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Framework on risk prioritisation of mycotoxins in food: a case study in two wheat-based products

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Abstract

In its simplest form, risk is the product of hazard, i.e. toxic potency of a chemical substance, and exposure, or dose. Hazard-based decision-making is based solely on hazard without any consideration of exposure. The development of mitigation strategies should prioritise mycotoxins that regularly occur at undesirable levels in commonly consumed commodities, wherein both the toxicological profiles and effectiveness of mitigation are understood with a reasonable degree of certainty. This manuscript presents a framework for risk prioritisation of mycotoxins in food, integrating hazard assessment, exposure evaluation, and for the first time appraisal of mitigation strategies. More specifically, by (1) identifying the mycotoxins relevant for each food categories, by (2) assigning a severity score for the pivotal effect of each mycotoxin; by (3) calculating the respective food-categories' contributions to the combined exposures and by (4) assessing the existing mitigation strategies, the framework aims to prioritise mycotoxins based on their health risks and potential for effective risk mitigation. As a proof of concept, the framework was applied in two wheat-based food commodities – bread and pasta –, focusing on Ochratoxin A (OTA), Deoxynivalenol (DON), and Zearalenone (ZEN), revealing that OTA in bread is the highest priority concern, followed by DON in bread.

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risk prioritisation – mitigation – mycotoxins – deoxynivalenol – Ochratoxin A – zearalenone – pasta – bread

1 Introduction

Mycotoxin contamination can occur at multiple stages throughout the food production chain, posing significant concerns from the handling of raw materials to the distribution of finished products. Foods of animal origin, such as meat, eggs, milk and dairy products, may also be impacted due to carryover effects when animals consume contaminated feed.

Ensuring the safety of both raw materials and final products requires strict monitoring and quality control measures across the entire supply chain. The increasing complexity of global supply networks exacerbates the risk of mycotoxin contamination, underscoring the importance of robust traceability systems and effective supplier management (Krska *et al.*, 2016).

Climate change further complicates the management of mycotoxins. Warmer and more humid conditions favour the development of mycotoxin producing fungi, potentially leading to higher contamination levels (Nešić, 2018). Shifts in environmental conditions may alter the prevalence of fungal species, thereby changing the patterns of encountered mycotoxins. The food industry must adapt to these evolving risks by developing new strategies for crop cultivation, storage and processing.

Regulatory authorities worldwide have established stringent limits for acceptable levels of specific mycotoxins in food and feed, making regulatory compliance a critical priority for the industry (Codex Alimentarius Commission, 1995; European Commission, 2023b; Food and Agriculture Organization of the United Nations, 2004). Numerous others are currently under risk assessment, while advances in analytical techniques continue to reveal additional variants, highlighting the need for ongoing vigilance. Navigating this regulatory landscape requires substantial investments in analytical testing and quality assurance infrastructure to avoid legal penalties, product recalls, and reputational damage.

The socio-economic impact of mycotoxin contamination is considerable. Contaminated crops may be rendered unsuitable for sale or export, resulting in reduced yields and financial losses (Leslie *et al.*, 2021). Consumer confidence is also at stake. Associations between a brand and mycotoxin contamination can lead to decreased sales and long-term reputational harm. Transparent communication regarding testing protocols and safety measures is essential to maintaining public trust.

In summary, mycotoxins represent a multifaceted threat to the food industry, encompassing public health risks, food security and nutrition, economic burdens, regulatory challenges, supply chain vulnerabilities and climate-related pressures.

Given this landscape, there is an urgent need for tools that enable the agri-food sector to prioritise risks effectively. In this paper, a pragmatic prioritisation approach is described to focus monitoring and mitigation efforts on those mycotoxins that pose the greatest risks in terms of consumers exposure.

2 Framework methodology

Risk prioritisation is a critical process in food safety management, aimed at identifying and ranking hazards based on their known and potential health risks. This process helps in efficiently allocating resources to mitigate the most significant risks, ensuring the safety of the food supply. Chemical contaminants in food can originate from various sources, including agricultural practises, food processing, packaging, and environmental pollution. Effective risk prioritisation involves a systematic assessment of these contaminants to protect public health.

The objectives of risk prioritisation can vary depending on the stakeholders involved, such as researchers, food authorities, or other relevant regulators. Each group may have different goals and approaches: Food Safety Authorities' goal is to identify chemical contaminants of higher concerns for future risk assessments or necessary updates. Regulators want to determine the most relevant safety standards and regulations based on scientific evidence to mitigate the risks potentially caused by chemical contaminants of higher concerns. Researchers aim to identify emerging chemical contaminants of higher concerns and new areas of research. Furthermore, they try to address the gaps identified in the hazard profile of chemicals of high concerns and develop adequate analytical capabilities to better estimate their risks.

The scope of a risk prioritisation exercise can be tailored to address specific questions or concerns. This flexibility allows for a more focused and relevant assessment. The scope can be adjusted by limiting to certain hazard types focusing on specific classes of contaminants, by targeting specific foodstuffs, and by considering only specific population groups (age, gender, dietary habits…, etc.). By adjusting the scope, risk prioritisation can provide more precise and actionable insights, enabling stakeholders to make informed decisions and implement effective risk management strategies.

Harm framework

A rapid overview of the existing literature on risk prioritisation identified several publications and reviews on the topic, aiming at prioritising chemical hazards.

Although there is no harmonised guidance on a harm severity / criticality scale, our literature review identified some commonalities between the proposed harm scales in order to justify that an adverse effect is more severe than another. In these papers, authors defined own rules to address the severity / criticality of the hazards, based on (a) a certain degree of pragmatism as regard to the variety of adverse effects the hazards are potentially responsible for likely reflecting a generic common sense, and (b) an unavoidable degree of subjectivity of what appears at higher concern than another.

Thus, these papers prioritised hazards that are reported to be potentially responsible for irreversible effects over transient adverse effects (Hanlon *et al.*, 2016; Mc Kernan *et al.*, 2019; Stroheker *et al.*, 2017). Similarly, hazards for which no threshold appears to exist were prioritised over hazards responsible for threshold adverse effects (Li *et al.*, 2021; Mc Kernan *et al.*, 2019; Stroheker *et al.*, 2017). And finally, life threatening acute adverse effects were prioritised over chronic ones (Li *et al.*, 2021; Mc Kernan *et al.*, 2019).

Our framework therefore proposes to use similar reasoning to distinguish three possible harm severity scores as follows:

- Harm score 1: Hazards responsible for transient and threshold adverse effects.
- Harm score 2: Hazards responsible for irreversible and threshold adverse effects on organs and/or systems, includes threshold carcinogenic and reprotoxic substances.
- Harm score 3: Life threatening acute toxicants and Hazards responsible for irreversible and non-threshold adverse effects, i.e. includes genotoxic carcinogens.

The expert group discussed the approach of considering the order of magnitude of the derived human health protective values, as suggested by some publications (Li *et al.*, 2021; Mc Kernan *et al.*, 2019), but decided to not use it, as another input for the harm score would put too much emphasis on non-threshold hazards. Indeed, it is assumed that the level of concern associated with non-threshold adverse effects is already reflected by the harm severity scale presented above and also addressed in some ways by the exposure scale component discussed further in this paper.

Exposure framework

The respective risk levels posed by different hazards can only be assessed in relation to the exposure levels of the studied population to these hazards, according to the familiar principle of Risk = Hazard × Exposure.

In the context of establishing a risk prioritisation matrix, this requires a rigorous assessment of the exposure levels of the studied population to the various hazards to be compared to their respective toxicological reference points.

A combined exposure assessment considers all known sources and routes of exposure with toxicological relevance – from oral to respiratory and dermal – for each of the hazards studied. Only the fulfilment of this last condition would allow the determination of the relative weight of each exposure route to the overall exposure.

As the scale for exposure scoring in the prioritisation scheme, our framework uses the combined exposure occupancy of hazards respective maximum levels assumed to be of no or low human health concerns.

For threshold adverse effects, the level of no concern, also named Health Based Guidance Value (HBGV) are determined from the analysis of the dose-response relationship and the use of adequate uncertainty factors as defined in hazard characterisation guidelines (World Health Organization, 2009).

In the absence of a health-based guidance value (HBGV) available, i.e. when a Margin of Exposure (MoE) approach was used by an Expert Panel, the concept of indicative HBGV (iHBGV) suggested by the Irish Food Safety Authority (Mc Kernan *et al.*, 2019) and Stroheker *et al.* (2017) may be applied. An iHBGV can be calculated from the benchmark dose lower bound (BMDL) determined for a defined excess risk by considering the minimum MoE that would then be reasonably considered as of low concern, according to the formula:

$$\text{iHBGV} = \text{BMDL}/\text{MoE of low concern}$$

For a given population studied, the hazard exposure score components of the risk prioritisation matrix are obtained by dividing the hazards combined exposure levels by their respective HBGVs or iHBGVs.

$$\text{Exposure score} = \text{Combined exposure level} / (\text{HBGV or iHBGV})$$

The exposure score component is aimed to be capped at one when the iHBGV is matched or exceeded.

Prioritisation based on total dietary exposure estimates

For food and beverages, dietary exposure estimates to hazards rely on food consumption surveys on the one hand and their occurrence data in foods on the other hand.

To this end, the European Food Safety Authority (EFSA) has compiled in a unique platform (data.europa.eu) of the latest national dietary surveys conducted across Europe, relying on a unique food classification system FoodEx 2 (FoodEx2 revision 2 | EFSA (europa.eu)). The food consumption database displays reliable information on the intakes of different foods and beverages per subgroups of population of same age ranges. Default body weight values exist to be considered for different population age groups (EFSA, 2012).

Depending on analytical capabilities in different food and beverage matrices, sampling plans (European Commission, 2023a) allow the determination of the distribution patterns of hazards and identification of foodstuffs of high concerns (International Agency for Research on Cancer (IARC), 2009).

Together with sufficient hazards occurrence data generated in different and representative foodstuffs that compose a human diet, the food intake levels are necessary to estimate the total dietary exposure by applying the following formula:

$$\text{Total dietary exposure} = \Sigma(\text{Foodstuff intakes} \times \text{Occurrence}) / \text{Body weight}$$

The total dietary exposure of natural toxins estimated by EFSA and other Expert Panels are the basis for risk characterisations.

Prioritisation per food commodity of the FoodEx2 food classification system

The FoodEx2 food classification system has been constructed to allow the refinement of the risk prioritisation exercise at more detailed food commodities levels and up to very specific food raw materials once sufficient and reliable foodstuffs intakes and hazard occurrence data are available.

Introducing a higher degree of detail would allow to compare the relative contribution of different food commodities to the total dietary exposure of hazards included in the scope of the problem formulation. Thus, this second step of the exposure assessment is of particular interest to identify food categories significantly contributing to the hazard's total dietary exposures.

The Codex Committee on Food Additives and Contaminants (CCFAC) defines foods or food groups as significantly contributing to the total dietary exposure of a hazard (Food and Agriculture Organization of the United Nations, 2009)

- In case it contributes ≥10% of the tolerable intake (or similar health hazard endpoint) in at least one WHO Global Environment Monitoring System (GEMS)/Food cluster diets.
- Or in case it contributes ≥5% of the tolerable intake (or similar health hazard endpoint) in two or more WHO GEMS/Food cluster diets.
- Or, on a case-by-case basis, if the foodstuff has a significant impact on the exposure for specific groups of consumers, although exposure may not exceed 5% of the tolerable intake.

At this stage, it is worth mentioning that WHO GEMS/Food defines for instance three main cluster diets G07, G08 and G15 in western and central Europe and that therefore a food contributing to more than 5% of the tolerable intake based on EFSA consumption database and European occurrence data is likely to be a significant contributor according to CCFAC definition.

Our framework proposes to use the relative contribution of each foodstuff investigated as regards to the total dietary exposure of a hazard as Food Contribution Score based on the formula:

$$\text{Food contribution score} = \text{Food exposure} / (\text{HBGV or iHBGV})$$

$$\text{where Food exposure} = \text{Food intake} * \text{Food hazard occurrence level} / \text{Body weight}$$

Mitigation framework

Possible further refinement of the risk-based prioritisation obtained from the combination of the Harm and Exposure scores discussed above is suggested below. By considering (a) the currently existing and scientifically validated mitigation options, their effectiveness and their level of implementation to date in the prevention of natural toxins development in crops and reduction of the extent of the contamination across the value-chain, as well as (b) a qualitative appraisal of the future foreseen trends on the occurrence of the different mycotoxins per crops and geographies due to climate change, this mitigation section aims to provide to the risk prioritisation assessors a way to transform a rather static risk prioritisation exercise based on currently observed occurrence data into a predictive model incorporating documented trends for future mycotoxins occurrence levels.

In this section, a framework is proposed to determine a mitigation score based on several criteria that the assessors can decide to apply, alone or in combination, based on expert judgement and in alignment with the scope of the risk prioritisation exercise. These criteria can be divided into groups:

- Criteria related to the most suitable mitigation options available *before further processing of raw materials*, in terms of:
  – Cost / Effectiveness of toxigenic fungal species control at farm level and during storage of the raws
  – Availability and sensibility of early-detection tools for the respective hazards
  – Hazards' existing regulatory standards, foreseen sustainability over time and resilience towards climate change
- Criteria related to possible *further mitigation at food business operator and final consumer levels*, in terms of:
  – Effectiveness of contaminants reduction from the processing of the raw materials to produce the different food commodities considered in the scope of the assessment, including physical steps and heating treatments. This criterion is only applicable if the occurrence data used to determine the exposure scores are only available for raw materials and not available for the final food commodities to be ranked.
  – Effectiveness of cooking treatments on foodstuffs during meal preparation

A final mitigation score is obtained from the average of different scores considered as follows:

$$\text{Mitigation Score} = \Sigma(\text{mitigation criteria}) / \text{n assessed criteria}$$

The proposed mitigation score is aimed to reflect the levels of effectiveness and implementation of the most suitable mitigation options existing to reduce contaminants prevalence in foodstuffs, subject that the mitigation options are of course adequate for the following human consumption by not introducing other hazardous compounds and are authorised in the country where applied.

To balance the risk-based prioritisation scores anticipated to range from 0 to 3 from the combination of Harm and Exposure scores, and where 3 represents the highest level of priority, our framework proposes to use a similar scale with possible scores ranging from 0 – fully implemented and effective mitigation options – to 3 – absence of mitigation option or to be implemented.

For couples of hazards and food commodities sharing a close risk-based prioritisation level, the application of the mitigation score is therefore anticipated to distinguish where to allocate efforts to further develop and implement mitigation actions to allow extra consumer protection.

3 Framework application: case study using three mycotoxins in two wheat-based products

The exercise displayed below consists of a risk prioritisation of mycotoxins naturally occurring in Europe, and also worldwide, in two wheat-based products: bread and pasta. As a proof of concept, our work included three toxicological data rich and regulated mycotoxins in the scope, namely Deoxynivalenol (DON), Ochratoxin A (OTA) and Zearalenone (ZEN).

Case study – harm framework application

To determine the harm score of the selected mycotoxins, the group did not perform a thorough hazard characterisation but instead relied on latest official opinions from the European Food Safety Authority.

The mycotoxin DON is one of the trichothecenes compounds mainly produced by several toxigenic fungal species of *Fusarium* genus and predominantly detected in cereal grains such as wheat, barley, oats, rye and maize. The toxin is also commonly found in cereal-based foods owing to its chemical and thermal stability. Human exposure to DON may cause general toxic effects and immunotoxicity. In acute DON toxicity, exposed individuals may have high temperature, nausea, vomiting, diarrhea, abdominal discomfort, and dizziness. The current Tolerable Daily Intake (TDI) value set by the European Commission for DON together with its acetylated and modified forms is 1 µg/kg bw per day (Knutsen *et al.*, 2017). By establishing a scale of three increasing levels, a harm score of one was assigned to DON' transient and reversible adverse effects.

OTA is produced by several toxigenic fungal species of *Aspergillus* and *Penicillium* genera, contaminating various food commodities (Schrenk *et al.*, 2020). OTA targets mainly the kidneys causing nephrotoxicity. In addition, the toxin is known for its genotoxicity, but it is still unclear whether DNA damage is caused through indirect or direct effects. For the characterisation of these effects, EFSA calculated two $BMDL_{10}$ of 4.73 and 14.5 µg/kg bw/d for non-neoplastic kidney lesions in pigs and kidney tumours in rats, respectively. A MoE greater than 200 is considered as of low health concern regarding non-neoplastic effects, while a MoE of 10,000 and above would be considered as of low health concern for genotoxic carcinogens. A harm score of three was assigned to OTA's irreversible and non-threshold adverse effects.

ZEN is a resorcylic acid lactone compound produced primarily by different *Fusarium* species, contaminating maize and occasionally in other crops like wheat, barley, sorghum, and rye. The toxin was also detected in processed food as it is resistant to most standard food-processing methods. This non-steroidal estrogenic mycotoxin poses hormonal imbalance because of its binding activity to estrogenic receptors. The current TDI value for ZEN and its modified forms is 0.25 µg/kg bw per day (EFSA Panel on Contaminants in the Food Chain (CONTAM), 2016). A harm score of two was assigned to ZEN's irreversible threshold adverse effects.

Case study – exposure framework application

In the context of the present exercise of risk prioritisation of mycotoxins, the predominant, if not exclusive, route of exposure is undoubtedly the oral route through food and, to some extent, beverages. Therefore, for the purpose of this exercise, the levels of exposure estimated through total dietary exposure assessments available in the literature are directly comparable to their respective HBGVs / iHBGVs. Otherwise, to determine whether the studied population is at risk of overexposure or not, risk assessments need to consider other sources of exposure by including for example buffer zones covering other sources of exposure.

Prioritisation based on total dietary exposure estimates

Here, the total dietary exposure estimates available in recent EFSA opinions on natural toxins were used and compared to the respective hazards' HBGVs / iHBGVs in order to determine the exposure scores components of the framework. Conversely to other contaminants that are ubiquitous in all food samples, mycotoxins (a) can be present in a limited number of products and (b) have a high proportion of left censored data points in analytical assays, justifying to consider the dietary exposure estimates that were calculated using the Lower Bound (LB) approach, i.e. with all results below the Limit of Detection (LoD) considered as devoid of contaminations.

Herein, in the children subpopulation group, EFSA concluded a health concern for OTA and DON in high-end exposed consumers (Knutsen *et al.*, 2017; Schrenk *et al.*, 2020). In other words, the respective HBGVs / iHBGVs are indicated to be exceeded for these two mycotoxins. Therefore, exposure scores of one are attributed to OTA and DON in children.

In case of ZEN, EFSA concluded that the high-end exposed children's consumers at the 95th percentile are not at risk of overexposure and estimated a total dietary exposure of 22 ng/kg bw/d (median LB), representing 9% of the HBGV (EFSA, 2011). Therefore, exposure score of 0.09 is attributed to ZEN in children.

Prioritisation per food commodities of the FoodEx2 food classification system

In Europe, the weighted average intakes of 'Bread and similar products' and 'Pasta, dough and similar products' were, respectively, estimated to be 110 g and 38 g (EFSA, 2025) per day for other children from the results of all national surveys available in the EFSA Food Consumption statistics database.

According to the different EFSA opinions, the respective average occurrence levels of DON, OTA and ZEN at the Lower Bound were 68.7 (Knutsen *et al.*, 2017), 0.09 (Schrenk *et al.*, 2020) and 0.2 (EFSA, 2011) µg/kg of Wheat Bread and 81.6 (Knutsen *et al.*, 2017), 0.09 (Schrenk *et al.*, 2020) and 0.6 (EFSA, 2011) µg/kg of Pasta, respectively.

These inputs were used to determine the respective Food Contribution Scores to the respective reference values of the studied mycotoxins (Table 1).

TABLE 1 Calculation of the food contribution score for children considering an average body weight of 23.1 kg

Hazard	Foods	Occurrence levels (µg/kg)	Food intake (kg)	Exposure from foods (ng/kg bw)	Reference dose	HBGV/iHBGV (ng/kg bw per day)	Food contrib score ©
DON	Bread	68.7	0.110	327	TDI	1000	33%
DON	Pasta	81.6	0.038	134	TDI	1000	13%
OTA	Bread	0.09	0.110	0.428	BMDL10	1.45	30%
OTA	Pasta	0.09	0.038	0.148	BMDL10	1.45	10%
ZEN	Bread	0.2	0.110	0.952	TDI	250	1%
ZEN	Pasta	0.6	0.038	0.987	TDI	250	1%

Based on the available information in the literature it was observed that both Bread and Pasta are significantly contributing to the total dietary exposure of at least two out of the three hazards included in the exercise.

Based on this new input, the risk ranking prioritisation of mycotoxins in the selected food commodities is indicating that the mitigation of OTA in bread (score of 0.90) is of highest priority; but that the mitigation of DON in bread (score of 0.33) is possibly of higher impact than OTA in pasta (score of 0.30).

Case study – mitigation framework application

In the present exercise, it is a given that Good Agriculture Practices for growing, harvesting of crops and storage of grains are already applied. Examples include selection of crop varieties with fungal resistance, appropriate use of fungicides, ensuring crops are stored at recommended moisture levels and so on.

Regarding the criteria related to the most suitable mitigation options available before further processing of wheat, no major differences in mitigation performances could be observed between the three mycotoxins included in the scope of the exercise. For instance: (i) milling processing is similarly effective in terms of reducing the contamination level from the raw materials to the milled product (Lancova *et al.*, 2008; Peng *et al.*, 2015; Pinton *et al.*, 2019), (ii) in Europe, DON, OTA and ZEN are all covered by maximum limits in grains as required from the regulation 2023/915 (European Commission, 2023), (iii) existing early-detection tools and analytical techniques are sensitive enough to meet respective existing maximum limits.

In summary, maintaining again a three-level increasing scale, the following scores have been attributed for DON, OTA and ZEN in wheat:

- Cost / Effectiveness fungal development prevention at field level and during storage of the crops: N/A since the scope of the assessment covered only one crop, wheat
- Availability and sensibility of early-detection tools for the respective hazards: score of one was applied for DON, OTA and ZEN, given that the existing analytical capabilities are adequate to demonstrate compliance
- Hazards' existing regulatory standards, foreseen sustainability over time and Resilience towards climate change: score of two was applied for DON, OTA and ZEN, given that they are all regulated and, from what is currently available in the scientific literature, there is a tendency to assume for the time being a similar impacts of climate change in Europe.

Regarding the criteria related to possible further mitigation at food business operator and final consumer levels, those are more interesting to determine as some differences can be observed for DON, OTA and ZEN:

- Effectiveness of mycotoxin reduction from the processing of grains to produce the different food commodities, in the present case wheat-based Bread and Pasta: N/A since the exposure scores determined above considered occurrence levels directly in bread and pasta. There is no need here to apply corrective factors to the mycotoxin occurrence levels in wheat grains.
- Effectiveness of cooking treatments on foodstuffs during meal preparation: Main differences are observed for this score:
  - A score of three is proposed for all hazards in bread as it can be consumed as is
  - Scores of one and two are, respectively, proposed for DON and OTA in pasta as the cooking in boiling water (just boil it and discard the excess water and not cook it with other ingredients, such as when preparing pasta in broth where water is not finally discarded) (Cano-Sancho *et al.*, 2013; Vidal *et al.*, 2015; Visconti *et al.*, 2004) is anticipated to reduce the final consumer exposure level due to their hydrophilicity, while a score of three is proposed for ZEN in absence of a fully documented and reported reduction.

TABLE 2 Calculation of the mitigation scores

Children		Mitigation framework individual sub-scores					Final score
Hazard	Foods	Field/storage	Analytics	Regulations and resilience	Industrial processing	Consumer processing	
DON	Bread	N/A	1	2	N/A	3	2
DON	Pasta	N/A	1	2	N/A	1	1.3
OTA	Bread	N/A	1	2	N/A	3	2
OTA	Pasta	N/A	1	2	N/A	2	1.7
ZEN	Bread	N/A	1	2	N/A	3	2
ZEN	Pasta	N/A	1	2	N/A	3	2

TABLE 3 Overview of the different scores from the harm, exposure and mitigation framework, as well as the final prioritisation score and rank of the hazard-food category for children

Children		Harm framework	Exposure framework		Mitigation framework	Final prioritisation	
Hazard	Food	Severity score (A)	Total diet exposure score (B)	Food contrib score (C)	Mitigation score (D)	Scores A * B * C * D	Rank
DON	Bread	1	1	0.33	2	0.66	2
DON	Pasta	1	1	0.13	1.3	0.17	4
OTA	Bread	3	1	0.30	2	1.80	1
OTA	Pasta	3	1	0.10	1.7	0.51	3
ZEN	Bread	2	0.09	0.01	2	0.004	5
ZEN	Pasta	2	0.09	0.01	2	0.004	5

Table 2 displays the respective mitigation criterion and calculation of the mitigation scores for each hazards/food commodity couples.

Case study – learnings from the exercise

In the proof of concept discussed above, the application of mitigation scores to each couple Hazard – Food Commodity had only a slight impact on the final risk ranking, as it can observed in the Table 3. This is explained by the scope of the exercise, on one hand limited to three well-known regulated mycotoxins, and on the other hand investigating only two food commodities made from the same cereal: wheat. However, it is expected that the proposed mitigation framework makes a higher impact on the final risk ranking when assessing more diverse hazards, including emerging mycotoxins, as well as more diverse foodstuffs from different cereals and geographical harvest origins.

While the three mycotoxins included in the scope are mitigated through strict maximum limits, the risk prioritisation framework allowed to identify the couples – Hazard / Food commodity – of highest priority for continued mitigation using a concrete example and supported by publicly available data.

For a food business operator, the outcomes of the exercise conducted above can serve for instance: (a) at sourcing level and upon margin of maneuver, as the basis to negotiate tighter raw material specifications for the production of bread over pasta with wheat' suppliers or (b) at storage and manufacturing stages, as a need to allocate more resources in the identification and deployment of innovative technologies to prevent OTA and DON over ZEN and allow extra-consumer protection.

4 Final discussion and conclusion

The framework described previously can be endlessly adapted as long as the data available to the evaluator is sufficiently precise to draw conclusions from it. The tool's main strength is its versatility in the choice of data to be considered, allowing for instance comparisons between supply zones with different contamination histories, as well as between geographies with different consumption patterns reflecting dietary habits specific to each group of individuals.

Emerging mycotoxins represent an evolving challenge for food safety risk assessment. While the current framework focuses on regulated toxins such as DON, OTA, and ZEN, expanding its application to emerging compounds such as Enniatins (ENNs), Beauvericin (BEA), and Alternaria toxins (e.g. alternariol, tentoxin) would significantly strengthen its predictive capacity. Although these compounds are not yet comprehensively regulated, evidence of their widespread occurrence and potential health effects is increasing.

Regarding the characterisation of the hazard and the associated risk level, the tool may encounter an initial limitation when comparing hazards with very different levels of knowledge, bringing together mycotoxins with well-documented toxicological profiles and more emerging ones for which literature data may be non-existent, or limited to a low weight of evidence. Here, the use of predictive models can serve as a substitute to assign the appropriate severity level to these emerging mycotoxins. And, while scientific literature is increasingly focusing on the combined effects of simultaneous exposure to multiple hazards, the tool would benefit from being adapted to take these new data into account.

Regarding the assessment of exposure levels in relation to their respective toxicological reference values or other benchmarks, again the tool can encounter a limitation in the quality and quantity of available data. Uncertainties related to variability of mycotoxins levels amongst samples/batches, the sensitivity of analytical methods specific to each mycotoxin and each food matrix can accumulate with those related to sampling plans and the non-ubiquitous nature of this family of contaminants in foods at risk of contamination. The high level of non-detection of these hazards requires the use of large datasets, which can limit the prioritisation exercise to comparisons between well-documented food groups rather than at a more refined detail level. Furthermore, depending on the individual diets, consumption rates of selected food groups may vary.

Finally, climate change is increasingly recognised as a major factor influencing fungal growth patterns and mycotoxin contamination profiles. Rising temperatures, altered precipitation patterns, and increased frequency of extreme weather events can shift the geographic prevalence and seasonal intensity of toxigenic fungi. To future-proof the proposed risk prioritisation framework, integration of climate-driven risk modelling should be considered in the mitigation framework. Incorporating predictive models based on regional climate scenarios would enable dynamic updating of mycotoxin risk rankings. This approach would allow food safety management to move from a static to a climate-resilient dynamic system, anticipating future contamination risks and supporting more effective, forward-looking mitigation planning.

As a proof of concept, the risk prioritisation framework was applied using literature data focusing on the mycotoxins OTA, DON and ZEN in wheat-based products, specifically bread and pasta. It highlighted the importance of continued mitigation efforts. Ochratoxin A (OTA) in bread emerged as the highest risk, followed by Deoxynivalenol (DON) in bread.

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Authors' contribution

Conceptualisation: previously done by the members of the ILSI Europe task force group

Methodology: MS, MO, EV, AM, MFA

Validation: MS, MO, EV, MFA

Formal analysis: MO, EV, MFA

Resources: KJK

Writing – original draft preparation: MS, MO

Writing – review and editing: MS, MO, EV, AM, MFA, KJK, AMV, AS, CH

Supervision: MS, KJK, MM

Project administration: KJK

All authors have read and agreed to the published version of the manuscript.

Conflict of interest

This is an ILSI Europe activity from its Food Contaminants Task Force group. Authors declare no conflict of interest.

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