates a request, and an exemption is not an automatic self-declaration. Its public TOR database identifies exempted substances and intended uses. [1, 3, 4]

The proposed amendment would replace the limiting reference to food-contact articles with wording covering a substance used in food **or** as a food-contact substance. Proposed §170.39(a) would allow exemption from food-additive regulation or, in defined circumstances, from the proposed GRAS-notification requirement, provided the TOR criteria are satisfied. Proposed §170.39(c) still requires a request containing substance identity, conditions of use, exposure information and an assessment of available toxicological information. FDA would retain discretion to decline an exemption if available evidence indicates a public-health risk. [1]

It would therefore be inaccurate to state that the proposal simply permits any chemical to be added to food without any FDA involvement or scientific screening. It would also be inaccurate to describe the proposal as a full conventional food-additive safety assessment. The TOR procedure expressly relies on a **reduced evidentiary burden** appropriate, in FDA's view, to sufficiently low exposures. The consequential issue is whether that reduced burden is scientifically sufficient for every category of **direct** use.

3 | The numerical change: from 0.5 ppb to 0.025 µg/kg body weight/day

The proposed §170.39(a)(2)(i) replaces a dietary-concentration criterion of 0.5 parts per billion with an estimated daily intake at or below **0.025 micrograms per kilogram of body weight per day**. FDA explains that this normalises exposure across population groups rather than relying on a fixed adult diet. The legacy 0.5 ppb benchmark corresponds to approximately 1.5 µg/person/day using an assumed 3 kg of food and drink per day. At 60 kg body weight, the proposed 0.025 µg/kg/day also equals 1.5 µg/day; at 70 kg it equals 1.75 µg/day. [1]

For a 20 kg child the corresponding illustrative daily exposure is 0.50 µg; for a 10 kg child it is 0.25 µg. These are mathematical conversions of the proposed general threshold, **not** conclusions that these exposures are safe for

every substance or every child. They do not address pregnancy, developmental windows, food-specific intake distributions or concurrent exposure from other products.

Crucially, the new threshold is an estimate of **total dietary intake from the proposed use**, not a universal legal maximum of 0.025 µg/kg in each individual food. Concentration in a food and dose per kilogram body weight are different quantities. For a simplified single-food illustration, a 20 kg child consuming 100 g of a food containing 5 µg/kg of a substance would receive 0.5 µg from that food: exactly 0.025 µg/kg body weight. The example is arithmetic only and assumes no exposure from any other food. It is not an approved formulation or a safe-use recommendation.

4 | A second, easily missed pathway: one percent of an existing ADI

Proposed §170.39(a)(2)(ii) contains a separate alternative. If a substance is **already regulated for direct addition to food**, a proposed use could qualify where the resulting exposure is at or below **1% of its acceptable daily intake (ADI)** as determined from appropriate safety data. [1]

This branch is not interchangeable with the general 0.025 µg/kg/day route. An ADI is substance-specific and is normally derived from toxicological evidence and uncertainty factors. One percent of a particular ADI may be lower or higher than the generic TOR exposure threshold. A valid analysis must identify the ADI source, population assumptions, existing authorised uses and cumulative dietary exposure.

The presence of this alternative also weakens the popular shorthand that the proposal is merely an expansion of a “0.5 ppb loophole”. The proposed architecture combines **two different exposure tests**, an existing-food-additive branch and a general low-exposure branch, with separate hazard exclusions and an FDA review mechanism. Precision matters because the scientific merits and weaknesses of each branch are not identical.

5 | Why intentional technological function changes the analysis

Food-contact migration is normally an unintended consequence of packaging or equipment use. A deliberately added ingredient is present because a manufacturer seeks a technological effect as flavour modification, colour, preservation, emulsification, processing performance or another function. The proposed text would remove the current §170.39(a)(3) condition requiring that a migrating substance have **no technical effect** in or on the food. [1]

That deletion is legally and scientifically consequential. A substance may be biologically active at very low concentrations and it may also be technologically active at levels far below those needed for conventional preservatives or texturisers. However, one should not assume that a substance effective in a food matrix is necessarily biologically hazardous. Nor should one assume that the extremely low exposure threshold would support the practical use of ordinary emulsifiers, binders or preservatives: most such functions require substantially greater concentrations. The point is not that the proposal will inevitably enable large-scale substitution of additives. It is that the **functional-intent boundary** would change.

For regulators, the question is whether a low-dose toxicological screen designed around incidental exposure captures the additional evidence normally examined when the substance is purposefully introduced, marketed and used across many food categories. That includes technological necessity, realistic use levels, impurities, transformation products, stability, population exposure and the likelihood of cumulative applications.

6 | The strongest argument in favour of TOR expansion

The pro-exemption argument deserves fair treatment. Food safety authorities cannot realistically demand a complete chronic-toxicity package for every substance present at vanishingly small exposure. A scientifically defensible *de minimis* approach may allocate regulatory resources to hazards and exposures with plausible public-health significance. FDA’s original TOR framework was designed around that premise, and its 2026

proposal retains exclusions for known or suspected carcinogens, limits on carcinogenic impurities, other safety concerns and environmental effects. [1, 3]

A body-weight-normalised threshold is, in principle, more responsive to population differences than an adult-only dietary-concentration surrogate. The requirement to submit identity and exposure information creates a record and permits FDA to reject requests when information indicates risk. The agency also proposes public listing of granted exemptions. None of those safeguards should be ignored.

But a sensible argument for regulatory proportionality does not resolve the central question. **Low exposure can reduce expected risk; it cannot independently establish that all relevant hazards have been recognised, or that aggregate exposure remains low when many firms use the same substance.** The adequacy of the method depends on the chemical domain, exposure model, data quality and the conditions attached to the exemption.

7 | The strongest argument against an undifferentiated threshold

The principal scientific objection is not that every trace exposure is dangerous. It is that **one numerical screen is not a universal substitute for substance-specific hazard characterisation.** Potency varies by orders of magnitude. Certain mechanisms involve critical developmental windows, receptor-mediated activity, bioaccumulation, immunological sensitisation or shared toxicological pathways. The absence of carcinogenicity does not establish the absence of developmental, neurological, endocrine or immune effects.

FDA's proposed text addresses "**other health or safety concerns**" and reserves the ability to deny an exemption. But those provisions could be important protective gates. Nevertheless, the public rulemaking would benefit from explicit explanation of how reviewers will screen endocrine activity, developmental toxicity, highly potent non-carcinogenic compounds, substances with long biological half-lives and emerging mechanistic evidence. [1]

EFSA's 2021 scientific opinion on non-monotonic dose responses confirmed that non-monotonic patterns occur in some studies and can be relevant to receptor-mediated effects, while recommending a structured evaluation rather than assuming that all claimed low-dose effects are valid. This is the appropriate scientific posture: neither categorical dismissal nor automatic acceptance. [7]

8 | TOR is not the same as the Threshold of Toxicological Concern

The U.S. **TOR** mechanism and the **Threshold of Toxicological Concern (TTC)** used in European risk assessment are related in philosophy but **not legally or scientifically identical.** TOR is a regulatory exemption procedure with specific statutory consequences. TTC is a tiered toxicological screening and prioritisation method applicable only within defined chemical and data domains. [1, 5]

EFSA's 2019 TTC guidance gives, among other values, 0.0025 µg/kg body weight/day for substances of potential DNA-reactive mutagenic or carcinogenic concern; 0.3 µg/kg/day for organophosphates and carbamates; and 1.5, 9 and 30 µg/kg/day for Cramer structural classes III, II and I, respectively. EFSA also identifies exclusions and warns that TTC must not substitute for data that EU legislation specifically requires. [5]

A superficial comparison could observe that FDA's proposed general 0.025 µg/kg/day threshold is ten times EFSA's 0.0025 µg/kg/day value for potential DNA-reactive mutagens. That arithmetic is correct; the implied conclusion that the two systems therefore accept tenfold different risks is **not** justified. FDA's proposed TOR route excludes substances shown or suspected to be carcinogenic, whereas the cited EFSA TTC tier explicitly addresses a different hazard category. The decision trees, legal consequences and applicability domains differ. A rigorous comparison must begin with **eligibility**, not just the number.

9 | Cumulative exposure is the most serious operational blind spot

A manufacturer can estimate exposure from one proposed use. A consumer encounters the diet as a whole. If multiple firms introduce the same substance into different products under individually low-exposure exemptions, the combined intake may exceed the premise of any one request. Likewise, multiple chemicals acting on a common biological pathway may produce additive or otherwise interacting effects, even when each has a low individual exposure. [6, 8]

The issue has two distinct levels. **Aggregate exposure** concerns the same chemical from multiple foods and sources. **Cumulative risk** concerns combined effects of different chemicals, particularly when they share mechanisms or adverse outcomes. These concepts should not be conflated. Their data requirements differ, as do the methods used to evaluate them.

EFSA's harmonised framework for chemical mixtures and its subsequent guidance on grouping chemicals provide an established methodological starting point. They do not mean that every conceivable mixture can be quantified, but they show that single-substance assessment is not the only scientifically available approach. [6, 8]

An expanded TOR system would be more defensible if exemptions were associated with persistent chemical identifiers, specific use categories, exposure assumptions, maximum use levels where appropriate, population groups and explicit triggers for re-evaluation as additional exemptions accumulate. A public list without machine-readable exposure context would provide transparency of existence but only limited capacity for cumulative assessment.

10 | The exposure estimate is only as good as its denominator

A body-weight-adjusted threshold appears more protective of children than a fixed adult dietary concentration. But the estimate still depends on the underlying food-consumption data and the proposed use pattern. High consumers of one product, children with unusually concentrated diets, consumers of specialised foods and those using several products containing the same substance may not be represented by an average scenario.

The first EU monitoring pilot for food additives and flavourings, reported in 2026, illustrates how difficult real-world exposure estimation can be. It used thousands of analytical results and multiple consumption scenarios, yet identified data-quality and misreporting limitations significant enough to constrain regulatory interpretation. This is not evidence that the U.S. proposal will fail; it is evidence that exposure modelling is a **measurement and data-governance problem**, not merely a mathematical division by body weight. [9]

For direct-use TOR requests, reviewers should expect sensitivity analyses for food-category allocation, market penetration, high-percentile consumption, repeat consumption, ingredient carry-over and analytical uncertainty. A threshold without robust exposure data risks appearing precise while resting on fragile assumptions.

11 | Analytical chemistry: below the threshold is not the same as below detection

The proposed TOR test concerns estimated dietary exposure, not an instruction to regard an undetectable residue as safe. Analytical non-detection can mean that a substance is absent, present below the method's limit of detection, unrecovered from the matrix or transformed into products not targeted by the assay.

Direct intentional addition makes this distinction operationally important. Manufacturers can know nominal dosing, but nominal dosing is not equivalent to measured consumer exposure. Process losses, adsorption, partitioning, degradation, concentration during drying, interaction with packaging and carry-over into other food streams may change the amount actually consumed.

A robust evidence package should distinguish identity, method specificity, limit of quantification, recovery, uncertainty, stability and transformation products. It should also specify whether the exposure calculation uses measured concentrations, conservative maximum-use assumptions or both. No analytical method is adequate

merely because its detection limit is numerically below the proposed threshold: the relevant food matrices, sampling plan and consumption model must also be appropriate.

12 | The legal paradox inside the GRAS reform

The GRAS part of FDA's August proposal would make submission of notices mandatory for many uses claimed to be GRAS, subject to stated exceptions. It is not a conventional premarket-approval requirement, and the proposal should not be described as an enacted abolition of the GRAS statutory exemption. FDA's proposal also contains transition provisions for certain uses already in commerce. The public-comment deadline is **9 December 2026**. [1, 10]

The same proposal would create an exception to that notification requirement where a use receives a TOR exemption. The interaction is not logically inconsistent: a regulator may decide that very-low-exposure uses deserve a lighter administrative route. But it creates a **substitution effect**. If firms can satisfy TOR rather than prepare a fuller GRAS notice, the quality of the TOR screening becomes more important, not less.

There is also a transparency trade-off. A public TOR list is useful, but a full GRAS notice may contain substantially richer public scientific reasoning. The policy choice is therefore not simply "more transparency versus less transparency". It is about **which information becomes visible**, at what stage, under what confidentiality rules and with what ability for independent re-evaluation.

13 | United States: a proposed rule, not a current authorisation

As of 11 October 2026, the August rule remains a **proposal**. The existing TOR provisions continue to govern qualifying food-contact applications. A manufacturer cannot rely on the proposed extension as though it were already effective law. The proposed amendments to 21 CFR Parts 170 and 570 concern FDA-regulated human and animal food, but the TOR text examined here is the human-food provision in §170.39. [1, 3, 10]

The competent federal authority is FDA, operating under the Federal Food, Drug, and Cosmetic Act. The agency may issue a final rule, modify the proposal or decline to adopt particular provisions following notice-and-comment rulemaking. Any legal assessment must therefore track the docket and final Federal Register text rather than relying on press announcements.

For a U.S. ingredient supplier, the immediate practical consequence is a **regulatory scenario review**, not a licence to reformulate. Existing authorised food-additive uses, valid GRAS determinations, food-contact notifications and other relevant statutory categories must still be analysed under current law.

14 | European Union and Spain: positive-list authorisation remains the rule

The EU model for food additives differs structurally from the proposed U.S. TOR expansion. Regulation (EC) No 1333/2008 provides that only additives authorised and listed for specified food categories and conditions may be used. Article 6 requires, among other things, that an additive does not pose a safety concern at the proposed level, fulfils a reasonable technological need and does not mislead consumers. Regulation (EC) No 1331/2008 establishes the common authorisation procedure for additives, enzymes and flavourings. [11, 12]

A generic finding of low exposure does **not**, by itself, confer EU market authorisation for an intentionally added technological food additive. EFSA's TTC guidance is explicit that TTC should not replace toxicological data required by legislation. [5]

In Spain, the EU regulations apply directly. Spanish operators must also meet the general food-safety duties of Regulation (EC) No 178/2002, including Article 14's prohibition on unsafe food and consideration of cumulative toxic effects and susceptible consumer groups. The competent regulatory framework involves the European Commission, EFSA and national enforcement authorities, including Spain's food-safety administration. [13]

There is no valid legal inference that a U.S. TOR exemption, if granted in the future, would authorise the same direct food use in Spain or elsewhere in the EU. Export dossiers must be jurisdiction-specific.

15 | Great Britain and Northern Ireland: one country, different applicable systems

Great Britain operates a domestic authorisation regime for regulated food and feed products. Since 1 April 2025, authorisations can take effect through ministerial decisions recorded in the official electronic register, rather than requiring a new statutory instrument for each authorisation. The register remains the authoritative source for the permitted food additive, its specifications, food categories and conditions of use. [14, 15]

Northern Ireland requires separate analysis because EU food law continues to apply there under the Windsor Framework, subject to the relevant arrangements for qualifying goods and trade. A general statement that “the UK permits” or “the UK prohibits” an additive can therefore be legally incomplete. [16]

The United States’ proposed TOR expansion does not create automatic authorisation in Great Britain or Northern Ireland. For companies in the segment of **international ingredient suppliers**, a market-access matrix should distinguish the EU/Spain, Great Britain, Northern Ireland and U.S. pathways rather than compressing them into a single “Western markets” category.

16 | The same substance can occupy four regulatory identities

A chemical’s regulatory treatment depends not only on molecular identity but also on **why it is present** and how it reaches food. The same molecule may be considered an intentionally added food additive in one application, a food-contact migrant in another, an impurity in a third and a processing-related residual in a fourth. Each identity can trigger different evidence requirements.

This is not an invitation to reclassify an ingredient opportunistically. Regulators assess actual technological purpose, process conditions, exposure and the relevant statutory definitions. The proposed U.S. change matters because it would reduce the legal separation between two of these identities for purposes of a low-exposure exemption.

For companies manufacturing enzymes, flavours, mineral ingredients, fermentation-derived compounds or process aids, the proper sequence is first, to identify the substance and impurities, second, to establish the intended technological function, third, to characterise the route of entry into food, fourth, to quantify residual and dietary exposure, fifth, to determine the relevant legal category and sixth, only then assess whether an exemption or authorisation pathway is available. Classification must follow the facts, not the preferred commercial outcome.

17 | A comparative legal matrix

The three systems share a concern for food safety but implement it through different legal instruments. The matrix below is a **high-level decision aid**, not a substitute for substance- and use-specific legal advice.

Question	United States	EU / Spain	Great Britain / NI
Primary route	FDA food-additive / GRAS law; TOR food-contact currently	Positive-list additive authorisation; EU law applies in Spain	GB domestic authorisations; EU rules generally apply in NI
2026 change	Direct-use TOR extension is proposed, not effective	No analogous generic TOR direct-additive authorisation	No automatic recognition of U.S. TOR exemptions
Core evidence	Use identity, exposure and hazard screening under proposed §170.39	Safety, technological need, non-misleading use and listed conditions	FSA/FSS assessment and register conditions in GB
Regulatory authority	FDA	European Commission / EFSA; national controls	GB ministers / FSA-FSS; NI under EU framework

Sources: [1], [11]–[16]. Legal position checked as of 11 October 2026.

18 | The public-health debate: two overstatements to avoid

One overstatement is that FDA has already opened a route for toxic chemicals to be freely poured into food. It has not. The text is proposed, the TOR mechanism requires an application, the carcinogenicity and other-risk screens remain relevant, and FDA retains discretion to deny exemptions. [1]

The opposite overstatement is that the proposal is necessarily safe because 0.025 µg/kg/day is a very small number. Dose matters, but it is not an adequate description of hazard, cumulative exposure, sensitive populations or data uncertainty. Moreover, the proposal contains an alternative 1%-of-ADI pathway for already regulated direct additives, so one number does not characterise every possible exemption. [1]

The sound position is more demanding: a low-exposure exemption may be appropriate for some substances and uses, but its **eligibility criteria, hazard exclusions, cumulative-exposure safeguards, transparency and re-evaluation triggers** should be specified and empirically tested before the scope is enlarged.

19 | Research & Innovation Opportunity

Proposed concept: Exposure–Function Evidence Matrix (EFEM). This is an original analytical proposal for evaluation, not an established regulatory standard or a claim of exclusive novelty. Existing TTC decision trees, exposure models, mixture frameworks and regulatory databases already provide important components. The proposed contribution is to connect them specifically to the legal transition from incidental migration to intentional technological use. [5, 6, 8]

Unresolved problem. Conventional exemption decisions are organised around chemical identity and estimated dose. Deliberately added ingredients also have technological functions, formulation patterns, repeat-use pathways and market diffusion. The relation between these dimensions is not systematically captured by a single threshold.

Why it matters. A use may be individually negligible yet become material through multi-product exposure; another may remain genuinely negligible even at large commercial scale. Without a transparent way to distinguish them, both over-regulation and under-protection are possible.

What is known. FDA has an existing TOR application and exemption database. EFSA has established TTC and chemical-mixture methodologies. Food-additive exposure can be modelled by consumption group and product category. Analytical chemistry can measure relevant residual concentrations when validated methods are available.

What remains unknown. There is no demonstrated universal conversion from a low-dose exemption to a reliable prediction of aggregate market exposure. It is also unclear how well a generic hazard screen would identify emerging low-dose mechanisms across all candidate chemical classes.

Plausible hypothesis. A structured matrix combining **chemical hazard domain × intended function × matrix concentration × population-specific exposure × existing market uses × mixture grouping × uncertainty** could outperform a dose-only triage process for identifying cases requiring substance-specific toxicology.

Validation programme. Assemble anonymised historical TOR and food-additive cases; reconstruct population-specific dietary exposures; classify substances by mechanistic hazard and use purpose; test performance against expert review; run prospective multi-product scenarios; quantify false reassurance and unnecessary escalation; and publish reproducible decision rules. Where necessary, commission targeted in vitro or mechanistic studies rather than assume the threshold resolves every uncertainty.

Regulatory constraints. The framework would support decision-making and dossier quality; it would not create an EU authorisation, a U.S. exemption or a safe-use claim. Confidential formulation data, intellectual property and commercially sensitive exposure assumptions would require governance.

Industrial relevance. The matrix could support international ingredient qualification, supplier screening, formulation decisions, risk-based testing and evidence-led regulatory submissions.

20 | A second research question: when does technological function become a warning signal?

A useful but explicitly speculative line of research is the **function–hazard correlation problem**. Some molecules exert desired technological effects through physicochemical mechanisms that have little relationship to human receptor biology. Others, particularly potent sensory-active substances, may act through biological recognition pathways. Technological potency therefore neither proves nor disproves toxicological potency.

The research question is whether information about the **mechanism of technological action** can improve prioritisation of very-low-dose direct-use substances for targeted hazard evaluation. The answer requires chemical-class-specific analysis; it cannot be inferred from the label “flavour”, “preservative” or “processing aid”.

A feasible study could compare a diverse set of known direct-use substances, recording their effective technological concentrations, molecular targets where known, relevant ADIs or points of departure, mechanistic bioactivity, food-matrix stability and actual dietary exposures. Statistical correlations should be validated prospectively and controlled for publication and selection bias.

If a meaningful relationship were demonstrated for selected chemical classes, it could help regulators identify which low-exposure requests deserve enhanced review. If no relationship emerges, that result would be equally useful: it would prevent the misleading assumption that a powerful food effect is automatically a human-health warning.

21 | What industry should do before the consultation closes

For businesses supplying ingredients to the U.S. market, the most constructive immediate step is to review the **actual proposed text**, especially **§170.39** and its interaction with proposed **§170.205**, rather than infer future obligations from headlines. The public-comment period runs to **9 December 2026** under docket FDA-2025-N-3262. [1]

A technically serious response should address the scope of eligible chemical classes, requirements for population-specific exposure estimates, screening of non-carcinogenic low-dose hazards, aggregation across multiple exemptions, the 1%-of-ADI branch, handling of impurities and degradation products, publication of exemption metadata, and criteria for re-opening an exemption when new evidence emerges.

Food companies should also audit whether existing ingredient dossiers distinguish **actual authorised use** from GRAS status, food-contact clearance, processing-aid classification and foreign-market permission. These categories are not interchangeable. The most expensive compliance errors often begin with a technically accurate statement that is legally overextended.

22 | Specific implications for Industry

The issue is relevant to Industries’ international portfolio of food ingredients and processing technologies, but it does not justify implying that any specific proprietary product qualifies for a TOR exemption. Eligibility would depend on substance identity, intended use, exposure, toxicology, manufacturing impurities and the eventual legal text.

A useful internal response would be a **jurisdictional evidence passport** for each ingredient and use: identity and specification; manufacturing-route and impurity profile; technological function; food-category inclusion rate; residual exposure; population-specific consumption; toxicological basis; authorisation status by market; and

change-control history. This would complement, but not replace, product technical data sheets and safety assessments.

The R&D opportunity lies in improving how evidence is generated and reused. A matrix-aware formulation database could identify when a proposed application changes the legal classification or exposure model, when a supplier substitution changes impurity assumptions, and when an existing authorisation cannot be extrapolated to a new market. Such a system is more immediately valuable than speculative claims that the regulatory proposal will liberalise all low-dose ingredients.

23 | Conclusions: exposure is necessary, but not sufficient

The August 2026 FDA proposal contains two distinct reforms, in one side, the greater visibility of uses claimed to be GRAS and a possible expansion of the TOR exemption to direct food uses. The second reform entered a wider public debate on 10 October. Neither is currently final law. [1, 2]

The proposed change is scientifically defensible in one respect: risk assessment should be proportional to plausible exposure, and body-weight adjustment can improve the logic of a generic screen. It is scientifically contestable in another: **the absence of appreciable exposure from one proposed use does not automatically establish the absence of relevant hazard or cumulative exposure across a food system.**

Europe and Great Britain retain authorisation structures that do not translate a generic low-dose screen into permission for intentional additive use. The resulting divergence will matter to multinational manufacturers, ingredient distributors and innovation teams.

The appropriate research response is neither to reject thresholds categorically nor to treat them as universal safe harbours. It is to build **exposure-function evidence systems** that connect hazard, dose, technological purpose, population, analytical verification and market diffusion.

A trace is a quantitative description of exposure. An ingredient is a deliberate technological intervention. Regulation should recognise the difference even when the molecule is the same.

Related Knowledge Areas

Regulatory Affairs; Food Safety; Functional Ingredients; Processing Technologies; Biotechnology; AI & Food; Emerging Research.

References and Primary-Source Links

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