The Enzyme Is Not the Dossier

What a November 2026 EFSA Glucoamylase Assessment Reveals About Process Identity, Exposure and the Regulatory Limits of Enzyme Innovation

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Abstract

A scientific opinion listed by the European Food Safety Authority on 3 November 2026 concerns glucan 1,4-α-glucosidase produced by a non-genetically modified Aspergillus niger strain. A publicly indexed account of its abstract reports an unusual documentary discrepancy: the applicant's description of manufacture refers to a pectinase rather than the enzyme under evaluation. The complete opinion was not independently accessible for this analysis, and no final EFSA conclusion is attributed to it. The episode nevertheless provides a timely lens on a wider, demonstrable issue. Enzyme identity, production-organism identity, manufacturing history, residual organic solids, intended food processes and downstream exposure form a single evidence chain. A familiar catalytic activity does not make production strains interchangeable; nor does heat inactivation establish removal of enzyme-derived material. Drawing on accessible EFSA assessments, European legislation and UK guidance, this article proposes a process-identity evidence framework for enzyme developers and ingredient users. Its suggested digital implementation is a research proposition, not a validated regulatory method.

Keywords: *food enzymes; glucoamylase; Aspergillus niger; process identity; total organic solids; allergenicity; regulatory dossiers; industrial biotechnology*

1 | A current signal, and its verification boundary

EFSA's food-enzyme topic index records a scientific opinion dated 3 November 2026 on glucan 1,4-α-glucosidase (EC 3.2.1.3) produced by non-genetically modified Aspergillus niger AN-SHGA-100. An indexed abstract attributed to the publication states that the applicant's manufacturing description referred to a pectinase rather than the enzyme under assessment. The opinion is identified as DOI 10.2903/j.efsa.2026.10404. At the time of this editorial review, its publisher-hosted full text could not be retrieved reliably. Accordingly, the discrepancy is reported as an attributed abstract-level observation, not independently verified as a substantive deficiency or an EFSA safety determination. [1,2]

That qualification is important. A mismatch may represent a document-control error, a templating problem, an inadequately explained shared production operation or a more consequential inconsistency. Without the full dossier, correspondence and adopted opinion, none can be established. It would be irresponsible to infer contamination, intentional misrepresentation, unsafe enzyme manufacture or regulatory rejection. What can be analysed is the evidence architecture required to resolve such inconsistencies. The question is not simply whether an enzyme performs the desired reaction, but whether the assessed product is demonstrably the product actually manufactured and sold.

2 | Catalytic identity is only one identity

Glucoamylase releases glucose units from the non-reducing ends of starch polymers. It is widely relevant to saccharification, fermentable-sugar production and certain bakery and beverage applications. Its catalytic nomenclature describes an activity, not a complete commercial specification. Two preparations sharing EC 3.2.1.3 may differ in host strain, genetic construction, fermentation substrate, secondary enzymatic activities, residual proteins, fermentation metabolites, formulation carriers and exposure profile. [3,4]

A robust identity statement must therefore specify at least the enzyme activity and assay conditions; the production organism and traceable strain; the genetic status and stability evidence; the fermentation and purification route; the preparation's total organic solids (TOS); potentially relevant contaminants and microbial residues; and the intended technological uses. Enzyme units without a stated substrate, pH, temperature and assay method are not interchangeable across suppliers. Likewise, a high activity-to-TOS ratio does not by itself demonstrate toxicological safety.

3 | Why production-process documentation is toxicological evidence

An industrial enzyme is produced in a biological manufacturing system. Fermentation media, antifoams, pH-control agents, nutrient sources, cell separation, filtration, concentration and stabilisation determine what accompanies the active protein. A process narrative that does not correspond to the evaluated enzyme may compromise the assessor's ability to connect manufacturing inputs to the tested material. This is a general evidentiary concern, not a finding about the November applicant.

A quality dossier should reconcile the master manufacturing record with batch production records, sample identities, analytical certificates, toxicology-test batch identifiers and the marketed formulation. Changes to fermentation feedstock or purification membranes may alter residual solids without changing the nominal catalytic name. The scientific relevance of a change depends on its effect on composition, impurities, exposure and the validity of the safety evidence. Good

manufacturing practice and HACCP controls address operational hazards, but they do not replace the product-specific toxicological justification.

4 | TOS, activity and residual exposure: three different quantities

EFSA commonly estimates dietary exposure to food-enzyme total organic solids where these are expected to remain in food. TOS is a compositional measure of organic material in the preparation; it is neither synonymous with enzyme protein nor a direct measurement of catalytic activity. In a 2026 assessment of A. niger AE-GN glucoamylase, EFSA estimated exposure up to 1.739 mg TOS/kg body weight/day across retained-use processes and reported a margin of exposure of at least 576, based on the tested material and specified uses. These are dossier-specific figures, not general limits for glucoamylase. [3]

Another 2026 opinion concerning an extension of use for genetically modified A. niger NZYM-BF reported exposure up to 4.431 mg TOS/kg body weight/day and a margin of exposure of at least 307. These different results illustrate that the process portfolio, residual fraction and toxicology package matter; they cannot be ranked as a simple comparison of commercial product safety. [4]

Enzyme deactivation by heat is not equivalent to removal of TOS. Denatured proteins and other residual organic matter may remain. Conversely, validated purification processes can remove substantial TOS even if the enzyme was catalytically active earlier. Assertions about removal must be process-specific, supported by suitable measurements and aligned with EFSA exposure methodology.

5 | Allergenicity: sequence signals are not clinical diagnoses

Food-enzyme proteins may share sequence motifs with known allergens. EFSA's accessible 2026 AE-GN opinion identified sequence matches with respiratory allergens and considered dietary allergic reactions unlikely, although not categorically excluded for relevant uses. This distinction matters: occupational respiratory sensitisation and clinical food allergy are not equivalent endpoints, yet neither can be dismissed solely because an enzyme is used at low concentrations. [3]

Allergen assessment should distinguish the catalytic protein from residual host proteins and allergenic fermentation-medium constituents. The relevant questions include sequence similarity, literature reports, exposure, removal or carryover, and the final food matrix. An absence of reported clinical cases is not proof of zero risk. Nor does a positive bioinformatics match establish that ingestion will cause an allergic reaction. Worker protection, including inhalation exposure to enzyme dust or aerosols, remains a separate occupational-health obligation.

6 | The same enzyme can have different exposure pathways

Consider starch hydrolysis for glucose syrup, bread dough, plant-based drinks and fermented beverages. In syrup manufacture, downstream purification may remove enzyme-derived TOS; in dough or beverages, residual material may remain. EFSA explicitly distinguishes retained and removed TOS in its published assessments, and uses manufacturing-process classifications when estimating dietary exposure. [3–5]

Consequently, a supplier's generic assertion that the enzyme is "a processing aid" does not settle exposure or labelling in every jurisdiction. Processing-aid status is a legal classification determined by function and conditions, not a universal chemical guarantee of absence. A product used to

increase glucose release may also alter reducing-sugar concentration, browning reactions, sweetness, fermentation kinetics and nutritional composition. Technological success and food-safety evaluation therefore require different datasets.

7 | An overlooked product-development question: the reaction product

Glucoamylase increases free glucose under suitable substrate and processing conditions. That biochemical transformation may be desirable for fermentation yield or sweetness, but can also affect nutritional positioning, Maillard chemistry and finished-product specifications. A manufacturer developing reduced-sugar or protein-enriched beverages cannot infer that a starch-converting enzyme is beneficial simply because it improves processing. The net effect depends on substrate availability, residence time, enzyme dosage, subsequent fermentation and the food's composition.

This raises a dual-control requirement: verify the safety of the enzyme preparation and independently characterise the nutritional and chemical consequences of its use. Where glucose is converted further during fermentation, the final product may differ sharply from a non-fermented system. Claims about sugar reduction, digestibility or glycaemic response require product-specific evidence and applicable claims-law review; enzyme activity alone cannot substantiate them.

8 | EU law: scientific opinion is not market authorisation

Regulation (EC) No 1332/2008 governs food enzymes and establishes the principle of a Union list and conditions for authorisation. Regulation (EC) No 1331/2008 supplies the common authorisation procedure. EFSA conducts scientific risk assessment; the European Commission and Member States manage authorisation decisions. A positive EFSA opinion is not itself an authorisation, and a published assessment should never be described as a licence to use any supplier's preparation in any food. [6,7]

The regulatory transition surrounding the Union list and national arrangements must be checked at the date of commercial placement. The legal analysis must also distinguish food enzymes from food additives and other substances that perform a technological function. Regulation (EC) No 852/2004 remains relevant to hygiene and HACCP, while Regulation (EC) No 178/2002 establishes general food-law responsibilities and traceability principles. [8,9]

For Spain, directly applicable EU rules are complemented by national competent-authority controls. A Spanish operator should retain the strain-specific supplier dossier, intended-use specification, batch traceability and evidence supporting its regulatory classification. Reliance on a generic "EU compliant" certificate without a precise legal basis is weak due diligence.

9 | UK and US: similar scientific questions, different legal routes

Great Britain's food-enzyme position must be assessed under applicable domestic law and retained or assimilated rules as amended, together with relevant Food Standards Agency guidance. Northern Ireland requires separate consideration of applicable EU-linked arrangements. It is unsafe to assume that a single "UK approval" covers every territory or that an EU opinion automatically resolves British obligations. The UK FSA's March 2026 supplementary guidance on fermentation-derived novel foods concerns a different legal question but usefully reinforces the importance of

production-strain characterisation, manufacturing consistency and residual material evidence. It should not be misrepresented as a dedicated enzyme-authorisation rule. [10]

In the United States, enzyme preparations may be marketed through legally appropriate routes, including applicable food-additive regulations or substantiated generally recognised as safe (GRAS) status, depending on the substance and use. The US approach is not equivalent to an EFSA opinion or a European Union listing. Claims of GRAS status must be grounded in the specific substance, manufacturing process, intended conditions and adequate scientific evidence, not merely the historical use of glucoamylase. Cross-border dossiers should map the precise legal status of each preparation rather than assume international equivalence. [11]

10 | Industrial consequences for ingredient manufacturers

A supplier should treat enzyme documentation as an evolving configuration-controlled system. Each marketed grade should have a unique identity linking the production strain, enzyme activity, formulation composition, specifications, manufacturing site and validated uses. Changes to carriers, filtration, feedstock or upstream strain should trigger documented impact assessment. An apparently administrative mismatch can be costly if it prevents customers from reconciling their HACCP files, supplier approvals and finished-product specifications.

For INTABIOTECH's wider interests in enzyme-enabled processing, protein hydrolysates, functional beverages and ingredient development, the strategically defensible contribution is technical qualification rather than promotional generalisation. Enzymatic treatments should be evaluated for reaction kinetics, substrate specificity, unintended changes in sugar or peptide profiles, residual preparation material and market-specific legal eligibility. No assertion is made here that any particular INTABIOTECH product has been evaluated or authorised for the uses discussed.

11 | Research & Innovation Opportunity

Unresolved problem. Conventional enzyme qualification frequently stores strain identity, batch composition, process parameters, toxicology references and intended-use information in separate documents. A mismatch may be discovered late, after commercial sampling or customer validation. The underlying practices of document control, mass balance and digital traceability are established; their integration into a cross-market, enzyme-specific evidence workflow is the proposed research subject, not a claimed new scientific principle.

Hypothesis—not established fact. A "Process-Identity Evidence Graph" linking each enzyme grade to its production strain, fermentation recipe version, purification sequence, toxicology batch, TOS profile, activity assay, intended use and jurisdictional status could detect dossier inconsistencies earlier than conventional manual document checks. Its effectiveness, cost and regulatory acceptability remain unproven.

Validation pathway. Construct a retrospective set of anonymised enzyme dossiers with verified version histories. Define error classes, including wrong-enzyme process narratives, strain-code discrepancies, missing toxicology batch traceability and unsupported claims of residual removal. Compare trained reviewers using existing workflows with reviewers assisted by a structured rules engine. Measure sensitivity, false-positive rates, review time, reproducibility and correction quality. Test the system on held-out dossiers and across multiple manufacturers. Include human review of every flagged discrepancy and safeguards against fabricated references or inferred authorisations.

Regulatory constraints. A private evidence graph would not replace an EFSA assessment, official authorisation, GMP controls or statutory recordkeeping. Confidential strain and process information would require access controls, data-governance agreements and auditable change histories. If independently validated, the framework might improve supplier qualification, regulatory submission quality and technical due diligence. It must not be marketed as an approved safety assessment method without competent-authority acceptance.

12 | Evidence hierarchy and conclusion

Established evidence: food-enzyme safety assessment is preparation- and use-specific; catalytic activity, residual TOS and dietary exposure are distinct; EU food-enzyme authorisation is a legal process separate from scientific assessment. Accessible EFSA opinions demonstrate quantitative, process-dependent exposure assessment. [3–7]

Emerging signal: EFSA listed a 3 November 2026 opinion on A. niger AN-SHGA-100 glucoamylase, and a public abstract index reports a manufacturing-description inconsistency. The full opinion was not independently retrieved; no final safety conclusion is asserted here. [1,2]

Expert interpretation: industrial confidence depends on an uninterrupted chain between the tested material, the manufacturing process, the marketed preparation and the intended food. Research proposal: structured, auditable evidence linking may improve early detection of inconsistencies, but needs controlled validation.

The larger lesson is not that a particular glucoamylase is unsafe. It is that enzyme innovation cannot be reduced to an EC number, an activity unit or a generic supplier certificate. The most valuable next generation of enzyme documentation will make product identity, process history and exposure assumptions as reproducible as the catalytic reaction itself.

Related Knowledge Areas

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

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