The Invisible Mycotoxin Portfolio

Why EFSA's November 2026 Alternaria reassessment changes the science of ingredient qualification, process validation and food-chain surveillance

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Abstract

EFSA's updated assessment of Alternaria toxins, published in November 2026, reframes an industrial problem frequently obscured by routine mould counts: toxicological hazard, measurable contamination and actual dietary exposure are not equivalent. Five of eight evaluated toxins were judged genotoxic; for two prevalent compounds, estimated dietary exposures exceeded the threshold of toxicological concern, while insufficient occurrence and toxicological data prevented comprehensive risk characterisation for several others. This article examines the implications for tomato products, paprika, oilseeds, fruit beverages, infant foods and animal feed. It distinguishes surveillance recommendations from binding maximum levels, considers analytical limitations and the fate of toxins during processing, and compares European, British and American regulatory approaches. Its central proposition is that the next improvement in mycotoxin control requires a process-aware evidence chain joining supplier history, multi-analyte measurement, transformation-product research and exposure modelling. The proposed validation architecture is a research hypothesis, not an existing regulatory requirement or a proven commercial technology.

Keywords: *Alternaria toxins; genotoxicity; alternariol; tenuazonic acid; LC–MS/MS; food processing; mycotoxin surveillance; regulatory science*.

1. A scientific opinion that changes priorities without changing legal limits

On 11 November 2026 EFSA communicated its updated risk assessment of Alternaria toxins; the full EFSA Journal opinion was published on 13 November, having been adopted by the CONTAM Panel on 30 September. The opinion revisits the 2011 assessment using newer toxicology and occurrence data. Its immediate importance is scientific and operational. It does not itself establish an EU maximum concentration for any Alternaria toxin. The legal distinction matters: a risk signal can justify stronger procurement, monitoring and preventive controls before a numerical maximum is enacted, but it cannot be presented as a new statutory limit. [1,2]

The assessment covers eight substances: alternariol (AOH), alternariol monomethyl ether (AME), altenuene (ALT), altertoxin I (ATX-I), altertoxin II (ATX-II), stemphyltoxin III (STTX-III), tenuazonic acid (TeA) and tentoxin (TEN). These compounds do not share a single toxicological mechanism,

occurrence profile or analytical maturity. Referring to them collectively as “Alternaria toxin” is useful for surveillance but insufficient for risk assessment. An ingredient specification that tests only TeA may miss a distinct genotoxic concern; a test panel limited to AOH and AME may fail to characterise prevalent TeA. [1]

2. The hazard map: five genotoxic substances, different evidence deficits

2.1 DNA-reactive hazards and the meaning of the TTC

EFSA considered AOH, AME, ATX-I, ATX-II and STTX-III genotoxic. For AOH and AME, the Panel described a non-threshold mode of action and reported mean chronic dietary exposures exceeding the 2.5 ng/kg body-weight/day threshold of toxicological concern (TTC) for potentially DNA-reactive mutagenic or carcinogenic substances in most population groups. This does not mean that a specific clinical cancer incidence has been measured, nor that 2.5 ng/kg is a legally permitted food concentration. The TTC is a screening construct for prioritising concern under limited substance-specific data. EFSA expressly indicated that a non-TTC approach is required for fuller risk characterisation of these compounds. [1]

For ATX-I, ATX-II and STTX-III, occurrence data were insufficient to apply a comparable exposure-based TTC assessment. This is an important asymmetry: the compounds may be biologically concerning while routine food datasets are too sparse to quantify population exposure. The absence of a numerical risk estimate must not be interpreted as evidence of negligible risk. Conversely, the evidence does not support asserting that every food containing an analytically detectable trace of these compounds is unsafe. Hazard identification, exposure estimation and risk characterisation remain separate scientific steps. [1]

2.2 Tenuazonic acid and non-genotoxic comparators

TeA was the most frequently quantified Alternaria toxin in the available food dataset. EFSA could not draw a firm conclusion about its genotoxic potential from existing studies; for the assessed non-genotoxic effects, however, the Panel concluded with 98% certainty that dietary exposure would not exceed the Cramer Class III TTC of 1,500 ng/kg body-weight/day. This is a qualified conclusion about the particular endpoint and exposure model, not proof of universal safety or a substitute for resolving the genotoxicity question. [1]

ALT and TEN were regarded as non-genotoxic within the evaluated evidence, with estimated dietary exposures below the relevant Cramer Class III TTC. These findings permit prioritisation, not abandonment of surveillance. As analytical methods improve, a different distribution of measured concentrations or newly identified metabolites could modify the evidence base. [1]

3. What 57,104 analytical results reveal, and what it conceals

EFSA’s final exposure dataset comprised 57,104 analytical results from 16,283 samples, principally covering AOH, AME, ALT, TeA and TEN. The sampling period ran from 2015 to 2024 and included food samples from 16 EU countries. The large dataset is an asset, but 87% of the reported results were left-censored: values below detection or quantification limits. Censoring was especially pronounced for ALT (99%) and less so for TeA (55%). The gap between lower-bound and upper-bound estimates is therefore not a cosmetic statistical detail. It reflects how much of the apparent distribution depends on analytical sensitivity and treatment of non-quantified results. [1]

An industrial surveillance programme should report, alongside each result, the analyte, matrix, extraction protocol, laboratory accreditation scope, limit of detection, limit of quantification, measurement uncertainty and decision rule. A certificate stating “not detected” without a numerical detection capability is not transferable evidence. For a compound with a low toxicological screening threshold, a high reporting limit may leave the commercially important question unanswered.

3.1 Commodity signals and the danger of treating averages as specifications

The highest reported mean TeA levels included 14,373 µg/kg in mulberries (30 samples) and 11,650 µg/kg in paprika powder (19 samples). These are category-specific observations from limited samples, not typical values for all commercial mulberries or paprika and certainly not proposed legal limits. Processed tomato products also exhibited relatively high TeA levels compared with fresh tomatoes. AOH was observed in linseed, sesame and sunflower seeds; AME in sesame and certain oils and fruit-derived products; TEN was comparatively prominent in sunflower seeds. These patterns justify risk-based selection of matrices for testing but cannot be used to stigmatise an entire origin or supplier without representative sampling. [1]

For procurement, the useful question is not whether a raw material belongs to a “high-risk category” in the abstract. It is whether its cultivar, region, harvest conditions, drying method, storage history, sorting regime and processing route create a credible exposure pathway for the intended final food. Sampling plans should capture lot heterogeneity, including damaged fruit, fines, dust and poorly dried fractions. Composite samples may conceal hotspots if sample design and homogenisation are inadequate.

4. Processing can change the analyte without eliminating the hazard

Thermal processing, dehydration, extraction, fermentation and storage may reduce or increase measured parent-toxin concentrations depending on the matrix and conditions. A fall in the parent compound is not necessarily detoxification: transformation products may form, with poorly characterised identities or toxicological profiles. Concentration changes must also be normalised for water loss; solids yield and material balance. Comparing micrograms per kilogram of wet tomato with micrograms per kilogram of tomato paste without accounting for concentration can create a false inference about toxin generation. [1]

4.1 A mass-balance approach

A rigorous processing trial should quantify toxin mass entering and leaving each operation, not merely report concentration before and after heating. It should distinguish losses through physical separation, adsorption to residues, chemical transformation and analytical recovery changes. Controls need matched moisture, matrix blanks, fortified recoveries and independently measured yield. Where feasible, high-resolution mass spectrometry can be used to investigate unknown transformation signals, but putative identities must be reported at an appropriate confidence level and confirmed with standards when available.

The same logic applies to fermentation-based ingredients. A microbial treatment that suppresses visible mould growth may prevent additional toxin production under certain conditions, yet it does not demonstrate removal of toxin already present. A process marketed as antimicrobial, antifungal or preservative should not automatically be described as mycotoxin-detoxifying. Such a claim requires direct, compound-specific analytical evidence and appropriate safety assessment of reaction products.

4.2 Packaging, oxygen and water activity

Storage design influences fungal growth through temperature, water activity, oxygen availability and package integrity. Yet preventing subsequent fungal proliferation is not equivalent to eliminating a contaminant introduced upstream. For low-moisture ingredients such as paprika and seeds, a qualified supplier should demonstrate both preventive storage controls and representative incoming-lot analysis. For high-moisture tomato and fruit intermediates, time-to-processing, sorting, damaged-fruit rejection and process hygiene may be decisive. The intervention should match the hazard pathway rather than simply add another end-product test.

5. Analytical strategy: a tiered panel rather than a universal “negative”

Liquid chromatography coupled to tandem mass spectrometry, often following QuEChERS-style extraction, is a central technique for Alternaria toxin determination. However, method availability is uneven across the eight compounds and their conjugated forms. The EFSA opinion explicitly identifies shortages of analytical standards and harmonised methods. This limits both surveillance and the interpretation of apparent co-occurrence. [1]

A pragmatic programme can use three tiers. The first is a validated routine panel for well-characterised analytes in the company’s principal matrices. The second is targeted confirmation or expanded screening triggered by supplier changes, unusual climatic conditions, complaint investigations or anomalous chromatograms. The third is research-grade non-target analysis to investigate transformation products and poorly monitored perylene quinones. The tiers must not be misrepresented as equivalent regulatory tests: research screening may identify signals that are not yet quantifiable with validated accuracy.

Interlaboratory comparability deserves particular attention. Laboratories may report different results because of extraction efficiency, matrix suppression, standards, calibration ranges or data-treatment conventions. Blind proficiency exercises, matrix-matched quality controls and retention of raw chromatographic data can improve the credibility of supplier qualification. For low-level genotoxic compounds, an analytical false negative may matter more than a reassuring-looking certificate.

6. Exposure modelling: the missing bridge between a lot result and public health

Risk is shaped by the concentration of a toxin in food, the amount consumed, the consumer’s body weight, co-occurring dietary sources and the toxicological endpoint. EFSA identified substantial contributions from fruit products, cereals, vegetables, tomato-containing foods and, in some population groups, beverages and oils. Young children deserve particular attention because consumption relative to body weight can be high and because their diets may rely on a limited range of foods. [1]

A purchasing specification should not be built by simply copying a TTC value into a microgram-per-kilogram limit. Conversion requires an explicit consumption scenario and allocation of exposure among foods. For illustration only, if a consumer ingests 0.1 kg of a food daily and weighs 20 kg, a concentration of 1 µg/kg corresponds to 5 ng/kg body-weight/day from that food alone. This arithmetic is not a proposed limit, does not incorporate other dietary sources, and is not a complete risk assessment. It shows why small concentration figures can have different implications across age groups and use patterns.

Mixture effects remain a major unresolved issue. EFSA could not derive reference points suitable for assessing combined exposure to all eight toxins. Co-occurrence should therefore be documented, but no validated universal “Alternaria toxicity index” should be claimed. Until interaction data improve, an individual-analyte framework with explicit uncertainty is more defensible than an invented additive potency factor.

7. Legal architecture: European monitoring is not an EU maximum-level regime

7.1 European Union and Spain

Council Regulation (EEC) No 315/93 establishes general principles on contaminants in food; Regulation (EU) 2023/915 sets maximum levels for specified contaminants and commodities. As stated in EFSA’s November 2026 opinion, Alternaria toxins did not have specific EU maximum levels under those instruments at the assessment date. Commission Recommendation (EU) 2022/553 calls for monitoring of AOH, AME and TeA in selected foods and supports evidence gathering; it is not itself a binding maximum-level regulation. Independently, Article 14 of Regulation (EC) No 178/2002 prohibits placing unsafe food on the market, and Article 15 addresses feed safety. The absence of an Alternaria-specific numerical limit is not a blanket exemption from those obligations. [1,3–6]

In Spain, directly applicable EU food law operates alongside competent national and autonomous-community authorities and official controls. Food businesses should integrate emerging toxin hazards into their risk-based supplier approval and HACCP-related assessment where relevant. However, this article does not claim that EFSA’s scientific opinion automatically imposes a new mandatory analyte panel on every Spanish food business. Decisions must reflect the product, reasonably foreseeable hazard and applicable legal requirements.

7.2 Great Britain and Northern Ireland

Great Britain requires a separate assessment under its applicable domestic food-safety and contaminants legislation and the guidance of the Food Standards Agency and Food Standards Scotland. EU scientific opinions are highly relevant evidence but do not automatically amend GB law. Northern Ireland’s applicable arrangements must be assessed separately. An exporter should verify current GB and Northern Ireland rules for the exact commodity rather than assume an EU recommendation has identical legal status throughout the United Kingdom. [7]

7.3 United States and international trade

In the United States, the Federal Food, Drug, and Cosmetic Act’s prohibition of adulterated food and FDA’s risk-based oversight remain relevant even where no toxin-specific federal action level has been established for the compound and commodity. FDA action levels for other mycotoxins cannot be transplanted to Alternaria toxins. Exporters should confirm the current status of applicable FDA guidance and any commodity-specific requirements, and avoid equating the absence of an established numerical tolerance with an affirmative finding of safety. International trade dossiers should distinguish enforceable limits, advisory monitoring, buyer specifications and scientific screening values. [8]

8. Feed safety: a different exposure problem

EFSA’s animal-health findings do not map directly onto the human food assessment. For chickens for fattening, adverse effects from currently estimated AOH and AME exposures were considered unlikely; the Panel nevertheless could not fully exclude concern about TeA. For other species,

insufficient data prevented reliable risk characterisation for multiple toxins. The implications vary with lifespan, feed composition, species-specific metabolism and cumulative exposure. [1]

Feed suppliers should not interpret a reassuring result for broilers as validation for laying hens, pigs, aquaculture species or companion animals. A feed ingredient may be consumed continuously at a high proportion of the diet, making exposure allocation materially different from an occasional human-food ingredient. Supplier qualification should therefore integrate species, life stage, ration inclusion, storage history and analytical capability. Where an ingredient is shared between food and feed supply chains, specifications may need different justifications even if the source lot is identical.

9. Research & Innovation Opportunity

9.1 The unresolved problem

The gap is not that mycotoxin analytics, predictive modelling or fungal control are newly invented. Each has an established literature and commercial practice. The narrower, testable question is whether a traceable, process-aware surveillance architecture can predict consequential Alternaria-toxin exposure changes more accurately than periodic parent-compound testing alone, particularly when analytical censoring and transformation products are significant. The 2026 EFSA opinion makes this gap visible but does not validate any proposed platform. [1,9]

9.2 Proposed hypothesis and validation

Hypothesis (unproven): combining supplier genealogy, harvest and storage conditions, validated multi-analyte LC–MS/MS data, process mass balances, non-target transformation fingerprints and consumption-specific exposure models will improve detection of high-consequence lots and reduce unjustified rejection of low-risk lots. The model would be decision support, not an automated declaration of food safety.

A staged research programme should first review existing methods, patents and public disclosures to avoid novelty claims unsupported by prior-art analysis. Next, multicentre laboratories would analyse blinded representative lots of paprika, tomato intermediates, fruit products and oilseeds. Processing trials would compare matched input and output material, with recovery controls and measurement of water and solids balances. Independent toxicology teams would prioritise plausible transformation products without assuming that every unidentified peak is harmful. A prospective study would test whether risk classification remains stable across laboratories, seasons, supplier changes and method updates.

Predefined failure criteria are essential: missed consequential contamination, high false-negative rates, unstable predictions across laboratories, inability to trace test results to actual lots, or models whose apparent performance depends on inaccessible proprietary assumptions. Regulators would retain authority over legal compliance. The output, if validated, could be a reproducible supplier-qualification protocol and an evidence-gap map rather than a proprietary “detoxification” claim.

10. Industrial implications for companies and their markets

The immediate relevance for an ingredient developer and technical supplier lies in analytical specification, raw-material selection and formulation/process compatibility. Tomato preparations, fruit-based beverages, botanical extracts, spice ingredients, seed-derived products and feed materials may each require different analyte panels and exposure assumptions. It would be

inappropriate to infer from the EFSA opinion that any particular developed ingredient or process reduces Alternaria toxins; such performance would require product-specific controlled experiments.

A practical qualification programme would start with a matrix–hazard inventory and a ranked supplier map, then define which analytes are routinely measurable and which require specialist research laboratories. Contracts should specify reporting limits, analytical methods, sampling plans and notification duties for material changes. Product development should assess whether drying, concentration, filtration or fermentation shifts parent toxins or produces unknown transformation signals. Commercial teams should avoid claims such as “mycotoxin-free” unless the analytes, methods, detection capabilities and intended meaning are precisely defined.

The strategic opportunity is broader than selling a treatment. It is to provide customers with defensible evidence linking ingredient composition, process history, analytical uncertainty, intended use and legal status. In an environment where scientific concern may precede harmonised numerical limits, the ability to explain what a test result does, and/or does not prove is a substantive industrial capability.

11. Conclusions

EFSA’s November 2026 Alternaria assessment is a consequential scientific update because it reveals several simultaneous truths: genotoxic hazards exist; exposure to certain compounds exceeds screening thresholds; some abundant compounds have unresolved toxicological questions; and major analytical gaps prevent complete risk characterisation. These are not contradictions but distinct layers of an incomplete evidence system.

For food and feed manufacturers, the correct response is neither complacency nor a universal testing mandate invented from a scientific opinion. It is proportionate, traceable hazard control focused on the actual matrix, supplier and consumer. For research, the most valuable next step is to close the chain between parent toxins, transformation products, analytical uncertainty and realistic exposure. Regulatory judgement will remain necessary; better science can make that judgement more informative.

References and primary sources

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Evidence classification: EFSA hazard, occurrence and exposure findings are established assessment conclusions subject to stated uncertainty; processing and supplier-control recommendations are expert interpretation; the integrated surveillance architecture is an unvalidated research hypothesis. Regulatory descriptions reflect cited sources as checked on 19 November 2026.

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