

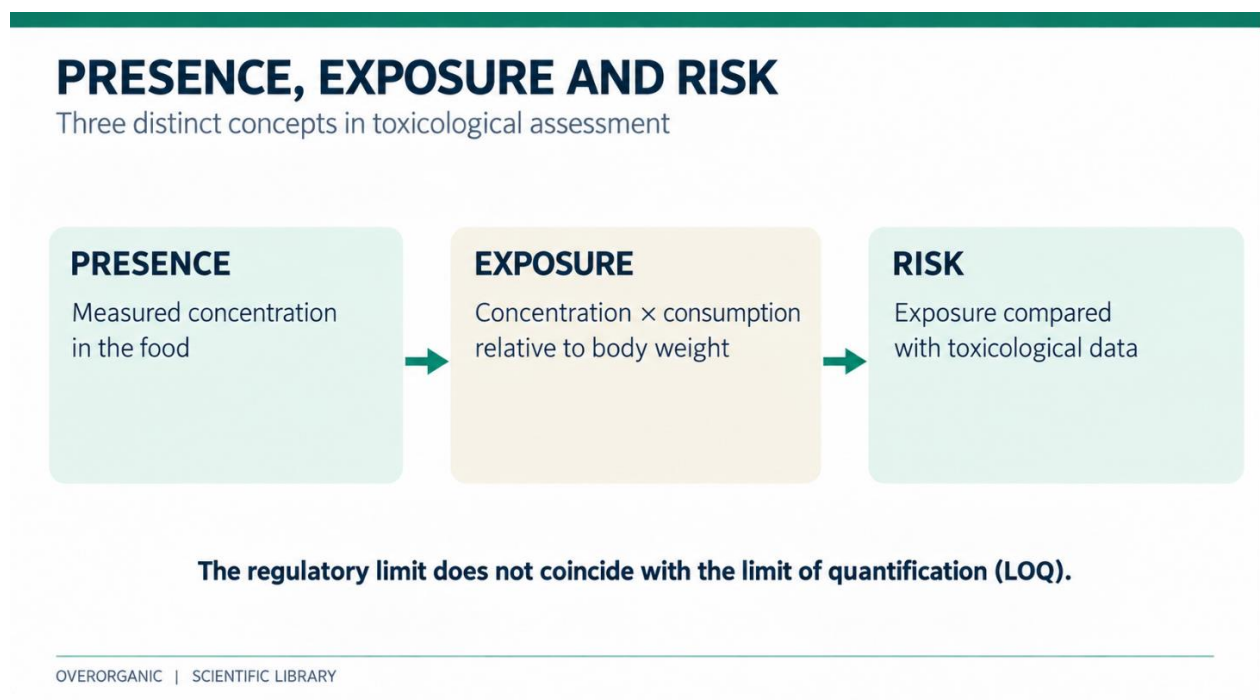
MYCOTOXINS AND HEALTH: RISKS, EU LIMITS AND CONTROLS

Mycotoxins are not a single toxicological hazard. The term encompasses substances that differ in chemical structure, target organs, severity of effects and the amounts required to produce them. Protecting health therefore calls for substance-specific assessment: knowing that a mycotoxin is present in food is not enough without its concentration, consumer exposure and toxicity.

PRESENCE, EXPOSURE AND RISK ARE NOT SYNONYMOUS

Presence is an analytical finding: it means a substance has been identified, potentially at a measurable concentration. Exposure also depends on how much food is eaten, how frequently and in relation to body weight. Health risk is assessed by comparing this exposure with evidence about the substance's effects, taking scientific uncertainties into account.

For example, the same concentration in a cereal may contribute differently to an adult's and a child's exposure because consumption and body weight differ. Equally, a rarely eaten food may contribute less to overall exposure than one eaten every day. A positive analytical result must therefore not automatically be equated with harm to health.



ACUTE AND CHRONIC EFFECTS

High exposure over a short period may cause acute effects, while repeated intake over time raises particular concerns about chronic toxicity. In either case the response depends on the specific mycotoxin. Aflatoxins, especially aflatoxin B1, warrant particular

attention because of their genotoxic and carcinogenic properties and their association with liver cancer. For substances with this profile the aim is to minimise exposure, without interpreting compliance with a legal limit as a guarantee of zero risk.

EFSA has assessed ochratoxin A mainly in relation to potential kidney effects and uncertainties about carcinogenicity. Deoxynivalenol (DON) may cause gastrointestinal effects and, at exposures relevant to chronic assessment, immune-system effects. Zearalenone has oestrogenic activity; fumonisins and T-2 and HT-2 toxins have different toxicological profiles. These differences explain why no single 'safe mycotoxin level' applies to all substances.

HOW EFSA ASSESSES RISK

Scientific assessments combine toxicity data, measured food concentrations and population food-consumption data. Where evidence allows, health-based guidance values can be established, such as tolerable daily intakes (TDIs) or acute reference doses (ARfDs), specific to a substance and type of effect. For genotoxic and carcinogenic contaminants, other approaches are often used, including the margin of exposure (MOE), which is neither a legal limit nor a threshold below which risk becomes zero.

Assessments also consider uncertainty: incomplete data, differences between individuals, modified forms and possible simultaneous exposure to several mycotoxins. However, available evidence on combined effects does not justify automatically attributing synergy to every mixture; specific assessments are needed.

WHAT EUROPEAN LIMITS ESTABLISH

Regulation (EU) 2023/915, as amended, sets maximum levels for certain mycotoxins in specified food categories. Its Annex distinguishes between products and uses, including certain commodities intended for further treatment and foods placed on the market for final consumers. No single limit therefore applies indiscriminately to all foods.

Maximum levels are risk-management instruments based on scientific assessment and the need to control contamination through measures that can realistically be implemented throughout the supply chain. Compliance is an essential legal requirement for foods to which a limit applies, but it does not mean the substance is absent or guarantee zero individual risk. Conversely, contamination below a limit does not make testing pointless.

Crucially, a maximum level for a food must not be confused with a tolerable intake, which concerns the body's exposure, or with the limit of quantification (LOQ), which describes a method's ability to measure a substance with adequate performance.

FROM BUSINESS SELF-CHECKS TO OFFICIAL CONTROLS

Primary responsibility for food safety rests with food business operators. Businesses must identify and manage relevant hazards through prevention, supplier verification, good practices and self-check systems based on HACCP principles where applicable. Official controls by competent authorities verify compliance and address non-compliance.

Sampling is particularly important for mycotoxins: an uneven distribution can make a single increment unrepresentative. Implementing Regulation (EU) 2023/2782 lays down sampling methods and preparation and analytical requirements used in official controls. Compliance assessments also consider technical factors such as recovery and measurement uncertainty.

When a non-compliant product is identified, consequences depend on the circumstances: an operator may need to prevent marketing, withdraw or recall products in accordance with the law; authorities may take action and exchange information, including via the European RASFF system. These mechanisms reduce consumer risk but do not replace prevention at source.

CHILDREN, FREQUENT CONSUMERS AND DIFFERENT DIETS

Exposure assessments examine different population groups. Children may consume more food relative to their body weight. Diets heavily reliant on a small number of raw materials may also influence exposure to a particular contaminant. Consequently, maximum levels for certain foods intended for infants and young children may be more restrictive, depending on the category and substance.

Individual consumers cannot rely on appearance as proof that food contains no mycotoxins. Protection comes from a combination of sound production practices, supply-chain testing, statutory limits and a varied diet, rather than a simplistic distinction between 'natural' and 'industrial' foods.

FROM COMPLIANCE TO KNOWLEDGE

EU controls are a fundamental element of food safety. However, compliance with an applicable limit answers a precise question: does the product meet that requirement? More extensive analysis can answer further questions: which mycotoxins were sought, at what concentrations were they measured and with what analytical limits? These two levels of knowledge are complementary, not opposed.

Correctly interpreting a certificate involves examining the matrix, sampling plan, target substances, measurement units, LOQ and any uncertainty together. A result 'below LOQ' does not demonstrate absolute absence: it indicates that the substance was not quantified above the threshold stated for the method.

IN SUMMARY

Mycotoxins require substance-specific assessments because their modes of action and potential severity differ. EU legislation sets maximum levels for certain toxin–food combinations, while operators and authorities carry out complementary controls. No single analytical result tells the whole story of a consumer's exposure: understanding what measurements mean and the limitations of testing is part of food safety.

SCIENTIFIC AND REGULATORY REFERENCES

- [EFSA – Mycotoxins: overview, risk assessments and exposure.](#)
- [EFSA – Aflatoxins in food.](#)
- [European Commission – Regulation \(EU\) 2023/915, consolidated text and subsequent amendments.](#)
- [European Commission – Implementing Regulation \(EU\) 2023/2782, sampling and analysis.](#)
- [European Commission – Sampling and analytical methods for contaminants.](#)
- [European Union – Regulation \(EU\) 2017/625 on official controls.](#)
- [European Union – Regulation \(EC\) 178/2002, general principles of food law.](#)