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Mycotoxins in European Union Regulations (2023-2025)

Sara Vitalini,[1] Marcello Iriti,[1] Lisa Vallone[2]

[1]Department of Biomedical, Surgical and Dental Sciences, University of Milan; [2]Department of Veterinary Medicine and Animal Sciences, University of Milan, Lodi, Italy

Abstract

Mycotoxins are secondary metabolites produced by fungi, mainly from the *Aspergillus, Penicillium* and *Fusarium* genera, under specific temperature and humidity conditions. They can enter the food chain through contaminated plant-based foods (*e.*g., cereals, legumes, dried fruits, herbs) and animal-derived products (*e.g.*, meat, dairy, eggs, honey) due to contaminated feed. This study analyzes the current European Union regulatory framework for mycotoxins, focusing on Regulation (EU) No. 915/2023 and subsequent amendments [Regulations (EU) No. 1022/2024, 1038/2024, 1756/2024, 1808/2024, 89/2025, and 691/2025] that define maximum levels and sampling procedures. Regulated mycotoxins include aflatoxins (B1, total B1+B2+G1+G2, M1), ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, T-2 and HT-2 toxins, citrinin, and *Claviceps* spp. alkaloids. The study highlights key updates in legislation, their impact on monitoring and compliance, and the need for ongoing research in the context of climate change to safeguard food safety and protect vulnerable populations.

Key words: secondary metabolites, animal nutrition, human nutrition, regulatory updates.

Correspondence: Lisa Vallone, Department of Veterinary Medicine and Animal Sciences, University of Milan, 26900 Lodi, Italy.
E-mail: lisa.vallone@unimi.it

Introduction

Mycotoxins are secondary metabolites produced by fungi (*e.g.*, *Aspergillus, Penicillium,* and *Fusarium*) as a defense mechanism in hostile environments influenced by various factors such as temperature, humidity, soil conditions, and agricultural practices (Khan, 2024). In particular, harmful mycotoxins include aflatoxins, especially aflatoxin B1, ochratoxin A, fumonisins, and deoxynivalenol, which often contaminate staple crops such as cereals, maize, and nuts, entering the human food supply and posing significant public health risks. Animals can also ingest contaminated feed, allowing mycotoxins to pass into the food chain through meat, milk, eggs, and other animal products (Li *et al.*, 2025). Mycotoxins can spread through the human food chain *via* contaminated food, either directly *via* crops consumed by humans or indirectly *via* animals that ingest contaminated feed, transferring toxins to animal products. The consumption of even small amounts of these toxins over time can lead to significant health effects. The impact of mycotoxins on human health can be profound, ranging from acute poisoning to long-term chronic diseases. Mycotoxins, such as aflatoxins, are potent carcinogens. Aflatoxin B1, in particular, has been implicated in the development of liver cancer, especially in regions where the consumption of contaminated food is widespread. The International Agency for Research on Cancer (IARC) has classified aflatoxin B1 as a group 1 carcinogen, meaning it is known to cause cancer in humans (IARC, 2012). Exposure to other mycotoxins, such as ochratoxin A and deoxynivalenol, can result in kidney damage, immune suppression, and gastrointestinal disorders (Mafe *et al.*, 2024; Li *et al.*, 2025; Magembe, 2025).

Vulnerable populations, such as children, pregnant women, the elderly, and individuals with pre-existing conditions, are especially at risk of experiencing harmful effects from these toxins (Awuchi *et al*., 2022; Coppock *et al.*, 2025). In recent years, climate change, with its associated disruptions to weather patterns, agricultural practices, and crop storage conditions, has increased the frequency, severity, and geographic distribution of fungal infestations, creating a growing public health challenge (Williams *et al.*, 2024). This study documents the maximum levels of mycotoxins in feed and food products, referencing the most recent (2023-2025) European regulatory framework. The comprehensive mycotoxin limits reflect the European Union (EU)'s risk analysis approach, balancing public health protection with practical considerations: i) maximum limits are established according to the ALARA ("As Low As Reasonably Achievable") principle, with stricter standards for high-risk products and vulnerable consumers; ii) by establishing differentiated limits at various processing stages, the framework promotes mycotoxin management throughout the entire food chain; iii) the regulations address multiple mycotoxins simultaneously, acknowledging their co-occurrence in many commodities and the need for comprehensive risk management (Mihalache *et al*., 2023; Khan, 2024; Pinton *et al.*, 2025).

Materials and Methods

For this study, EU regulations concerning mycotoxins in food products were analyzed. The research focused on the most recent legislative framework, following the repeal of Regulation (EC)

No. 1881/2006, which had long been a benchmark in the field (European Commission, 2006a). The new Regulation (EU) No. 915/2023 establishes maximum levels for specific mycotoxins, including aflatoxins, ochratoxin A, patulin, deoxynivalenol, zearalenone, fumonisins, citrinin, and sclerotia and alkaloids of *Claviceps* spp. This regulation introduces significant updates, improves the readability of provisions, and sets new standards for monitoring these toxins in foodstuffs.

In addition, we considered subsequent amendments, including Regulations (EU) 1022/2024, 1038/2024, 1756/2024, 1808/2024, 89/2025, and 691/2025, which further define or supplement the maximum levels of mycotoxins (European Commission, 2024a, 2024b, 2024c, 2024d, 2025a, 2025b). For sampling and analysis procedures, the relevant methods established in Regulations (EU) 401/2006, 2782/2023, and 885/2024 were applied (European Commission, 2006b).

This focused approach allowed us to evaluate the regulatory impact on mycotoxin monitoring and compliance in food products, providing insights into the current EU legislative landscape.

Results and Discussion

New maximum levels have been set out in the Annexes of the previously cited Regulations (EU), stating that foodstuffs exceeding these limits for contamination may not be placed on the market or used as raw materials or ingredients in feed and food production. In systems where the production and processing of cereals are integrated so that all incoming batches are cleaned, sorted, and processed in the same establishment, the maximum levels were applied to unprocessed cereals at the stage of the production chain prior to first processing [Article 2(4), European Commission, 2023].

For dried, diluted, processed or compound food (*i.e.*, consisting of more than one ingredient), Article 3(1) of the same Regulation takes into account the following aspects when the relevant maximum levels were applied to them: i) changes of the concentration of the contaminant caused by drying or dilution processes; ii) changes of the concentration of the contaminant caused by processing; iii) the relative proportions of the ingredients in the product; iv) the analytical limit of quantification.

The food business operator is obliged to provide and justify the specific concentration, dilution, or processing factors for the operations in question, as well as the proportion of the ingredients used for the mixing operations [Article 3(2)]. If the operator does not provide the necessary factors, or if the competent authority deems them unsuitable, the authority itself defines them based on available information, pursuing the objective of maximum public health protection.

A comprehensive overview of maximum mycotoxin levels is reported in *Supplementary Table 1*, while the main regulatory patterns are summarized below.

Dried fruits, nuts and oilseeds

The regulatory approach implements dual standards for these products, with higher aflatoxin B1 limits permitted for products "to be subjected to sorting or other physical treatment" (5.0-8.0 µg/kg) compared to those "for direct human consumption" (2.0-6.0 µg/kg). Particularly stringent controls apply to specific high-risk commodities like pistachios (8.0 µg/kg before processing *vs.* 2.0 µg/kg for direct consumption) and hazelnuts. This differentiated approach acknowledges that processing steps can significantly reduce mycotoxin contamination while enabling practical trade in raw agricultural commodities.

Herbs and spices

Uniform aflatoxin B1 limits of 5.0 µg/kg apply across dried herbs and spices, with total aflatoxin limits of 10.0 µg/kg. However, the framework recognizes specific risk factors for certain products, establishing higher ochratoxin A limits for certain spices (15.0-20.0 µg/kg). Notably, licorice extracts in confectionery receive special consideration (80.0 µg/kg for products containing >97% licorice extract), acknowledging the concentration effect during processing while maintaining consumer safety.

Cereals and cereal-based products

The most elaborate regulatory structure applies to cereals, with tiered limits for multiple mycotoxins reflecting both their dietary importance and susceptibility to fungal contamination. Key patterns include: i) processing stage differentiation – significantly higher limits for unprocessed cereals (*e.g.*, deoxynivalenol at 1250-1750 µg/kg in unprocessed wheat and corn) compared to processed products for direct consumption (750 µg/kg); ii) cereal-specific approaches – different cereals receive tailored limits based on their susceptibility to specific mycotoxins, with stricter T-2/HT-2 toxin limits for oat products (150 µg/kg) compared to other cereals (100 µg/kg); iii) supply chain progression – a progressive reduction in acceptable levels through the production chain, exemplified by fumonisins in maize (4000 µg/kg in unprocessed corn, 2000 µg/kg in products for final consumption, and just 200 µg/kg in infant foods).

Milk and products for infants and young children

The most stringent controls apply to products for vulnerable populations, particularly infants and young children. Aflatoxin M1 in infant formulas is limited to 0.025 µg/kg (half the limit for regular milk), ochratoxin A to 0.50 µg/kg in infant cereals, and patulin to 10 µg/kg in apple-based infant foods (*vs.* 50 µg/kg in adult products). This reflects both the heightened vulnerability of these populations and the application of the precautionary principle.

Beverages

The regulatory approach for beverages considers both processing effects and consumption patterns. Ochratoxin A limits vary between coffee types (8.0 µg/kg for roasted beans *vs.* 3.0 µg/kg for instant coffee), while patulin limits in apple juice (50 µg/kg) balance typical consumption with adequate health protection.

Supplements in special products

Regulation (EU) No. 915/2023 has undergone important changes regarding mycotoxins, introducing more stringent levels

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for several mycotoxins compared to previous regulations, particularly for aflatoxins in specific nut categories, ochratoxin A in spices, and T-2/HT-2 toxins in cereal products, reflecting the EU's commitment to ensuring greater food safety based on updated scientific evidence (European Commission, 2023). As for deoxynivalenol and T-2/HT-2 toxins, Regulations (EU) No. 1022/2024 and 1038/2024 made critical clarifications (European Commission, 2024a, 2024b): since some unprocessed cereals (oats, barley, maize, wheat) are placed on the market with the tegument before milling or before being used in products intended for the final consumer, the maximum content must now be applied to grains with the tegument, even if it is not edible. This addresses an important regulatory gap regarding how cereals are assessed at different stages in the supply chain.

Regulation (EU) No. 1756/2024 subsequently amended the T-2 and HT-2 toxin levels specifically for bakery products containing oats, reducing the qualifying percentage from 90% to 75-85% (European Commission, 2024c). This modification acknowledges the practical formulation of oat-based bakery products while maintaining appropriate safety standards.

The subsequent Regulation (EU) No. 1808/2024 amends Regulation (EU) No. 915/2023 specifically regarding the implementation timing for reduced maximum levels of ergot sclerotia and ergot alkaloids in food (European Commission, 2023, 2024d). Importantly, food that has been lawfully placed on the market before implementation may remain on the market until its minimum shelf life or expiry date, providing a practical transition period for industry compliance.

The regulatory framework for sampling and analysis methods has also been comprehensively updated. Regulation (EU) No. 401/2006 has been repealed and replaced by Regulation (EU) No. 2782/2023 (European Commission, 2006b). These updates harmonize analytical approaches with modern laboratory capabilities and ensure consistent enforcement across member states.

Regulation (EU) No. 885/2024 further amends Regulation (EU) No. 2782/2023, establishing specific sampling and analysis methods for dried herbs, herbal infusions, dried tea products, and powdered spices, acknowledging the unique analytical challenges these matrices present.

The last regulatory framework (2025) integrates novel foods by incorporating emerging food sources, as evidenced by specific provisions for UV-treated yellow mealworm larvae (*Tenebrio molitor*) and vitamin D2-containing mushroom powder (European Commission, 2025a, 2025b).

Currently, the European Commission is considering further reductions to maximum permitted levels in cereals, particularly proposing to reduce fumonisin limits in maize grain by 83%. As maize is the main ingredient in cattle, pig, and poultry feed, this would have significant implications for the entire food chain, including animal-derived products.

The regulatory landscape for mycotoxins continues to evolve in response to scientific advances and emerging concerns. Several developments are expected: i) as climate change alters the distribution and prevalence of toxinogenic fungal species and related mycotoxins, regulatory frameworks will likely require further adaptations (adaptation to climate change); ii) increased attention to 'masked' or modified mycotoxins may lead to more comprehensive regulatory approaches (modified mycotoxins); iii) human biomonitoring data could increasingly inform exposure assessment and risk-based regulation (Integration of biomarkers); iv) further international alignment of mycotoxin regulations could develop to facilitate global trade while maintaining robust consumer protection (harmonisation efforts). Although the full impact of these recent regulatory changes cannot yet be fully assessed, due to their recent introduction, they represent a significant advance in the EU's scientific approach to mycotoxin control, with important implications for food safety, international trade, and consumer protection. These examples highlight how the EU framework progressively differentiates maximum levels according to food category, processing stage, and consumer vulnerability, ensuring both public health protection and market feasibility.

Conclusions

In this study, we analyzed the current EU regulatory framework for mycotoxins, focusing on Regulations (EU) No. 915/2023 and subsequent amendments. Our findings highlight the key updates in maximum levels and sampling procedures, which directly influence mycotoxin monitoring and compliance in food products. The analysis shows that these regulations provide a clearer and more structured approach for managing mycotoxin risks, supporting food safety, and protecting public health.

While mycotoxins remain a significant threat – especially in the context of climate change – our study demonstrates how the updated legislative framework can guide effective mitigation strategies. Implementing sustainable agricultural practices and coordinated One Health approaches is essential to address these challenges comprehensively.

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Online supplementary material:
Supplementary Table 1. Comprehensive overview of maximum mycotoxin levels in food products.

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