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The Preservative Has Three Doses

Glycolipids E 246 in October 2026: Why a favourable safety opinion cannot substitute for surface geometry, antimicrobial validation or market authorisation

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ABSTRACT

On 23 October 2026, EFSA published a favourable opinion on extending glycolipids (E 246), a fermentation-derived preservative, to eleven additional food categories. The assessment creates a revealing industrial problem: proposed surface applications to cheese and meat are expressed in milligrams per square decimetre, while dietary exposure is modelled in milligrams per kilogram of food. EFSA used a conventional 6 dm^2/kg conversion, acknowledged modelling limitations and did not assess submitted shelf-life data as part of its safety conclusion. Meanwhile, a 2026 British assessment derived a lower acceptable daily intake from the same general product family, and the EU's strengthened Listeria criterion is already applicable. This article separates four propositions—chemical identity, dietary safety, technological efficacy and legal permission—and examines their interaction across the EU, Spain, Great Britain and the United States. It proposes a testable, geometry-aware validation framework for surface preservatives, without claiming that glycolipids, antimicrobial coatings or digital exposure models are new inventions.

KEYWORDS: *glycolipids E 246; Dacryopinax spathularia; food preservation; surface dosing; dietary exposure; Listeria monocytogenes; food additive authorisation; regulatory divergence*

KNOWLEDGE CENTER CATEGORY: Food Safety & Regulatory Affairs / Biotechnology / Processing Technologies

SEO SLUG: glycolipids-e246-surface-dose-safety-efficacy-regulation-2026

META DESCRIPTION: EFSA's 2026 glycolipid opinion exposes gaps between surface dose, dietary safety, microbial control and authorisation across EU, UK and US food markets.

INTERNAL TAGS: Glycolipids; E 246; Surface Preservation; Listeria; Food Additives; Exposure Modelling; Regulatory Affairs; Fermentation

01 | October 2026: one additive, four different questions

A scientific opinion published on 23 October 2026 by the European Food Safety Authority (EFSA) concluded that a proposed extension of glycolipids (E 246) to eleven additional food categories did not raise a safety concern at the applicant's proposed uses and levels. It did not amend the Union list. On the same evidence landscape, the British Food Standards Agency (FSA) and Food Standards Scotland (FSS) published a separate assessment of AM-1 glycolipids, and their derived acceptable daily intake (ADI) was materially different. The coincidence is more consequential than an ordinary additive update. [1,2]

Four propositions need to remain distinct. Identity asks whether a commercial preparation is the specified mixture made from the specified production strain. Safety asks whether estimated ingestion under defined uses is compatible with the toxicological reference point. Efficacy asks whether a treatment prevents growth or achieves a stated reduction in the actual food under worst-case conditions. Authorisation asks whether the relevant jurisdiction has legally permitted that specific use. None follows automatically from another.

The immediate industrial temptation is to treat EFSA's conclusion as an approval of surface preservation for meat or cheese, or as evidence that an ingredient can replace an established Listeria control. Neither interpretation is justified. The opinion is an assessment supporting risk-management deliberation; a validated microbial control requires its own experimental record, and lawful marketing depends on the applicable positive list. [1,3,4]

The more interesting research question concerns the units. A surface-applied ingredient is purchased and dispensed by mass, distributed over an area, retained or lost during processing, and eventually ingested in a food portion. Regulatory exposure models typically need a concentration per mass of food. Those quantities are connected, but they are not identical.

02 | What E 246 actually is: a defined fermentation product, not a generic biosurfactant

E 246 refers to a purified mixture of long-chain glycolipid congeners produced by fermentation with the wild-type fungus Dacryopinax spathularia, strain MUCL 53181. The 2022 Union specifications identify the production organism, downstream processing and composition: at least 93% total glycolipids on a dry basis, with defined limits for water, protein, metals and microbiological quality. The process removes fungal cells by filtration and microfiltration, followed by purification, pasteurisation and drying. The authorised additive is therefore neither a living probiotic nor an interchangeable family name for every glycolipid produced by any microorganism. [3,5]

The molecules comprise a long-chain fatty-acid region attached to a carbohydrate moiety and occur as a mixture of congeners with different acylation patterns. This structural heterogeneity matters for assay identity, stability and antimicrobial activity. The British assessment explicitly discussed hydrolysis and the possibility of retaining biological activity after deacylation; it also examined microbiome data in the context of repeated exposure. A certificate that merely states 'natural glycolipid' would not reproduce the identity or safety dossier. [2,4]

Fermentation origin does not create a 'clean-label' exemption. Under EU food law, a substance used for a preservative function in a finished food is assessed under the additive rules where their definitions and conditions apply. Nor should E 246 be equated with rhamnolipids, sophorolipids or glycolipid-coated packaging: similar amphiphilic chemistry does not imply identical toxicity, permitted use, antimicrobial spectrum or regulatory status.

The industrial identity file should include the strain and manufacturer, congener fingerprint, batch consistency, assay basis, impurity specifications, formulation carrier, relevant stability and analytical methods. Changes in production strain, composition or formulation must be evaluated against the authorised specification and evidence supporting it.

03 | The current EU permissions: beverages, not the proposed cheese and meat uses

Commission Regulation (EU) 2022/1037 placed E 246 on the Union list for three restricted beverage uses. In category 14.1.4, flavoured drinks excluding dairy-based drinks, the maximum permitted level is 50 mg/L. In category 14.1.5.2, only liquid tea concentrates and liquid fruit and herbal infusion concentrates, it is 20 mg/L. In category 14.2.1, only alcohol-free beer and malt beverages, it is 50 mg/L. These are the operative authorisations described in EFSA's October 2026 opinion. [1,3]

The newly assessed application seeks use in eleven additional categories: ripened-cheese rind, pomegranate arils, surfaces of non-heat-treated meat products, meat casings and coatings, several categories of alcoholic drinks and liquid food supplements. Its proposed maximum levels include 25 mg/dm^2 on edible cheese rind, 2.5 mg/dm^2 on specified meat surfaces, 100 mg/kg for pomegranate arils, 30–50 mg/L for various alcoholic beverages and 800 mg/L for liquid supplements. These are proposed levels submitted by an applicant, not limits that an operator can already apply across the Union. [1]

Article 6 of Regulation (EC) No 1333/2008 requires not just an acceptable safety assessment but a reasonable technological need, consumer benefit and absence of misleading practice. The Commission and Member States are responsible for the risk-management decision under the common procedure in Regulation (EC) No 1331/2008. A favourable EFSA opinion neither guarantees adoption nor determines the final authorised wording, levels or restrictions. [6,7]

For a manufacturer, the correct October 2026 status is therefore 'safety-assessed extension requested; further legal action required'. It is not 'approved for cheese and meat'. That distinction belongs on the first page of any regulatory assessment or commercial feasibility report.

04 | Why the surface-dose conversion is the real technical signal

EFSA reported that the applicant expressed three proposed surface uses in mg/dm^2 and did not provide corresponding mg/kg figures. The applicant had excluded them from its own exposure estimate on the assumption that their contribution would be negligible or that inclusion would overestimate exposure. EFSA did not fully accept that assumption. Instead, it converted the surface dose using 6 dm^2 of treated surface per kilogram of food, a conventional factor drawn from food-contact-material exposure methodology. [1]

The arithmetic is straightforward: 25 mg/dm^2 × 6 dm^2/kg = 150 mg/kg for the proposed maximum cheese-rind application; 10 mg/dm^2 becomes 60 mg/kg at the proposed typical level. For meat, 2.5 mg/dm^2 becomes 15 mg/kg and 1.5 mg/dm^2 becomes 9 mg/kg. These are model inputs for dietary exposure, not experimentally measured residues in all finished cheeses or meat products. [1]

The choice is scientifically reasonable for a broad screening assessment, but it has a domain of validity. A large, flat food surface, a thin slice, a small cylindrical sausage, a wheel of cheese and a food with an inedible or partially consumed coating have different treated-area-to-edible-mass ratios. Some applications involve drip loss, washing, abrasion, redistribution or penetration. The model can overestimate or underestimate actual ingested mass depending on geometry and retention.

This is not a criticism that invalidates EFSA's safety conclusion. It is a prompt to distinguish a protective regulatory screening assumption from the information required to optimise a specific production line. Food-contact migration conventions are not a universal physical law governing preservative deposition.

05 | A quantitative worked example: the same nominal dose, different food exposures

Define S as the applied surface loading in mg/dm^2, A as the treated area in dm^2, M as the finished edible food mass in kg, and f as the fraction of applied active substance ultimately retained in the consumed portion. A first-order estimate of the resulting concentration is C = S × (A/M) × f, in mg/kg. The model assumes no additional active material is generated or added later and that mass accounting is complete. In a real factory, f is measured rather than presumed.

Consider a hypothetical cheese treatment at the applicant's proposed maximum S = 25 mg/dm^2. With A/M = 2 dm^2/kg and full retention, C would be 50 mg/kg. At EFSA's conventional 6 dm^2/kg it would be 150 mg/kg. At 10 dm^2/kg it would be 250 mg/kg. If only 40% of the applied amount reached and remained in the consumed portion, those figures would become 20, 60 and 100 mg/kg. The examples are arithmetic, not observed residues, recommended dosages or legally permitted use levels.

For a proposed meat-surface treatment of 2.5 mg/dm^2, the same three ratios at full retention yield 5, 15 and 25 mg/kg. That difference is relevant both to exposure and to the amount of active material available per unit of contaminated surface. It would be unsound to assume that a constant whole-food mg/kg value guarantees an identical antimicrobial exposure at every surface point.

Two further qualifications matter. First, the edible portion must be defined: cheese rind that is removed before consumption should not be treated as fully eaten without justification, but neither should all consumers be assumed to remove it. Second, the residual distribution may be highly heterogeneous. An average laboratory result cannot replace measurements of hotspots, edges, crevices and untreated zones.

06 | EFSA's exposure finding: reassuring, conditional and method-dependent

The 2026 EFSA Panel retained the 2021 ADI of 10 mg/kg body weight/day for the defined glycolipids. It used the Food Additives Intake Model (FAIM 3.0) to calculate scenarios combining already authorised beverage uses and proposed additional uses. The highest reported 95th-percentile estimate for the general population was 6.2 mg/kg body weight/day in infants in the maximum

scenarios, with 5.6 mg/kg body weight/day in toddlers for one maximum scenario. Both were below the ADI. In a separate food-supplement-consumers-only scenario, the highest 95th-percentile estimate was 1.3 mg/kg body weight/day in children. [1]

The infant estimate does not mean that the application sought to authorise E 246 in infant supplements. It reflects the way broad food categories and their consumption data entered the model, including a parent category for fruit and vegetables that could not isolate pomegranate arils. The Panel identified multiple potential overestimation mechanisms: treating all foods in a broad category as if they contained the additive, applying maximum concentrations, and using parent categories where restrictions could not be represented. [1]

There were also uncertainties that could work in the other direction. EFSA noted that mead could not be entered directly in FAIM and that the 6 dm^2/kg conversion introduced uncertainty. The published conclusion is a reasoned assessment that overall exposure was overestimated, not proof that every model component is conservative under every food geometry or dietary pattern.

The ADI is a chronic intake reference, not a product concentration limit, and it does not establish antimicrobial efficacy. Dividing an ADI by a chosen daily serving to manufacture a universal 'permitted dose' would ignore background exposure, population differences, the proposed food category and the positive-list conditions.

07 | Great Britain derives a different ADI: divergence is not evidence of toxicity

A particularly significant October 2026 comparison comes from the FSA/FSS safety assessment of AM-1 glycolipids, published as RP1457. The British assessors agreed on a no-observed-adverse-effect level (NOAEL) of 1,000 mg/kg body weight/day from a 90-day rat study but applied a total uncertainty factor of 300, yielding an ADI of approximately 3.3 mg/kg body weight/day. EFSA's established ADI is 10 mg/kg body weight/day. Both bodies assessed the specifically identified fermentation product, but the reference values differ by roughly a factor of three. [2,4]

That difference should not be reported as 'Britain found E 246 unsafe' or 'EFSA is three times less protective'. Reference values reflect endpoint selection, uncertainty factors and expert assessment; they are not directly interchangeable with national maximum permitted levels. The British assessment itself reported no toxicity, genotoxicity or gut-microbiome concern for the defined preparation under its evidence base. [2]

A hypothetical 15 kg child has a calculated daily reference intake of 150 mg under an ADI of 10 mg/kg/day and 49.5 mg under an ADI of 3.3 mg/kg/day. Those numbers illustrate why market-specific exposure work matters; they are not product permissions or allowable daily amounts to allocate entirely to one item. Likewise, applying the British ADI to EFSA's population-level exposure scenario without reconstructing its assumptions would not establish a British legal breach.

Crucially, an FSA/FSS safety assessment is not the same as a ministerial authorisation in Great Britain. The operative status and any conditions must be checked in the official GB register before sale. Northern Ireland must be assessed separately under its relevant EU-linked food law. [2,17,18]

08 | A microbiome question is not the same as a preservative's microbiological efficacy

The British assessment recorded expert concern that chronic consumption of an antimicrobial glycolipid might affect intestinal microbiota even after chemical deacylation. Additional evidence included analysis of faecal and caecal material from rats exposed for 90 days at doses up to 1,000 mg/kg body weight/day. The FSA/FSS concluded that the results did not indicate biologically meaningful changes in microbiome composition at those tested exposures. [2]

That finding is useful but bounded. It does not prove that no microbiome effect could ever occur in every human population, diet or exposure duration; nor does it establish a positive microbiome benefit. It also says nothing directly about whether a surface-treated meat or cheese resists spoilage or pathogenic growth throughout a particular shelf life. Gut-microbiome safety, antimicrobial action in food and claimed consumer benefit are separate endpoints.

An industrial dossier should record the source of each conclusion. For microbiome safety, questions include exposure, duration, appropriate controls, absolute versus relative abundance, function and biological significance. For food preservation, questions include the challenge organism, inoculation level, dose distribution, temperature, pH, water activity, matrix interactions and intended shelf life.

The category error is subtle: a preservative may have an antimicrobial mechanism and still be compatible with a safety assessment; that does not allow a marketer to claim that it 'improves the gut microbiome', or a quality manager to claim that it 'controls all pathogens'.

09 | Antimicrobial spectrum: spoilage control is not universal pathogen control

The 2022 EU authorisation recitals describe E 246 as active against yeasts, moulds and Gram-positive bacteria. The British dossier records that AM-1 has reduced or no antimicrobial efficacy against Gram-negative pathogenic bacteria and is not sporicidal. These are material limitations when assessing foods vulnerable to Salmonella, pathogenic Escherichia coli, spores or mixed microbial communities. [2,3]

A result obtained against a laboratory yeast in an acidic beverage does not establish a corresponding log reduction against Listeria monocytogenes on a fat-rich cheese rind. Surface wetting, biofilms, protein binding, salt, oxygen, temperature and the composition of the native microbiota can alter efficacy. The distinction between bacteriostatic inhibition and bactericidal inactivation must also be preserved. Preventing visible mould for a defined storage period is not equivalent to meeting a pathogen reduction target.

Nor is every claim that an ingredient is 'natural' or fermentation-derived a guarantee of better organoleptic acceptance or consumer preference. Sensory stability, ingredient labelling, process compatibility and economic viability must be demonstrated. The same active ingredient may be useful as one hurdle in a food-safety system while being inappropriate as the sole control for another hazard.

A scientifically credible programme should test relevant strains and cocktails, including stress-adapted isolates where justified, and should report the inoculum, sampling power, analytical recovery and variability rather than presenting only a best-case photograph or one end-point measurement.

10 | The July 2026 Listeria rule changes the practical meaning of validation

Commission Regulation (EU) 2024/2895 has applied since 1 July 2026. It amended the Listeria monocytogenes food-safety criterion for ready-to-eat foods able to support growth, other than those intended for infants and for special medical purposes. Where the producer cannot demonstrate to the competent authority that levels will remain at or below 100 CFU/g throughout shelf life, the criterion of non-detection in 25 g applies to products placed on the market during their shelf life. The alternative criterion is conditional on adequate demonstration. [11,12]

This legal development makes shelf-life evidence more important, but it does not turn the October E 246 opinion into a validated anti-Listeria treatment. A future permission to apply an additive to certain meat surfaces would still require product-specific demonstration if the manufacturer intends to rely on that treatment as part of its Listeria control strategy. Microbiological criteria, HACCP procedures and general safety duties remain independent of the additive's authorisation. [11–14]

A challenge study must use a defensible experimental design: representative product variability, realistic contamination routes, worst-case storage, sufficient replication, a suitable sampling schedule and a predeclared acceptance criterion. The study should distinguish growth inhibition from inactivation and consider the possibility of recontamination after application. Any prediction of shelf-life performance must be validated in the target matrix.

It would be legally and scientifically misleading to claim that a favourable additive safety opinion allows a producer to relax sanitation, raw-material controls, environmental monitoring or the statutory Listeria criterion.

11 | Why EFSA's technological data were not an efficacy approval

A revealing sentence in the October opinion states that the applicant supplied data on stability of foods after E 246 addition for some requested categories, but that those data were not considered relevant for the safety opinion. The sentence does not imply that the data were false or that efficacy is absent. It tells us that the published scientific output addressed a defined risk-assessment question and did not adjudicate every technological-performance proposition. [1]

This distinction should be carried into procurement and product development. A manufacturer may be shown an EFSA conclusion and a brochure claiming shelf-life extension. The former supports a specific safety conclusion; the latter requires its own evidentiary basis, including study reports, methods, matrices, controls and commercial-scale reproducibility. One cannot borrow the authority of the EFSA opinion to validate unreviewed microbial efficacy.

Article 6 of Regulation (EC) No 1333/2008 adds a separate technological-need test to authorisation. It is not enough for a substance to be toxicologically acceptable; its use must be justified and must not mislead consumers or disguise unhygienic practices. [6]

The operational response is to maintain a regulatory dossier and a technical-performance dossier with clear cross-references. The first documents identity, permitted use, exposure and specifications. The second documents a process's actual contribution to hazard control and shelf-life performance. Both must be updated when the matrix, treatment method or supply chain changes.

12 | Application physics: delivered dose is not deposited dose

Surface treatments introduce additional variables between the nominal formulation concentration and the mass present on food. Spray nozzles, atomisation, viscosity, conveyor speed, product rotation, shadowing, drainage, foaming, dipping time, surface roughness and equipment geometry all affect deposition. A 1% working solution does not imply that every square decimetre receives the same mass of active material; a product's concentration in a tank is not its residue concentration in the food.

A process engineer should separate at least four quantities: active concentration in the application fluid; mass of fluid delivered; fraction actually deposited on the target surface; and fraction retained in the edible portion at consumption. Those quantities are linked through material balance and time-dependent loss. For a surface-sensitive antimicrobial, spatial uniformity may be as important as average retention.

Where an active ingredient can diffuse into food, the temporal profile matters. A thin contaminated surface may initially receive high local concentration, followed by redistribution into the bulk. Depending on mechanism, this may weaken local efficacy without greatly changing total recovered mass. Conversely, uneven deposition may leave niches unprotected despite a reassuring average analytical result.

This reasoning is established in coating, deposition and food-processing science. The present article does not claim to invent surface-dose accounting. The opportunity is to connect established process engineering to the specific uncertainty revealed by the 2026 additive-exposure model.

13 | Analytical validation: the method must answer the question

The chemical identity of a congener mixture creates analytical challenges. A release certificate stating total glycolipids on a dry basis is not necessarily a validated method for residues in a protein-rich meat extract or fatty cheese rind. Analytical recovery can vary with extraction solvent, matrix binding, pH, salt and the relative proportions of congeners. A manufacturer should determine whether the method measures total mixture, selected marker congeners or an operationally defined response calibrated to a reference preparation.

A fit-for-purpose residue method should report selectivity, calibration, limits of quantification, recovery, repeatability, matrix effects, stability and measurement uncertainty. Sampling should account for spatial heterogeneity, including edges and inaccessible surfaces. A whole-food homogenate may support dietary exposure calculations while concealing the spatial concentration gradient relevant to antimicrobial action.

A microbial validation study needs its own analytical discipline: method suitability in the presence of residual antimicrobial material, neutralisation of carry-over activity, limits of detection, strain confirmation and appropriate positive and negative controls. Without neutralisation, an antimicrobial carried into the laboratory enrichment or plating system may artificially depress recovery and make the treatment look more effective than it is.

The two assay streams should meet at a batch and sample identifier, but should not be reduced to a single 'passed' label. Residue measurement and microbial recovery answer different questions.

14 | EU and Spain: food additive, processing aid or active packaging?

A food-preservation intervention cannot be classified solely by the operator's preferred commercial description. If a substance is intentionally used to exert a preservative effect in a food and remains relevant in the finished product, the food-additive framework may apply. A processing-aid claim requires careful analysis of the legal definition, intended function, residual presence and technological effect. It is not created by describing the treatment as a rinse or by asserting that the active ingredient is 'natural'. [6,15]

A substance incorporated into an active food-contact material introduces another regulatory route: Regulation (EC) No 1935/2004 and, where applicable, Regulation (EC) No 450/2009 govern food-contact articles and active/intelligent materials.

The material's function, release and the legal status of intentionally released substances must be evaluated. A film or coating is not a universal workaround for food-additive restrictions. [19,20]

Spain applies directly applicable EU additive and food-hygiene rules. AESAN's public guidance distinguishes authorised additives, food categories and labelling obligations, while official controls are carried out through the competent national and autonomous-community structures. For a Spanish food manufacturer, a positive EFSA opinion is useful scientific evidence but not a national permission to bypass the Union list. [16]

In practice, a project should classify the actual application before samples are sent to a commercial customer: direct addition, surface application, processing aid, or food-contact coating. It should then identify the legal instrument, competent authority, intended category, label consequences and supporting validation needed for that route.

15 | Great Britain, Northern Ireland and the problem of importing EU assumptions

Great Britain has its own regulated-products authorisation arrangements and ministerial decisions, with FSA and FSS scientific assessment and advice. Following reforms implemented in April 2025, authorisations may be reflected in official registers rather than only in statutory instruments. The October 2026 British AM-1 assessment is therefore an important scientific milestone, but should not be presented as proof that all requested uses are currently authorised in England, Scotland and Wales. A business must verify the live register and any applicable decision and conditions. [2,17,18]

Northern Ireland requires separate analysis of the relevant EU-linked food rules. A statement that E 246 is 'UK approved' would be too broad without identifying the jurisdiction, product category and legal instrument. Equally, a GB risk assessment using a 3.3 mg/kg/day ADI does not automatically change the EU ADI or the EU positive list.

For a distributor serving both the EU and Great Britain, the most defensible system maintains one common technical identity dossier and separate jurisdiction-specific legal-status and exposure appendices. Those appendices should record the assessment date, applicable legal text, current permissions, proposed permissions and any conditions on dose, product type, labelling and manufacture.

This avoids an avoidable commercial failure: quoting the correct scientific source while making the wrong territorial claim.

16 | United States: the same glycolipid already has a different regulatory history

The FDA's GRAS Notice 740 provides a useful counterpoint. The notifier concluded that glycolipids from Dacryopinax spathularia were generally recognised as safe under specified intended conditions. The FDA closed the notice on 17 May 2018 with a 'no questions' letter. The public inventory describes use in selected non-alcoholic beverages at 2–100 ppm and on cheese and dry-cured sausage, including relevant casings, subject to finished-food levels of no more than 500 mg/kg and 100 mg/kg respectively. [9]

These are the intended uses described in a particular GRAS notification, not EU authorisations and not a general US approval of all glycolipids in all foods. FDA explains that a 'no questions' response means it did not question the basis of the notifier's GRAS conclusion on the submitted record; it is not the same as an affirmative food-additive approval. Other US regulatory obligations, including those of USDA-FSIS for relevant meat products, may be material. [10]

The comparison is instructive. The US notification describes certain finished-food mass concentrations, whereas the EU's pending surface proposal uses mg/dm^2 and EFSA converts them to mg/kg for exposure modelling. Comparing 500 mg/kg, 150 mg/kg and 25 mg/dm^2 as if they were three directly interchangeable legal limits is incorrect. They arise from different instruments, intended uses and measurement conventions.

An exporter must verify that the particular ingredient, supplier, food and use fall within the relevant US legal basis. The existence of GRN 740 does not validate a different supplier's glycolipid composition or an unexamined use in ready-to-eat meat.

17 | Existing patents and research: what is not new

The chemistry and antimicrobial application of Dacryopinax glycolipids have substantial prior art. International publication WO2012167920A1 described long-chain glycolipids for preventing microbial spoilage in food, beverages, cosmetics and other materials, including surface or coating applications. Later US patent publications and formulation disclosures developed related concepts. The FDA's 2018 GRAS notice and published safety evaluations further establish that E 246 is not a newly discovered antimicrobial class in 2026. [9,21,22]

Food-coating science likewise predates this opinion. Peer-reviewed studies have evaluated antimicrobial films, cheese coatings and coupled modelling of active-agent release and shelf life. A public research project in the US has specifically considered AM-1 glycolipids for Listeria control in queso fresco. These precedents defeat any claim that 'glycolipids on cheese' or 'combining antimicrobial treatment with challenge testing' is a new invention. [23,24]

What is current is the combination of a new EU extension assessment, an explicit conversion from surface area to food mass, a contemporaneous British assessment with a different ADI and a stricter operational context for Listeria shelf-life evidence. That combination exposes a practical evidence-integration problem worth investigating.

Any commercial research programme must perform a genuine freedom-to-operate review, including patent family, claims, jurisdiction, expiry, licences and the intended manufacturing and application method. A literature review cannot substitute for patent counsel's legal opinion.

18 | A risk-based industrial decision framework

A procurement decision should begin with legal status, not price per kilogram. Stage one identifies the exact substance and whether the proposed use is currently authorised in the destination market. Stage two tests supplier conformity with the relevant specification, including strain origin, manufacturing consistency, impurity controls and an analytically meaningful certificate. Stage three establishes intended dose in the correct units and the geometry and retention of the application. Stage four validates microbial performance in the specific food and process. Stage five integrates sensory quality, shelf-life evidence, total exposure and commercial feasibility.

The framework should include explicit stop conditions. An unapproved use cannot become marketable because the trial results are attractive. A positive challenge-test result cannot correct an inadequate toxicological dossier. A negative end-product sample cannot establish that a treatment provides a defined reduction. A cost model cannot assume that a 10 mg/L beverage dose can simply be transferred to a cheese surface.

Where a project is a formulation alternative to existing hurdles, the comparison must be fair: equivalent shelf-life target, product quality, target organisms, regulatory constraints, labour, process integration, residues, packaging and cost of failure. Potential benefits should be measured against a realistic control formulation, not against an intentionally unprotected product.

This disciplined approach is particularly relevant to manufacturers developing clean-label preservation systems, fermented ingredients, cheese, charcuterie, ready-to-eat foods and functional beverages. It does not presuppose that E 246 will be the winning technology.

19 | Research & Innovation Opportunity

Unresolved problem. There is no universally transferable relation between an applied antimicrobial surface loading (mg/dm^2), the retained dietary concentration (mg/kg), and the microbiological effect at spatially heterogeneous food surfaces. EFSA's 2026 use of a conventional conversion factor highlights that problem without resolving it for particular industrial geometries. The published safety assessment was not an efficacy validation. [1]

Established knowledge. Material balances, surface-area-to-mass ratios, residue analysis, antimicrobial challenge tests and predictive microbiology are established disciplines. E 246 is a characterised preservative with a prior toxicological and regulatory record, and antimicrobial coating concepts have been disclosed in patents and literature. The research opportunity is therefore integration and validation, not invention of these components. [4,21–24]

Proposed hypothesis. A geometry-aware, matrix-specific model combining measured deposition, retention, congener stability and spatial microbiological response will predict both consumed residue and shelf-life performance more reliably than a single conventional 6 dm^2/kg assumption or a nominal tank concentration. This is a testable hypothesis, not an established result or a patentability claim.

Development pathway. Select contrasting food geometries, as for example, small cured sausages, larger cured products, ripened cheese wheels and cut portions. Record actual treated area, edible mass, surface topology, working-fluid concentration, application efficiency and post-process losses. Use validated chemical methods to measure surface and bulk residues over time. Perform blinded microbial challenge studies under relevant worst-case storage conditions, with controls for analytical carry-over. Construct separate dose–residue and dose–effect models before linking them. Test whether the combined model predicts held-out production batches.

Validation gates. Require predefined mass-balance closure, residue-recovery limits, spatial sampling plans, inter-batch reproducibility, external-site replication, independent microbial enumeration and sensitivity analyses for geometry and retention. Quantify false reassurance: situations where average residue appears adequate but untreated microenvironments permit growth. Benchmark against a conventional model and an established preservation system.

Regulatory constraints. Experiments may be conducted within appropriate research and food-safety controls, but experimental use does not authorise commercial marketing of E 246 in currently unapproved EU categories. Claims about pathogen control must be supported by product-specific evidence; the project must also respect intellectual property, labelling and food-contact distinctions.

Industrial relevance. If validated, this framework could improve process design, dosing efficiency, supplier qualification and dossier preparation for surface preservatives generally. It could also reveal where an intervention is ineffective or uneconomic, which is as valuable to responsible R&D as a positive result.

20 | Implications for INTABIOTECH and the wider preservation market

For a technology developer working across food preservation, mineral process technologies, antimicrobials and functional ingredients, the most useful conclusion is methodological. Any proposed intervention should be evaluated through separate, auditable records of legal classification, delivered dose, actual exposure and target-specific efficacy. The present case provides a particularly clear example because one regulator's dietary model and another regulator's toxicological reference point cannot simply be collapsed into a sales specification.

A company evaluating E 246 as a potential ingredient or benchmark should first determine whether it has lawful access to the defined preparation, whether the contemplated use is authorised, whether intellectual-property restrictions apply and whether the treatment outperforms available alternatives under a predeclared test design. It should not suggest that an existing INTABIOTECH product contains E 246, has equivalent activity or can lawfully replace it without evidence.

The broader opportunity extends beyond glycolipids. Organic-acid systems, buffered vinegars, fermentation-derived preservatives, antimicrobial surface treatments and non-electrolytic water-conditioning technologies may all raise questions about matrix, application geometry, persistence and process validation. They do not share a regulatory classification or mode of action merely because they are marketed for food safety. Each requires its own legal and scientific dossier.

The defensible commercial position is to sell a validated, lawfully classified intervention under defined conditions, not an unsupported promise of universal microbial control.

21 | Evidence status and limitations

Established evidence. The identity and 2022 EU beverage authorisation of E 246, EFSA's 2021 ADI, EFSA's 23 October 2026 safety conclusion, the British RP1457 ADI and the July 2026 Listeria criterion are documented in primary sources. The relevant patents and earlier coating studies establish prior art. [1–4,11,21–24]

Emerging or application-specific evidence. The extension dossier contains technological information, but the published EFSA opinion did not assess those data for efficacy. The performance of surface glycolipids in individual cheese and meat matrices remains a product- and process-specific question requiring access to appropriate data and, where needed, new validation. [1]

Expert interpretation. The cross-jurisdictional divergence in ADI and the surface-to-mass conversion create a strong reason for an integrated industrial evidence architecture. That inference is the author's analysis, not a conclusion formally adopted by EFSA, FSA or FDA.

Hypothesis and proposed research. Geometry-aware deposition and residue models may improve exposure prediction and antimicrobial-control decisions; their predictive gain has not been established here. No new experimental dataset, systematic review or freedom-to-operate opinion is claimed. The cited patent search is illustrative, not exhaustive.

Limitations. Regulatory status is assessed as at 26 October 2026 and can change after publication. A current legal decision must use the latest consolidated legislation and official authorisation registers. Hypothetical calculations are explicitly identified and must not be used as product specifications.

22 | Conclusions: a safety opinion is the beginning of an industrial decision, not its end

The 2026 E 246 developments expose a recurring error in food technology: the assumption that a favourable toxicological assessment can stand in for a complete process-validation and market-access dossier. EFSA found the proposed extension compatible with its ADI under modelled exposure assumptions. The opinion did not authorise the additional uses and did not establish the microbial efficacy of every proposed surface application. The British assessment adopted a different ADI, while US GRAS Notice 740 describes its own specified uses and finished-food concentrations. [1,2,9]

For the food industry, the critical bridge is evidence. The active material must be the one assessed; the intended application must be legally permitted; the applied dose must be connected to retained exposure through measured geometry and process losses; and the antimicrobial effect must be validated in the actual food under realistic worst-case conditions. Only then can a manufacturer make a proportionate, technically defensible preservation decision.

The research opportunity is not a miracle molecule or a new label. It is the disciplined integration of chemical, microbial, engineering and legal evidence, with enough transparency to identify both successful applications and justified reasons not to proceed.

RELATED KNOWLEDGE AREAS

Food Safety; Biotechnology; Regulatory Affairs; Functional Ingredients; Processing Technologies; Sustainability; Emerging Research; Mineral Technologies (methodological comparison only).

EDITORIAL SCOPE AND CAUTIONS

Independent academic–industrial analysis prepared from publicly available evidence as at 26 October 2026. The hypothetical examples are not product recommendations or legal limits. This publication is not an EFSA, FSA/FSS, FDA or AESAN opinion, and it does not constitute a product-specific legal opinion, an experimental efficacy report or a patentability assessment. The author does not assert that INTABIOTECH manufactures, distributes or has validated E 246.

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