

The Hidden Mathematics of Food Texture

Europe's 2026 Hydrocolloid Reform Exposes the Gap Between Mixture Compliance, Microbial Purity and Infant Physiology

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Abstract

The European Union's revised rules for seven widely used hydrocolloids and modified starches became applicable on 18 August 2026. Their significance extends beyond new limits for guar gum, locust bean gum, xanthan, acacia gum, pectins, carrageenan and starch sodium octenyl succinate. Regulation (EU) 2026/196 combines formulation-specific restrictions, proportionate limits for mixtures in young-child milk-based drinks, and tighter chemical and microbiological specifications. This article argues that ingredient-level compliance is no longer an adequate proxy for formula-level safety or technological performance. Scientific evidence shows that hydrocolloid mixtures can exhibit nonlinear rheology, while infant exposure, gastric behaviour and contaminant risks depend on the complete matrix and manufacturing route. The analysis integrates EFSA's additive reassessments, the EU transition timetable, Britain's distinct authorisation system, and the FDA's July 2026 warning on infant-formula ingredient supply chains. A proposed **Mixture-Aware Formulation Evidence Model** offers a testable research agenda linking legal constraints, rheology, exposure, supplier purity and physiological endpoints without claiming that computational screening replaces regulatory assessment.

KEYWORDS *Hydrocolloids; infant formula; food additives; mixture effects; rheology; supplier assurance; Regulation (EU) 2026/196; food safety*

CATEGORY Food Ingredients & Additives | Food Safety | Regulatory Affairs

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META DESCRIPTION Europe's 2026 hydrocolloid rules expose why safe infant formulations require mixture-aware limits, verified ingredient purity and real-world rheology testing.

INTERNAL TAGS Hydrocolloids; Infant Nutrition; EU Food Law; Food Additives; Rheology; Microbiological Safety; Ingredient Traceability; Emerging Research

1. A regulatory change that reformulates the problem

On 18 August 2026, Commission Regulation (EU) 2026/196 became applicable across the European Union. Adopted on 28 January and published on 29 January, it amended the conditions of use of seven established food additives and revised specifications for six of them. The substances are familiar to formulators: **carrageenan (E 407)**, **locust bean gum (E 410)**, **guar gum (E 412)**, **acacia gum (E 414)**, **xanthan gum (E 415)**, **pectins (E 440)** and **starch sodium octenyl succinate (E 1450)**. Their familiarity is precisely why the change matters. [1]

The regulation is not a general prohibition of hydrocolloids, but it is a targeted response to re-evaluation findings, especially in foods for infants and young children, and it changes both permissions and ingredient specifications. The distinction is commercially consequential since an additive can remain lawful in many adult-food categories while no longer is being permitted in a specified infant-food category. And in other hand, a formulation may comply with its quantitative use limit while failing the revised purity specification of the ingredient supplied.

This article takes the new regime as a starting point for a broader question that it 's no other than: can the food industry continue to assess texturising systems additive by additive when the final food is a multicomponent material, consumed by a biologically specific population and produced through a multi-supplier chain? The answer to that question is not to invent a new toxicological hazard for every blend but to make the evidence architecture match the product that is actually marketed.

2. Why the October 2026 moment matters

The measure has been applicable for almost two months, but its transition has only begun. Certain stock provisions remain relevant, knowing that a specific temporary permission for guar gum in a defined category of foods for special medical purposes expires on 27 April 2027, and an E 1450 limit steps down in specified infant medical-food categories on 18 February 2028. These are operational deadlines, not historical footnotes. [1]

At the same time, EFSA's Food Additives and Flavourings Panel is meeting from 13 to 15 October 2026. The meeting itself is not evidence of any new decision on hydrocolloids, and none is presumed here, but significance is going further as it illustrates that food-additive reassessment remains an active regulatory process while manufacturers are already implementing the January act. [2]

Across the Atlantic, FDA issued a letter on 13 July 2026 urging infant-formula manufacturers and their suppliers to strengthen ingredient-source oversight following major contamination events. That letter is not about hydrocolloid mixtures specifically. It nevertheless adds a second, independent regulatory signal, centered on the issue that the safety of a sensitive finished food depends on the upstream ingredient chain, not merely the controls applied at final blending. [3]

The combined significance is practical. Food formulators must now think simultaneously about the lawfulness of the recipe, the quality of the ingredient, the behaviour of the mixture and the vulnerability of the consumer.

3. The legal unit is the authorised use, not the familiar ingredient name

Under Regulation (EC) No 1333/2008, food additives are authorised by reference to defined food categories and conditions. Regulation (EU) No 231/2012 establishes identity and purity specifications. Regulation (EU) 2026/196 amends both instruments. It follows that the question "Is xanthan gum approved in Europe?" is too imprecise to guide a development decision. The legally relevant question is whether a particular E number, in a specified food category, at the proposed use level, under the applicable notes and specifications, is permitted at the date the product is placed on the market. [1,4,5]

A second classification issue arises in infant nutrition. Category 01.10, milk-based drinks and similar products intended for young children, is not interchangeable with category 13.1.1, infant formula, or categories 13.1.5.1 and 13.1.5.2, foods for special medical purposes for infants and young children. They differ in target population, regulatory context and permitted additive uses. Copying a permitted level from one category into another can create an unlawful formulation even when the product names sound similar.

This matters in product development because commercial terms such as "toddler milk", "medical nutrition" and "hypoallergenic formula" do not by themselves settle the legal category. Classification must be resolved from the

product's composition, intended consumer, oriented presentation and applicable food law before the first laboratory optimisation exercise is treated as a marketable recipe.

4. The six-additive interaction rule in category 01.10

For milk-based drinks and similar products for young children in category 01.10, the amended entries set maxima of 300 mg/kg for E 407; 10,000 mg/kg each for E 410, E 412, E 414 and E 415; and 5,000 mg/kg for E 440. These are category-specific figures, not universal limits across infant nutrition. [1]

The more interesting provision is new footnote (X). When more than one of these six substances is added to a food, the maximum established for each must be reduced proportionately in light of the cumulative presence of the others. This rejects the *naïve* practice of stacking several individually permitted maxima as if each were an independent allowance. The text creates an interaction between recipe composition and regulatory compliance. It does not assert that the additives have equivalent toxicological potencies, nor does it provide an official toxicological mixture model. Far more, it is a legal condition for a particular category. Formulators should therefore distinguish its compliance function from any scientific claim that a given blend has a defined combined biological effect.

A useful internal screening convention is to express each additive's concentration as a fraction of its category-specific maximum and **examine the sum of those fractions**. Such a calculation can identify recipes needing closer review, but it must not be presented as an authoritative legal formula for footnote (X) without confirmation from the applicable text and competent authority.

5. An illustrative mixture calculation and its limits

Consider a hypothetical category 01.10 beverage containing 150 mg/kg carrageenan (E 407) and 5,000 mg/kg xanthan gum (E 415). Each concentration is half its stated single-substance maximum. A simple normalised-screening calculation would be $(150/300) + (5,000/10,000) = 1.00$. By contrast, using 300 mg/kg E 407 and 10,000 mg/kg E 415 would yield 2.00 and clearly contradict the principle that full individual maxima should not simply be stacked.

This example is a proposed internal compliance screen, not a Commission-endorsed equation or an opinion on the legality of any specific product. Real assessment requires checking the precise interpretation of footnote (X), all applicable restrictions, ingredient carry-over where relevant, measurement uncertainty and the marketed product's category.

The deeper scientific point is different when a recipe with a lower normalised legal fraction can still have a greater viscosity or altered gastric behaviour than another recipe with a higher fraction. Regulatory concentration shares are not rheological response coefficients. Nor are they directly equivalent to dose-response potency factors. The law regulates specified additions. The food matrix determines the actual technological behaviour. Safety science must interrogate both without conflating them.

6. The scientific nonlinearity of hydrocolloid mixtures

Hydrocolloids are not inert powders that contribute independently to a final viscosity. Their behaviour depends on molecular weight distribution, substitution pattern, ionic environment, hydration kinetics, temperature, shear history, pH, protein interactions and other polysaccharides. Xanthan and locust bean gum are a well-known example of interactions that can modify gel formation and viscoelastic response. Peer-reviewed work has documented substantial changes in hydrogel mechanics when xanthan and locust bean gum are combined with agar, and additional studies examine how cosolvents and composition affect xanthan–locust-bean systems. [6,7]

These findings establish the general scientific proposition that mixed hydrocolloid systems can behave non-additively. They do not establish a universal numerical synergy factor applicable to every infant formula. Results from agar gels or model aqueous systems cannot simply be transplanted into protein-hydrolysate formulae, fat-containing emulsions or gastrointestinal conditions.

The industrial consequence is that an ingredient substitution may produce a disproportionate functional response. Reducing one gum and increasing another to remain within a legal allowance may preserve bottle viscosity but change shear thinning, stability after reconstitution, sedimentation, gastric thickening or the response to heating. The functional

unit is the complete formulation under the relevant process and use conditions and not the ingredient's certificate of analysis.

7. The physiological endpoint is not the factory viscosity

Infant nutritional products illustrate why this distinction matters. A thickener may be used to reduce visible regurgitation or to obtain a specified handling property, but the same material can influence gastric emptying, stool characteristics, feeding effort and potentially the availability of nutrients. These outcomes are not interchangeable. A clinical study of locust-bean-gum-thickened formulae reported reduced regurgitation episodes, while the higher concentration tested was associated with slower gastric emptying. The study was limited in size and setting as it is evidence that physiological response deserves direct evaluation, not proof that all gum-thickened formulae have the same effect. [8]

EFSA's 2023 locust bean gum re-evaluation considered neonatal-piglet findings, including changes in blood zinc levels, and examined margins of exposure in specific infant categories. Its analysis demonstrates that the infant safety question may depend on physiological endpoints not visible in ordinary rheology testing. [9]

A responsible validation programme should therefore distinguish viscosity measured at manufacture, viscosity after consumer reconstitution, viscosity under simulated gastric conditions and clinically relevant endpoints. None of these can be substituted for another without evidence.

8. Why guar gum became a decisive test case

EFSA's 2024 re-evaluation of guar gum (E 412) concluded that the data submitted were **insufficient to support safe use** in the specified infant and young-child categories 13.1.1, 13.1.5.1 and 13.1.5.2. The opinion also supported further amendments to specifications. [10]

The resulting 2026 regulation **removes E 412 from infant formula** (13.1.1) and from the **defined infant foods for special medical purposes** in category 13.1.5.1. It retains a narrow, time-limited permission in category 13.1.5.2 for liquid formulae containing hydrolysed proteins, peptides or amino acids, up to 10,000 mg/kg, until 27 April 2027. [1]

It would be inaccurate to report this as a finding that guar gum is universally unsafe, or that the substance is banned from European food. The more exact statement is that EFSA could not establish safety for the relevant vulnerable-population uses on the submitted evidence, and the Commission adjusted authorisations accordingly.

The distinction matters scientifically and legally. "Insufficient evidence to establish safety" is not synonymous with "demonstrated harm"; equally, an absence of proven harm is not a sufficient basis for marketing a use whose authorisation has been withdrawn.

9. Locust bean gum: narrower use, stronger context

The 2026 amendment sets a maximum of 5,300 mg/kg for E 410 in the specified infant medical-food categories, restricted to products for reduction of gastro-oesophageal reflux. The provision is conditional: it is not a blanket permission for all infant foods. [1]

EFSA's 2023 re-evaluation had identified a reference point of 1,400 mg/kg body weight per day from a neonatal-piglet study, based on reduced blood zinc, and used margin-of-exposure reasoning. Some evaluated infant scenarios did not achieve the margin considered reassuring. [9]

The broader lesson is not that thickening is undesirable. In selected clinical contexts it can serve a legitimate nutritional-management purpose. Rather, the evidence required depends on who consumes the product, why the ingredient is present and how the complete formula behaves. A product developed for a healthy adult beverage cannot be presumed equivalent to a medically indicated infant formulation simply because both use E 410 and meet a numerical viscosity specification.

10. Pectins and modified starch: permission is conditional and temporal

The amended regime allows pectins (E 440) at 4,000 mg/kg in specified infant medical foods used for gastrointestinal disorders, and includes staged conditions for starch sodium octenyl succinate (E 1450). In relevant categories, the E

1450 maximum of 20,000 mg/kg applies until 18 February 2028 and 10,000 mg/kg thereafter. The exact category wording and conditions must be checked before use. [1]

This is a reformulation challenge, not a trivial arithmetic exercise. Modified starch can influence emulsion stability, drying, reconstitution and viscosity through mechanisms different from those of high-molecular-weight gums. Replacing half a permitted E 1450 dose with another hydrocolloid may change powder processing, water binding, digestive behaviour and the microstructure of the reconstituted food. A 2026 in-vitro study on starch-based thickening of infant formula specifically investigated behaviour in the bottle and under gastric conditions. That research direction is directly relevant to the problem, but in-vitro results are not themselves clinical validation of a reformulated product. [11]

The regulatory deadline should therefore drive a staged programme of technical trials and nutritional assessment, not a last-minute exchange of E numbers.

11. The overlooked half of the reform: chemical and microbiological specifications

Regulation (EU) 2026/196 also revises identity and purity requirements in Regulation (EU) No 231/2012. The amended specifications address toxic elements, residual solvents, microbial criteria and, for certain substances, residual enzyme activity. For acacia gum and xanthan, additional microbiological conditions are especially relevant when ingredients enter dried infant formulae or specified infant medical foods. [1]

These provisions create a two-level compliance system. First, the additive must be permitted for the intended use. Second, the actual lot must meet the correct specification. A supplier's generic food-grade certificate may not be sufficient to establish compliance with an infant-specific criterion.

For example, the revised acacia-gum specification includes additional criteria addressing Enterobacteriaceae and Cronobacter in defined applications. The xanthan specification includes source-organism identification requirements and states that the final product must not show residual enzyme activity. These details are not optional marketing enhancements; they are components of the applicable legal specification. [1] A company should not assume that an old certificate or a broad "food grade" declaration covers every new requirement. Supplier documentation, laboratory methods, sampling plans and batch-release procedures must be mapped to the current legal text.

12. Why Cronobacter-related specifications matter beyond the organism named

Powdered infant formula is not sterile. Its risk-management architecture therefore depends on preventing introduction and survival of hazardous organisms through raw materials, equipment, environment and packaging. A negative test on a small sample does not mathematically establish the absence of a heterogeneously distributed pathogen from an entire lot. Thus far, the new ingredient specifications make a useful point in the level that microbial risk is partly an upstream ingredient property. However, meeting an additive's specified Cronobacter or Enterobacteriaceae criterion does not by itself validate the entire finished-product microbiological control system.

The same caution applies to other hazards. In July 2026, FDA highlighted two infant-botulism investigations and a multinational cereulide contamination event linked to an arachidonic-acid oil ingredient. Those incidents do not implicate hydrocolloids. They demonstrate that ingredients from different functional classes can introduce hazards which the final formulation process may not remove. [3,12]

The transferable lesson is supply-chain control centered: where there is no validated lethal treatment after ingredient addition, the upstream supplier's preventive controls become part of the finished-product safety system.

13. The certificate-of-analysis paradox

A certificate of analysis is often treated as proof of safety. Properly interpreted, it is evidence about specified characteristics of a sampled lot, obtained using stated methods and sampling assumptions. It is not a complete risk assessment. A lot may meet heavy-metal limits while carrying a poorly characterised microbiological hazard. It may meet microbial specifications while having an unsuitable molecular-weight distribution for the intended function. It may be analytically compliant but lack evidence that the production organism meets the definition required by the revised specification. It may be acceptable for general food use but not for a restricted infant application.

For hydrocolloids, the certificate should be embedded within a broader dossier: identity, origin, manufacturing process, impurity profile, microbiological controls, functional specification, validated methods, traceability, change control and intended-use classification.

The distinction is not bureaucratic. It prevents the dangerous assumption that “within specification” means “safe and effective in any formula”.

14. The 2026 FDA signal: ingredient sources are an extension of the factory

FDA’s 13 July 2026 industry communication called for stronger supplier oversight following contamination events affecting infant formula. The agency reported investigations of botulism outbreaks associated with two powdered-formula brands and a global cereulide incident involving an ARA oil ingredient. FDA’s public material distinguishes observed genetic relationships and supplier commonalities from unresolved root-cause questions; that distinction must be preserved. [3,12]

The letter is particularly relevant to ingredient distributors. A customer may expect a supplier to provide not only a specification but also evidence of where the ingredient originated, how it was processed, what hazards were considered and how changes are controlled.

This does not make every distributor legally equivalent to the infant-formula manufacturer. It does mean that upstream information can become indispensable to the manufacturer’s own compliance obligations. In the United States, infant-formula manufacturers must also meet the specific requirements of the Federal Food, Drug, and Cosmetic Act and 21 CFR Parts 106 and 107. [13]

The new European purity requirements and FDA’s supply-chain warning converge on a practical principle since ingredient qualification must be tied to the specific finished-food risk, not to a generic commodity label.

15. EU and Spain: the present legal position

In the European Union, Regulation (EU) 2026/196 is binding and directly applicable. Its relevant amendments apply from 18 August 2026, subject to the act’s specific transitional and staged provisions. Spain does not need to enact a separate law to make the regulation applicable; Spanish food operators must comply with the directly applicable EU regime and are subject to national official-control and enforcement arrangements. [1]

The principal legal instruments are Regulation (EC) No 1333/2008 for additive authorisations and conditions, Regulation (EU) No 231/2012 for specifications, Regulation (EU) No 609/2013 for the framework covering certain foods for infants and special medical purposes, and Regulation (EC) No 178/2002 for general food-law duties. Product-category interpretation must be checked against the relevant consolidated texts. [1,4,5,14]

Regulatory responsibility does not end with compliance on the date of recipe approval. Change in supplier, specification, manufacturing route, marketed claim or food category can require a renewed assessment. A formulation approved internally in 2025 may no longer be compliant in 2026 even if the recipe has not changed.

16. Great Britain and Northern Ireland: do not assume automatic alignment

Great Britain operates under its own food-additive authorisation system. Since 1 April 2025, the Food Standards Agency and Food Standards Scotland register has become the primary public record of authorised food additives and their terms in Great Britain, with preserved conditions from the applicable assimilated legislation where relevant. An EU amendment adopted in 2026 must not simply be presumed to amend the Great Britain register. [15]

Northern Ireland has a different legal position under the Windsor Framework, with EU food law continuing to play a central role for goods. Certain retail-movement arrangements may affect specific GB-to-Northern-Ireland supply routes, but they are not a blanket exemption from assessing the applicable food-additive rules. [16]

Accordingly, a UK-facing technical dossier should contain an explicit jurisdiction field: EU/Spain, Northern Ireland or Great Britain. It should identify the authoritative source used for the applicable additive permission and purity specification on the relevant date.

This is not a theoretical compliance nicety. Two products with the same formulation and packaging may require separate legal assessments for different UK destinations.

17. United States: ingredient law plus infant-formula obligations

The United States does not use the EU's E-number category tables as its controlling legal instrument. A substance intended for infant formula must have a lawful basis for its particular intended use, such as an applicable food-additive authorisation or a sufficiently supported GRAS status. The finished infant formula must independently satisfy statutory and regulatory requirements for nutrient composition, quality factors, manufacturing controls, records, notification and other obligations. [13,17]

FDA states that manufacturers of new infant formula generally must submit information at least 90 days before marketing. A supplier's general GRAS position does not eliminate the finished-product manufacturer's separate responsibilities. [13]

The U.S. approach therefore illustrates a different legal architecture with a comparable scientific challenge: the safety of an ingredient under one use condition does not automatically validate its use in a nutritionally complete product for a vulnerable population. So it's clear that for transatlantic manufacturers, the appropriate strategy is a common technical evidence core plus jurisdiction-specific legal modules, not one universal "approved globally" declaration.

18. Exposure is a property of the complete diet

Ingredient specifications and use maxima are indispensable, but they do not by themselves measure actual exposure. Exposure depends on concentration in the consumed food, portion size, feeding frequency, body weight, the fraction of the diet represented by the product and any contribution from other sources.

For infants consuming a formula as their principal or sole nutrition, small differences in concentration can have greater exposure implications than they would in a diverse adult diet. EFSA's guidance for substances in food intended for infants below 16 weeks reflects that population-specific challenge. [18]

A useful calculation is daily additive exposure (mg/kg body weight/day) = concentration in prepared food (mg/kg food) × food consumed (kg/day) ÷ body weight (kg). This is a general exposure identity, not an additive-specific safety threshold.

It should be supplemented by uncertainty analysis, age-specific consumption distributions, worst-case reconstitution, ingredient carry-over where relevant and the toxicological endpoint appropriate to the substance. It cannot substitute for the legal food-category maximum or for a required clinical/nutritional assessment.

19. Reformulation may move risks rather than eliminate them

Replacing an additive whose use has been restricted may reduce one regulatory concern while creating others. A substitute can alter the processing window, change mineral interactions, increase water demand, affect microbiological susceptibility during manufacture, or require a new supplier with a different impurity profile. There is also a particular danger in substituting by matching a single viscosity number. Two formulations can produce the same *Brookfield* viscosity at one temperature and shear rate while differing in extensional viscosity, time-dependent recovery, particle suspension, phase separation and gastric response. They can also differ in tolerance to consumer preparation errors.

An appropriate reformulation dossier should therefore include comparative process trials, shelf-life data, reconstitution behaviour, relevant gastrointestinal simulation, nutritional assessment and supplier qualification. When a product is intended to manage a medical condition, clinically relevant performance claims require their own evidence.

Regulatory compliance is a necessary boundary condition and it is not a substitute for a scientifically complete product design.

20. Research & Innovation Opportunity

Mixture-Aware Formulation Evidence Model (MAFEM)

Unresolved problem. Current industrial workflows often separate additive-law checks, ingredient certificates, rheological optimisation, toxicological exposure and infant-product validation. This fragmentation makes it difficult to see how a small formulation change propagates through legal, technical and safety constraints.

What is already known. Hydrocolloid mixtures can show nonlinear rheology; EU law now includes an explicit proportionate-use condition for specified mixtures in category 01.10; EFSA has identified infant-specific evidence limitations for certain gums; and public patent disclosures already describe combinations of xanthan and locust bean gum for infant formulations. The use of such blends is therefore not a new invention in itself. [1,6,7,8,10,19]

What remains unknown. There is no demonstrated, generally applicable industrial model that simultaneously predicts regulatory compliance, batch-level impurity exposure, process rheology and infant-relevant functional outcomes across hydrocolloid systems. The relative value of such integration over current expert-led practice has not been established.

Proposed hypothesis. A structured, auditable model that links additive identity and jurisdiction-specific conditions to measured composition, rheology, ingredient purity and exposure scenarios could reduce avoidable reformulation iterations and identify risks missed by single-variable optimisation.

Development pathway. Build a rule-controlled ingredient and product ontology; connect current legal conditions to a dated version of the formulation; incorporate raw-material assay and contaminant data; run design-of-experiments studies over concentrations and process conditions; train constrained predictive models; and validate them against blinded prospective trials. The system should return traceable evidence and explicit uncertainty, not a black-box verdict of safety.

Key validation steps. Compare predicted and observed viscosity curves, phase stability, reconstitution behaviour and gastric-simulation outputs; evaluate legal-screening sensitivity against expert review; test supplier-lot variability; and measure false-negative rates for purity and microbiological flags. Clinical endpoints should be investigated only where justified and under appropriate ethical oversight.

Regulatory constraints. The model cannot authorise an additive, change a category maximum, replace EFSA's safety assessment, or establish the legality of a proprietary formula by itself. Its outputs must be reviewed against the current binding legal text and, where needed, competent-authority guidance.

Potential industrial relevance. The strongest initial application is high-value reformulation and supplier qualification in products with narrow regulatory windows, especially special medical nutrition and young-child drinks. This is a research proposal, not an established method.

21. A second research question: does mixture-aware design improve nutrient availability?

A more biologically ambitious line of investigation concerns whether combinations of hydrocolloids alter the availability of minerals or other nutrients under physiologically realistic conditions. The question is plausible because polysaccharides can modify viscosity, transport and food microstructure, and EFSA has considered nutrient-related endpoints in assessing certain gums. It is not established that the mixtures covered by footnote (X) produce clinically meaningful nutrient deficiencies. [9]

A staged research programme should begin with standardised in-vitro digestion and mineral bioaccessibility, continue to appropriate intestinal uptake models and progress to human or clinically relevant studies only when earlier evidence warrants it. The protocol must separate chemical binding, reduced bioaccessibility and actual impaired nutritional status; these are different endpoints.

Crucially, the literature and patent record already contain work on hydrocolloids and nutrient interactions. The potentially useful contribution would be a transparent, reproducible comparison across legally permissible mixture designs and not the claim that the basic idea of hydrocolloid interaction has just been discovered. [19,20] The research

should be prioritised by vulnerable population, realistic exposure, technological necessity and the magnitude of plausible effects.

22. Patent and freedom-to-operate considerations

The innovation space is not empty. Published patent family WO2024089061A1, and related European and U.S. publications, describe combinations of xanthan and locust bean gum in hypoallergenic infant nutritional compositions, including claims concerning concentration ranges and manufacturing approaches. This is relevant prior public disclosure, not proof of enforceable rights in every jurisdiction. [19]

Consequently, a company pursuing a new blend should distinguish scientific novelty, patentability, regulatory permissibility and freedom to operate. A blend may be scientifically useful but anticipated by a patent publication; it may be patentable in a particular improvement yet unlawful for a proposed food category; and a permitted use under food law does not immunise the manufacturer against private intellectual-property rights.

A serious R&D programme should include a targeted patent landscape, claim mapping, territorial status review and documentation of independently generated results. Public patent text is valuable for identifying existing concepts, but the current legal status of individual claims requires separate professional verification.

23. Implications for ingredient suppliers

For an ingredient and technology business, the immediate opportunity is to make technical documentation more application-specific. Acacia gum, xanthan, pectins and related ingredients should not be marketed to a sensitive-use customer on the strength of a generic TDS alone.

A defensible dossier architecture would distinguish: identity and manufacturing source; the legally applicable specification; lot-level analytical evidence; intended food category; permissible use conditions; mixture restrictions; functional characterisation; customer processing conditions; and change-control procedures. If the customer develops infant or medical nutrition, the supplier should be prepared to provide enhanced impurity and microbiological documentation where legally required.

Industry and certain operators' broader ingredient portfolio make the question relevant to technical advisory work, particularly when multiple texturisers or stabilisers are combined. The appropriate contribution is an evidence-based formulation and regulatory-screening service—not an unsupported assertion that a proprietary ingredient or technology solves the safety problem.

A company that can supply structured, auditable application evidence may create more durable value than one competing exclusively on price per kilogram. That is a strategic interpretation, not a measured commercial outcome.

24. A practical implementation protocol for manufacturers

Manufacturers should first classify every affected finished product under the correct EU food category and confirm whether it is sold in the EU, Great Britain, Northern Ireland, the United States or several jurisdictions. They should then inventory all relevant E numbers, use levels and mixture combinations, check each against the amended category entries and footnotes and separately confirm compliance with the latest ingredient specifications.

Next, purchasing and quality teams should obtain revised declarations from suppliers and identify which laboratory results are lot-specific, which are periodic, and which rely on historical specifications. Supplier-change controls should explicitly trigger reassessment of microbiological hazards, toxic elements, process performance and documentation.

R&D teams should avoid single-point viscosity matching. At minimum, relevant systems need a reproducible rheological profile, reconstitution testing, stability under process conditions and justified gastrointestinal or nutritional evaluation when the target consumer makes it necessary. Regulatory affairs should control the calendar for 27 April 2027 and 18 February 2028 transitions, and preserve evidence supporting any applicable stock or sell-through provision.

Finally, management should review reformulation as a cross-functional risk decision, not simply as a purchasing substitution. A cheaper gum that requires a more fragile process, weaker supplier evidence or an uncertain legal interpretation may increase total business risk.

25. Evidence status and limitations

Established evidence: Regulation (EU) 2026/196 is in force and applicable from 18 August 2026, subject to its express transitional provisions. It changes specified permissions and specifications. EFSA's 2023–2024 assessments identify particular infant-use evidence and exposure issues. Published studies establish that hydrocolloid systems can show non-additive rheological behaviour. [1,6,7,9,10]

Emerging evidence: New work on the behaviour of starch-based infant-formula thickeners under bottle and simulated gastric conditions helps connect formulation physics to use context, but does not eliminate the need for validation in the intended product. [11]

Expert interpretation: Ingredient-level compliance is an insufficient proxy for complete formula-level risk control, especially in vulnerable populations and complex supply chains. This follows from the combined legal, toxicological and technological evidence but is not a separate EFSA conclusion.

Hypotheses: Mixture-aware data integration may improve development efficiency and safety screening; some mixtures may change nutrient bioaccessibility in ways not captured by ordinary rheology. Neither proposition is established across the affected additive classes.

Proposed research: MAFEM and the associated validation agenda are editorial R&D proposals. No claims are made that they are regulatory standards, validated AI products or patentably novel methods.

26. Conclusions: formulation science must catch up with formulation law

The EU's 2026 hydrocolloid reform is often presented as a technical revision to additive lists. Its deeper significance is that it exposes the inadequacy of treating the additive, the recipe, the supplier and the consumer as separate objects.

The same E number can have different legal consequences in different food categories. Two lawful ingredients may be subject to a proportional combination rule. Two blends with similar concentrations may have different rheological behaviour. A supplier certificate may meet an old specification but not the revised one. A formulation that functions well in a bottle may behave differently under gastric conditions.

For the food industry, the correct response is neither regulatory alarm nor formula-by-formula improvisation. It is an integrated, traceable design discipline that brings legal permissions, material science, infant physiology, ingredient purity and supplier evidence into one controlled decision process.

The central conclusion is simple: **the ingredient is not the formulation, and the formulation is not the evidence of its own safety.**

Related Knowledge Areas

- Food Safety — ingredient microbiology, contamination prevention and supplier verification.
- Food Ingredients & Additives — hydrocolloid functionality, specifications and regulatory status.
- Nutrition — infant physiology, exposure and nutrient bioaccessibility.
- Regulatory Affairs — EU, Spain, Great Britain, Northern Ireland and United States.
- Processing Technologies — rheology, powder reconstitution and process robustness.
- AI & Food — constrained optimisation, evidence graphs and validated decision support.
- Emerging Research — mixture-aware formulation and translational testing.

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