MYMATCH

Deliverable 4.2
Baseline exposure scenarios under different dietary habits

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Nature of the deliverable		
R	Document, report	X
DMP	Data Management Plan	
DATA	Data sets, microdata, etc	
ETHICS		
DEC	Websites, patent filings, videos, etc	
OTHER		

Dissemination level		
PU	Public (*fully open*)	
SEN	Sensitive (*limited under the conditions of the Grant Agreement*)	X
EU CI	EU Classified (*eu-restricted, eu-confidential, eu-secret under Decision 2015/444*)	

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Project's summary

Climate change amplifies food safety risks by fostering the proliferation of pathogens and contaminants in the food supply chain and introducing unfamiliar or novel hazards.

Among the food safety threats, because of their ubiquity, MYMATCH will consider the effects of climate change on a selection of mycotoxins (related to fungi belonging to *Aspergillus*, *Fusarium*, and *Alternaria*) occurring in maize, wheat, tomato, and nuts.

Thanks to a strong and multi-actor partnership, MYMATCH will contribute to:

1. the prediction and mitigation of risk related to fungi and mycotoxin occurrence,
2. the assessment of mycotoxins exposure in humans (concerning different diets) and animals, and
3. the implementation of proper risk management measures.

This will be achieved with data collection taking place at different levels, from literature considering events that happened in the past, under controlled environments and open fields, enabling the generation of the missing datasets needed to fulfil the project aims.

This will support the development and implementation of fungi and mycotoxin predictive models founded on accurate climate change scenarios to anticipate the changes in mycotoxin occurrence in European food systems.

MYMATCH AI mycotoxin management Platform will be the final output, the support for all food system actors with tailored predictions, recommendations, and mitigation approaches. By using this platform, the agri-food researchers, farmers, industry stakeholders, and policymakers, involved in the project through the MYMATCH's Multi-Actor Framework, will be assisted in taking

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threat-mitigation initiatives and in decision-making, both in the short- and strategic long-term planning.

MYMATCH tools and methods will be generated in a way that is easily extendable to other contaminant issues and co-created and developed with a strong interaction with potential users like EFSA.

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Document Objectives

Deliverable D4.2 aims to define, characterise, and critically appraise the current European baseline for dietary exposure to mycotoxins, establishing the methodological reference point for scenario-based exposure modelling within the MYMATCH project. The deliverable consolidates regulatory practice, data infrastructures, and exposure assessment methodologies used in the European Union, while explicitly identifying their strengths, limitations, and areas of uncertainty.

Specifically, D4.2 seeks to:

- consolidate the regulatory, methodological, and institutional frameworks governing mycotoxin exposure assessment at EU and international level, with reference to EFSA guidance and practices;
- describe and compare deterministic and probabilistic exposure assessment approaches, including the treatment of left-censored data and the integration of mixture and cumulative exposure concepts;
- map and critically assess the dietary consumption data sources currently available in Europe, highlighting issues of harmonisation, temporal relevance, and population coverage;
- define the current EFSA-derived baseline exposure scenario for major regulated mycotoxins (aflatoxins, ochratoxin A, deoxynivalenol, zearalenone, fumonisins, and T-2/HT-2 toxins), identifying population groups with higher relative exposure;
- evaluate data gaps and methodological constraints affecting exposure estimates, including occurrence data quality, dietary survey limitations, and uncertainties related to emerging and modified mycotoxins;
- assess the applicability and limits of burden-of-disease metrics for mycotoxins in Europe, distinguishing between compounds for which DALY estimation is scientifically justified and those for which it is not;

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- integrate and document the methodological curation of the HOLIFOOD-CHEFS database as a scenario-ready occurrence data backbone, highlighting cross-project interoperability within the Horizon Europe ecosystem; and
- provide the methodological foundation for subsequent MYMATCH activities, notably WP7 (advanced exposure forecasting), WP8 (emerging toxins and mixture assessment), and WP10 (policy integration and risk communication).

Executive Summary

Deliverable D4.2 defines and characterises the current European baseline for dietary exposure to mycotoxins, establishing the methodological reference point for scenario-based exposure modelling within the MYMATCH project. Anchored in EFSA guidance and regulatory practice, the deliverable consolidates how exposure to major regulated mycotoxins is currently assessed in the European Union and identifies both the strengths and structural limitations of the existing framework.

The report confirms that Europe possesses a highly developed regulatory and analytical infrastructure for mycotoxin exposure assessment, based on harmonised methodologies, extensive monitoring data, and comprehensive food consumption databases. Deterministic exposure modelling, implemented through EFSA-aligned tools such as DietEx, remains the regulatory standard for baseline assessments, ensuring transparency and comparability across Member States. Probabilistic approaches, operationalised through platforms such as MCRA, provide more detailed characterisation of variability and uncertainty when harmonised microdata are available, but their

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routine application remains constrained by data availability and computational requirements.

Baseline exposure estimates derived from EFSA scientific opinions indicate that, for most consumers, chronic exposure to major regulated mycotoxins remains below health-based guidance values (HBGVs). However, vulnerable population groups - particularly infants and toddlers - consistently exhibit higher relative exposure, with upper-bound estimates for certain mycotoxins (notably DON and T-2/HT-2 toxins) approaching or exceeding toxicological reference values. For genotoxic carcinogens such as AFB_1 and OTA, even low mean exposures translate into potential health concern under the MoE framework, highlighting narrow safety margins and sensitivity to small changes in contamination patterns or dietary behaviour.

A central contribution of D4.2 is the integration and methodological curation of the HOLIFOOD-CHEFS database as a scenario-ready occurrence data backbone. Through systematic cleaning, filtering, and quality-based refinement, HOLIFOOD-CHEFS is transformed from a large-scale monitoring repository into an operational dataset suitable for exposure and scenario modelling. This work exemplifies cross-project interoperability within Horizon Europe, linking outputs from HOLiFOOD and EFSA data infrastructures to MYMATCH modelling needs, while explicitly acknowledging that improved occurrence data alone cannot resolve toxicological or epidemiological gaps.

The deliverable also critically evaluates the applicability of burden-of-disease metrics. Quantitative DALY estimation is shown to be scientifically justified only for AFB_1, for which validated exposure–response relationships and epidemiological data exist. For other mycotoxins, the absence of causal risk–outcome pairs, disease incidence data, and disability weights precludes reliable

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burden estimation, and risk characterisation appropriately remains anchored to HBGVs or MOE thresholds.

Overall, D4.2 demonstrates that the European baseline for mycotoxin exposure should be interpreted not as a fixed or definitive estimate, but as a dynamic reference shaped by data quality, methodological choices, and evolving external drivers such as climate change and global trade. By clearly delineating what the current baseline can and cannot support, the deliverable provides the methodological hinge for subsequent MYMATCH activities, enabling WP7 (advanced exposure forecasting), WP8 (emerging toxins and mixture assessment), and WP10 (policy integration and risk communication). Strengthening data stewardship, harmonisation, and modelling coherence emerges as a prerequisite for transforming static baseline assessments into a climate-resilient and forward-looking framework for mycotoxin risk assessment in Europe.

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List of abbreviations

AF — Aflatoxins

AFB_1 — Aflatoxin B_1

AFM_1 — Aflatoxin M_1

ARfD — Acute Reference Dose

AW — Water Activity

BoD — Burden of Disease

$BMDL_{10}$ — Benchmark Dose Lower Confidence Limit for a 10% response

BW — Body Weight

CAG — Cumulative Assessment Group

CHEFS — CompreHensive European Food Safety database

CRA — Cumulative Risk Assessment

DALY — Disability-Adjusted Life Year

DCF — Data Collection Framework (EFSA)

DON — Deoxynivalenol

DOM-1 — De-epoxy deoxynivalenol

EEA — European Environment Agency

EFSA — European Food Safety Authority

ELISA — Enzyme-Linked Immunosorbent Assay

EU — European Union

FAIR — Findable, Accessible, Interoperable, Reusable (data principles)

FB_1 — Fumonisin B_1

FoodEx2 — EFSA Food Classification and Description System

FERG — Foodborne Disease Burden Epidemiology Reference Group

GBD — Global Burden of Disease

HBV — Hepatitis B Virus

HBGV — Health-Based Guidance Value

HCC — Hepatocellular Carcinoma

HI — Hazard Index

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HPLC — High-Performance Liquid Chromatography

JECFA — Joint FAO/WHO Expert Committee on Food Additives

LB/MB/UB — Lower, Middle, Upper Bound scenarios

LC — Left-Censoring

LC–MS/MS — Liquid Chromatography Tandem Mass Spectrometry

LOD/LOQ — Limit of Detection / Limit of Quantification

MCRA — Monte Carlo Risk Assessment platform

MLE — Maximum Likelihood Estimation

MOE — Margin of Exposure

OTA — Ochratoxin A

PAF — Population Attributable Fraction

PF — Processing Factor

PRISMA — Preferred Reporting Items for Systematic Reviews and Meta-Analyses

RPF — Relative Potency Factor

ROS — Regression on Order Statistics

SSD2 — Standard Sample Description, version 2

TDI/TWI — Tolerable Daily Intake / Tolerable Weekly Intake

TeA — Tenuazonic Acid

T-2/HT-2 — Type A trichothecenes (T-2 and HT-2 toxins)

WHO — World Health Organization

YLD — Years Lived with Disability

YLL — Years of Life Lost

ZEN — Zearalenone

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1. Landscape: how exposure to mycotoxins is currently assessed in the EU and beyond

Exposure assessment of mycotoxins in the food chain represents a major challenge at the intersection of toxicology, analytical chemistry, food-consumption science and regulatory risk assessment. Mycotoxins—secondary metabolites of moulds—are found ubiquitously across plant-derived foods (and via carry-over in animal-derived foods). Given their potential adverse health effects (carcinogenicity, immunotoxicity, nephrotoxicity) even at low levels, robust exposure assessment is essential to underpin risk management decisions and protect public health. The landscape of dietary exposure assessment to mycotoxins has evolved considerably in the European Food Safety Authority (EFSA)/EU context over the past two decades, yet substantial methodological, data and interpretative challenges remain.

What follows is a detailed review of (1) the regulatory backbone in the EU and the key institutional frameworks, (2) how occurrence and monitoring of mycotoxins are structured (including emerging toxins), (3) how left-censoring (non-detects) is handled in practice, and (4) the global context and major European projects that underpin or extend the EU approach. These topics set the stage for subsequent detailed discussion of exposure-assessment methodologies, toolchains, software comparisons and limitations linked to data availability and quality.

1.1 Regulatory backbone (EU)

1.1.1 Institutional and legislative framework

In the European Union, assessment of mycotoxin exposure is firmly anchored in EFSA's scientific opinions and databases, which provide the reference point for regulatory decision-making by the European Commission (EC) and Member

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States. EFSA's Panel on Contaminants in the Food Chain (CONTAM) plays the central role: its mandate includes assembling occurrence data, consumption data, toxicological evidence (hazard identification and characterisation) and exposure assessment for natural contaminants such as mycotoxins.

From the regulatory side, the keystone is Regulation (EC) No 1881/2006 which sets maximum levels (MLs) for certain contaminants including some mycotoxins in foodstuffs. For example, AFB1 and total AF, OTA, DON, FUM, ZEN, and T-2/HT-2 in defined food categories. Sampling and analytical methodology are set out in implementing regulations (e.g., Regulation 401/2006) to ensure harmonised controls across Member States.

1.1.2 Consumption and classification standards

EFSA supports exposure assessment via its **Comprehensive European Food Consumption Database**, which collates individual-level food consumption surveys from Member States and stratifies by age class, country, survey period and other variables. Foods are coded using the **FoodEx2** classification system, an EU-wide harmonised taxonomy that enables alignment of consumption data with occurrence/monitoring data and processing-factor mapping. Through FoodEx2, comparability (and thus aggregation) across different national surveys is facilitated. EFSA further provides the tool DietEx for chronic exposure estimation in deterministic mode. (While public details about DietEx are limited, EFSA lists it under "Tools and resources".)

1.1.3 Risk assessment integration

EFSA's scientific opinions on various mycotoxins (e.g., AF, DON, OTA, ZEN) use combined occurrence and consumption data, applying exposure models aligned with regulatory thresholds, such as tolerable daily intakes (TDIs) or MOE approaches for genotoxic carcinogens. The assessments then support EC decision-making on whether MLs remain appropriate, or whether monitoring/surveillance strategies need revision. For example, EFSA's work on

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AF has emphasised that exposure should be “as low as reasonably achievable” (ALARA) given the genotoxic/carcinogenic nature.

1.1.4 Strengths and gaps in the regulatory backbone

Strengths:

- A well-defined legislative framework with MLs in place and harmonised across Member States.
- Use of harmonised consumption and classification tools (FoodEx2) allows pan-European exposure modelling and comparability.
- Continuous data collection and EFSA leadership ensure assessments are updated as new data emerge. For example, the EFSA topic page on mycotoxins clearly shows updated scientific opinions and the ambition to re-assess as new evidence becomes available.
- Presence of clear methodological guidance from EFSA on assessment practices, uncertainty, and data quality.

Gaps / areas for improvement:

- While MLs exist for many classic mycotoxins, emerging toxins (e.g., *Alternaria* toxins, phomopsins, sterigmatocystin, citrinin) remain less fully regulated or have limited monitoring data. For example, the EC catalogue lists monitoring recommendations for these emerging toxins.
- The representativeness and harmonisation of occurrence data across Member States (and across time, commodity, processing) can be variable. Survey methodologies differ, and linking occurrence data to consumption classes via FoodEx2 categories still poses challenges in practice.
- The regulatory backbone supports deterministic exposure modelling well, but probabilistic (distributional) modelling and mixture assessment integration are less embedded in legislation (though research frameworks are advancing).

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- Data timeliness and adaptability to influence of climate change (e.g., shifts in mycotoxin prevalence due to altered fungal ecology) remain concerns. EFSA itself links mycotoxin risks with climate change in its topic page.

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1.2 Occurrence, monitoring and scope of mycotoxin exposure assessments

1.2.1 Regulated mycotoxins vs emerging ones

Historically, exposure assessment has concentrated on a core suite of mycotoxins: AFB1, AFB2, AFG1, AFG2, OTA, DON and its acetylated/sulfated forms, T-2/HT-2, FB1, FB2, and ZEN. These compounds have robust toxicological characterisation and MLs established under Regulation 1881/2006.

However, the scope is widening. The European Commission's contaminants catalogue on mycotoxins states that following EFSA opinions, monitoring recommendations have been extended to sterigmatocystin, ergot alkaloids, phomopsins, citrinin, and *Alternaria* toxins. These compounds present new exposure assessment challenges: lower volumes of occurrence data, often higher LC, potentially distinct toxicological endpoints and limited processing-factor information.

1.2.2 Monitoring frameworks and data collection

Monitoring of mycotoxins in food (and feed) rests on national/regional surveillance, targeted sampling, regulatory controls, and harmonised analytical methods. For instance, the "Guidance document on identification of mycotoxins and plant toxins in food and feed" provides criteria for confirmatory analysis (LC-MS/MS and other methods) and defines minimum performance requirements. The EC catalogue lists Commission Regulation 401/2006 (sampling and analysis methods), Commission Recommendation 2012/154/EU on ergot alkaloids, and other measures.

In parallel, academic and project-based occurrence datasets augment regulatory monitoring. For example, the H2020 projects MyToolBox and MycoKey (see Section 4) generated open data and tools relevant to occurrence, early-warning and exposure modelling.

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1.2.3 Linking occurrence to exposure assessment

To compute dietary exposure, occurrence (i.e., concentration of mycotoxin in food/commodity) must be linked to consumption data (via FoodEx2), processing factors (to reflect reduction or concentration through treatment, cooking, storage) and body-weight/age-class stratification. In practice, occurrence datasets often have high proportions of results below the LOD/LOQ (left-censoring). The right handling of these non-detects is critical because substitution or naive handling can bias mean or high-percentile estimates (upwards or downwards). We will explore this in depth in a later section.

1.2.4 Climate change, supply chain/international trade and emerging risks

A further dimension to the exposure landscape is the dynamic nature of mycotoxin occurrence in the context of climate change and shifting production/processing patterns. Additionally, EU trade and import patterns influence exposure: raw materials imported from outside the EU may carry different mycotoxin burdens, which in turn affect processed foods consumed intra-EU. For example, the EU–China partnership via MyToolBox/MycoKey underscores cross-regional contamination flows (see Section 4).

1.2.5 Strengths and current challenges

Strengths:

- Continuous monitoring backed by legislative compulsory controls ensures the availability of occurrence data (though variable quality).
- The extension to “emerging” toxins shows regulatory/scientific responsiveness and signals future shifts in exposure assessments.
- Projects like MyToolBox and MycoKey generate novel data/ICT tools, improving upstream chain control and ultimately the exposure base.

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Challenges:

- Representativity: Occurrence data may be biased towards non-compliance, hotspot years, specific commodities/regions—making population-wide exposure modelling more uncertain.
- Left-censoring (many ND/LOQ values) is significant in mycotoxin datasets.
- Processing factors are often missing or uncertain for many commodities and toxins (especially emerging ones).
- Data often lag temporally; the dynamics of climate change or new supply-chain practices may not yet be reflected.
- Co-occurrence of mycotoxins (mixture effects) is still under-represented in monitoring datasets.

1.3 Handling nondetects / left-censoring in exposure assessment

In the assessment of dietary exposure to mycotoxins, left-censoring (LC) refers to analytical results reported as "below the limit of detection (LOD)" or "below the limit of quantification (LOQ)". Because occurrence datasets for mycotoxins often contain large fractions of ND/LOQ values, the way these are treated has material impact on exposure distributions, risk characterisation and uncertainty quantification.

1.3.1 EFSA baseline approach (2010 onward)

In its 2010 guidance "Management of left-censored data in dietary exposure assessment of chemical contaminants"[1], EFSA recommended the classical lower bound / middle bound / upper bound (LB/MB/UB) substitution approach:

LB: nondetects = 0.
MB: nondetects = ½ LOD (or ½ LOQ) depending on context.
UB: nondetects = LOD (or LOQ).

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These scenarios are computed to bracket plausible exposure ranges under different assumptions about undetected occurrences. The guidance also notes stratification prior to pooling, and that when LC is very high (say >60 % of results) the interpretation of UB becomes unstable.

The comparison of the main approaches adopted for left-censored data is reported in Table 1.

Table 1: *Comparison of methodological approaches for handling left-censored data in dietary exposure assessment, summarising data requirements, potential bias, transparency, and statistical robustness. The classical LB/MB/UB substitution approach is shown alongside more advanced model-based methods increasingly applied in refined exposure assessments.*

Approach	Data requirement	Bias potential	Transparency	Statistical robustness
LB/MB/UB substitution	Minimal	High (esp. UB at >60 % ND)	High	Low–Moderate
LOQ cut-off substitution	Moderate	Reduced (less inflation)	High	Moderate
MLE (lognormal/gamma)	≥5–10 quantifiable	Low (if fit adequate)	Moderate	High
ROS / semi-parametric	≥5 quantifiable	Low–Moderate	Moderate	Moderate–High
Multiple imputation / Bayesian	Large & hierarchical	Low	Lower (complex)	Very high

1.3.2 Advances: LOQ cut-off and model-based methods

Recognising that simple substitution may introduce bias - especially when LOQs vary widely across laboratories or years - EFSA and the research community have moved toward more advanced treatment. For example:

- A “LOQ cut-off” approach: high LOQs (above a threshold) may be considered “not sufficiently informative” and excluded or treated differently to avoid artificial inflation of UB estimates. This helps reduce over-conservatism when large proportions of data are reported at high LOQs.
- Model-based approaches: parametric maximum-likelihood estimation (MLE) of censored distributions (lognormal, gamma) or non-parametric methods (e.g., ROS) better exploit the data structure, use the actual distribution of values above LOQ, and reduce bias compared with substitution approaches. For example, EFSA’s recent external scientific report on exposure modelling[2] illustrated such strategies.

1.3.3 Key practical issues and trade-offs

Sample size and distributional fit: Model-based methods require adequate sample size (including sufficient non-censored values) and diagnostic check of distribution assumptions. In many mycotoxin-occurrence datasets, the structure (many NDs, few quantified positives) limits model applicability or reduces confidence in parameter estimates.

Heterogeneity of LOQs: Different labs/years/commodities may have different LOD/LOQ limits, making pooling tricky. High heterogeneity can obscure the true underlying distribution of contamination.

Impact on exposure percentiles: Especially for high-percentile exposure estimates (e.g., 95th percentile), the UB scenario under substitution can be overly conservative if many values are ND; conversely, naïve exclusion of ND values can underestimate. The choice affects risk characterisation (e.g., comparing exposure to TDI).

Transparency and reproducibility: Use of LB/MB/UB remains simple and transparent; model-based methods require statistical expertise and clear

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documentation of assumptions and diagnostics. For regulatory assessments, EFSA emphasises uncertainty analysis and justification of chosen approach.

1.3.4 Strengths and deficiencies of current practice

Strengths:

- The EFSA substitution-based approach provides a consistent baseline across assessments and allows comparability among different mycotoxin dossiers.
- Increasing awareness of the methodological limitations has driven adoption of better statistical approaches and improved reporting of LOD/LOQ in occurrence datasets.

Deficiencies / research gaps:

- Many occurrence datasets simply do not report exact LOD/LOQ per sample, or report values aggregated by commodity or year—hindering refined censoring treatment.
- Model-based methods are under-utilised in many regulatory assessments, often for pragmatic reasons (lack of quantifiable values, heterogeneity, time constraints).
- There is limited guidance on how to handle extremely high censoring (e.g., >90 %) when model fit is poor.
- Exposure assessments for emerging mycotoxins (with even fewer quantifiable values) face particularly acute censoring and require bespoke approaches (e.g., mixture modelling with imputations).

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1.4 EU initiatives, platforms and global context

1.4.1 EU platforms: MCRA and data-tools

One of the significant enablers of advanced exposure assessment in the EU is the probabilistic modelling platform MCRA (Monte Carlo Risk Assessment), developed by National Institute for Public Health and the Environment (RIVM) and Wageningen University & Research (WUR), in collaboration with EFSA (https://mcra.rivm.nl/mcra/#/). MCRA allows probabilistic assessment of exposure distributions, acute and chronic exposures, and mixture modelling of contaminants including mycotoxins. The platform supports FoodEx2 classification, processing factors, correlation of consumption/occurrence and numerous scenario analyses, thus moving beyond deterministic point estimates.

1.4.2 Horizon EU/FP7/H2020 projects: MyToolBox, MycoKey

The H2020 project MyToolBox ("Safe Food and Feed through an Integrated ToolBox for Mycotoxin Management" - https://www.mytoolbox.eu) addressed the full chain from forecasting, monitoring, detection, post-harvest interventions, decision support and stakeholder engagement. The project emphasised user-friendly e-platforms, early-warning systems and integrated approaches to reduce contamination and thereby exposure.

Similarly, the MycoKey project ("Integrated and innovative key actions for mycotoxin management in the food & feed chain" - http://www.mycokey.eu) extended the approach, linking EU and China, developing ICT tools, on-site detection, chain management strategies and knowledge-transfer.

These projects contribute to exposure assessment indirectly by generating better occurrence data, forecasting tools (which can inform scenario modelling), and interventions that may shift exposure distributions (thus influencing baseline/before vs after comparisons). They also highlight the

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international dimension of mycotoxin exposure (e.g., trade flows, climate change, emerging toxins).

1.4.3 Global context: WHO, Codex and trade

On the global stage, the World Health Organization's GEMS/Food (Global Environment Monitoring System – Food Contamination Monitoring and Assessment Programme[1]) provides a framework for global occurrence data, dietary exposure modelling and risk assessment of chemical contaminants. While not specific to mycotoxins in every case, its architecture and methodology underpin many international comparisons and provide data when EU-specific datasets are lacking. Additionally, the Codex Alimentarius Commission sets international standards for analytical method validation, MLs for certain mycotoxins and guidance on submission of occurrence/exposure data for risk assessment[2]. These global systems inform and complement EU approaches, especially when imported commodities or global trade patterns influence exposure. For example, the MyToolBox–China collaboration addressed differing occurrence profiles in Chinese raw materials and import implications for the EU.

1.4.4 Strengths and limitations of the initiative landscape

Strengths:

- The EU initiative ecosystem (EFSA tools, MCRA, Horizon projects) fosters methodological evolution, data-sharing, stakeholder engagement and international collaboration.

[1] *Available at: https://extranet.who.int/gemsfood/?DisplayFormat=1*
[2] *Available at: https://www.fao.org/fao-who-codexalimentarius/thematic-areas/contaminants/en/*

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- The linkage between monitoring, chain control, modelling and risk assessment is increasingly explicit—allowing exposure assessments to better reflect real-world dynamics and potential mitigation.
- Global partnerships (e.g., EU–China) recognise that exposure assessment cannot treat the EU in isolation—raw material imports, global supply chains and climate change influence the internal EU picture.

Limitations:

- Even with these initiatives, many exposure modelling tasks still rely on legacy data or monitoring programmes not designed for probabilistic/mixture modelling, thus constraining innovation.
- Uptake of advanced tools (e.g., model-based LC methods, mixture modelling) into mainstream regulatory assessments is slower than methodological research.
- The international standardisation of occurrence data (LOD/LOQ, sampling frameworks, processing factor documentation) remains fragmentary, limiting comparability across jurisdictions and over time.
- The pace of climate-driven change in mycotoxin occurrence may outstrip the update frequency of exposure models, leading to lagged risk characterisation.

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2. Methodological Framework for Dietary Exposure Assessment of Mycotoxins

2.1 Conceptual basis and structure

Exposure assessment quantifies the internal dose an individual or population receives through dietary intake of a contaminant. For mycotoxins, this assessment forms one of the four pillars of risk assessment (hazard identification, hazard characterisation, exposure assessment, and risk characterisation), as defined in Regulation (EC) No 178/2002 and codified in EFSA's *Guidance on Exposure Assessment*[3–5]

In quantitative terms, dietary exposure (E) is expressed as:

$$E_{i,f} = \frac{C_{i,f} \times O_f \times PF_f}{BW_i}$$

where

$C_{i,f}$ = consumption of food f by individual i (kg food/day),

O_f = mean or distribution of mycotoxin concentration in that food (µg/kg food),

PF_f = processing factor accounting for degradation or concentration,

BW_i = body weight (kg).

Aggregating across foods yields the individual's total exposure per contaminant. Chronic exposure is the long-term mean daily intake (mg/kg bw/day); acute exposure represents a single-day high intake or contamination event.

2.2 Deterministic (point-estimate) approach

- *Definition and rationale*

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Deterministic exposure assessment uses single values (usually mean or percentile statistics) for each input variable to produce a single estimate or limited set of scenario estimates (e.g., LB/MB/UB). It represents the standard baseline method for regulatory assessments in the EU, ensuring transparency, reproducibility, and comparability across contaminants and populations.

EFSA applies deterministic methods extensively in its CONTAM opinions[3,6–8]. Data are extracted from the EFSA Chemical Contaminants Database and combined with consumption information from the EFSA Comprehensive Food Consumption Database, mapped through FoodEx2 hierarchy levels[9,10].

- *Input data and harmonisation*

Food consumption data are harmonised at the FoodEx2 level; body-weight defaults (e.g., 70 kg adults, 23 kg children) are consistent with EFSA guidance. Occurrence data are processed using the *left-censored data management* approach (EFSA 2010), providing LB/MB/UB concentration scenarios.

Deterministic chronic and acute exposure are therefore expressed as:

$$E_{\text{chronic}} = \frac{\sum_f \bar{C}_f \times \bar{O}_f}{BW}$$

$$E_{\text{acute}} = \frac{\sum_f P95(C_f) \times P95(O_f)}{BW}$$

where:

$E_{chronic}$ is the chronic dietary exposure (µg/kg bw/day);

E_{acute} is the acute dietary exposure (µg/kg bw/day);

C_f is the mean daily consumption of food f in the population group considered (kg food/day);

O_f is the mean contaminant concentration in food f, typically derived under LB/MB/UB scenarios (µg/kg food);

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$P95(C_f)$ is the 95th percentile of consumption of food f among consumers (kg food/day);
$P95(O_f)$ is the 95th percentile of the contaminant concentration in food f ($\mu g \cdot kg^{-1}$ food);
BW is the default body weight for the population group considered (kg).

Strengths: simplicity, reproducibility, ease of communication to risk managers.
Limitations: it does not capture variability or uncertainty in consumption or concentration distributions; it assumes independence between food consumption and contamination; and it cannot easily address mixture exposures or co-occurrence patterns.

In the EU context, deterministic results are the "entry level" for regulatory discussion—probabilistic results, when available, serve as refinement rather than replacement.

2.3 Probabilistic exposure assessment

Principles

Probabilistic methods aim to describe the full distribution of exposure across a population, incorporating variability (between individuals, foods, days) and uncertainty (in data quality, measurement, sampling). They rely on random sampling (MCRA methods) or analytical integration to combine probability distributions of consumption and occurrence.
The MCRA samples thousands of combinations of $C_{i,f}$ and O_f values, propagating their variability through the exposure formula to obtain a simulated distribution of daily intakes. Each iteration can include random draws for processing factors, body weight, or LOD/LOQ imputation for censored data.

- *Implementation in EU frameworks*

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Within EFSA-supported systems, probabilistic modelling is implemented mainly through the MCRA web platform developed by RIVM/WUR in collaboration with EFSA. MCRA allows both deterministic and probabilistic runs, mixture exposure assessment, bootstrap uncertainty analysis, and FoodEx2-compatible import.

Probabilistic analysis can address both *acute* (per day, large portion/high contamination) and *chronic* (long-term habitual intake) exposure. In acute models, random draws of high consumption events and high-end concentration values are combined, while chronic models integrate average daily consumption over long periods with corresponding mean concentrations.

Benefits:

- Captures variability and uncertainty explicitly;
- Enables probabilistic risk characterisation (probability of exceeding TDI/ARfD);
- Can integrate correlations (e.g., co-consumption of correlated foods).

Challenges:

- Requires microdata (individual consumption days and analytical results), often restricted;
- Demands computational resources and statistical expertise;
- Communicating probabilistic outputs to risk managers remains complex.

EFSA's *Guidance on Uncertainty in Scientific Assessment* (2018)[4,11] stresses that probabilistic assessments should be accompanied by a structured qualitative and, when feasible, quantitative uncertainty evaluation.

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2.4 Mixture and cumulative exposure assessment

2.4.1 Concept and rationale

Mycotoxins rarely occur in isolation. Co-exposure to multiple toxins—e.g., DON with ZEN, FUM with AF, or *Alternaria* metabolites together—poses potential additive or synergistic effects. EFSA has therefore moved toward cumulative risk assessment (CRA), aligning with its 2019 guidance *Harmonisation of Methodologies for Human Health, Animal Health and Ecological Risk Assessment of Combined Exposure to Multiple Chemicals*[12].

2.4.2 Methodological frameworks

Cumulative assessment groups (CAGs) are established based on shared toxicological endpoints (e.g., estrogenic effects for ZEN and analogues, neurotoxicity for T-2/HT-2). Two main quantitative approaches are employed:

- *Hazard Index (HI):*

$$HI = \sum_{j} \frac{E_j}{TDI_j}$$

where:

HI is the Hazard Index for cumulative exposure;

E_j is the dietary exposure to contaminant j (µg/kg bw/day);

TDI_j is the tolerable daily intake for contaminant j (µg/kg bw/day)

An HI > 1 indicates that cumulative exposure exceeds the acceptable level under the assumption of dose addition.

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- *Relative Potency Factor (RPF) approach:*

Expresses potency of each congener relative to an index compound.

$$E_{RPF} = \sum_j E_j \times RPF_j$$

where:

- E_{RPF} is the combined exposure expressed in equivalents of the index compound (µg/kg bw/day)
- E_j is the dietary exposure to congener j (µg/kg bw/day);
- RPF_j is the relative potency factor of congener j relative to the index compound (dimensionless).

The combined exposure is compared with the toxicological reference value of the index compound.

These frameworks are already applied to trichothecenes and ZEN analogues in EFSA work.

2.4.3 Implementation through MCRA

The MCRA platform operationalises CRA through mixture modules: it allows definition of CAGs, specification of RPFs, and computation of cumulative distributions under uncertainty. This capability is pivotal for mycotoxin assessments, as datasets increasingly report multiple analytes per sample (LC–MS/MS multi-toxin methods).

2.4.4 Scientific and regulatory implications

The transition to cumulative approaches reflects growing recognition that additive low-level exposures may pose risk even when single-analyte exposures are below TDIs. Yet toxicological data for many emerging mycotoxins remain insufficient to assign reliable RPFs, leading EFSA to retain deterministic single-

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toxin evaluations as the regulatory default while developing CRA frameworks in parallel.

2.4.5 Uncertainty analysis and integration

EFSA distinguishes between *variability* (true heterogeneity among individuals, foods, or sampling units) and *uncertainty* (lack of knowledge). Uncertainties in exposure assessment arise from:

- analytical measurement errors,
- high proportions of left-censored data,
- limited representativeness of consumption surveys,
- uncertain processing factors,
- temporal/geographic extrapolation of occurrence data,
- assumptions in mixture modelling.

EFSA's 2018 guidance recommends a stepwise process:

- Identify and characterise uncertainties;
- Prioritise by expected impact;
- Quantify or bound them (e.g., sensitivity analysis, scenario bounds, probability distributions);
- Communicate clearly to decision-makers (qualitative or probabilistic expression).

In deterministic assessments, uncertainty is usually reflected via LB–UB scenario ranges. In probabilistic frameworks, it can be propagated explicitly through random draws (MCRA) or bootstrapping.

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2.4.6 Integration with toxicological benchmarks

The final stage of exposure assessment is comparison against toxicological reference values drawn from EFSA's OpenFoodTox database[13] [3].

For thresholded toxins (DON, OTA, ZEN, T-2/HT-2, FUM): exposures are compared to TDIs/TWIs.

For genotoxic carcinogens (i.e. AFB_1) the *MoE* approach applies:

$$MOE = \frac{BMDL_{10}}{E_{mean}}$$

where:

- MOE is the Margin of Exposure;
- $BMDL_{10}$ is the benchmark dose lower confidence limit corresponding to a 10% response (µg/kg bw/day);
- E_{mean} is the mean dietary exposure in the population group considered (µg/kg bw/day).

For genotoxic carcinogens, an MOE ≥ 10,000 is generally considered of low concern for public health.

This harmonised endpoint allows translation of exposure modelling outputs into regulatory decision contexts.

[3] *Available at: https://www.efsa.europa.eu/en/microstrategy/openfoodtox*

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2.5 Methodological synthesis

In the EU context, exposure assessment has matured from deterministic, single-chemical frameworks to more nuanced probabilistic and cumulative approaches integrating uncertainty analysis[14].

- **Deterministic baselines** remain indispensable for regulatory harmonisation.
- **Probabilistic models** (MCRA) provide refined risk characterisation when data allow.
- **Mixture frameworks** bridge exposure science and toxicology, though constrained by data gaps.
- **Uncertainty analysis** is now a formal component rather than an afterthought.

Together, these approaches form a continuum of refinement steps—each grounded in EFSA methodological guidance and the principles of transparency, reproducibility, and proportionality.

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3. Software and Open Tools for Mycotoxin Exposure Assessment

3.1 The digital ecosystem of exposure science

Exposure assessment in the EU has evolved from spreadsheet-based calculations toward sophisticated, reproducible digital ecosystems that integrate occurrence, consumption, and toxicological data through transparent algorithms. This evolution parallels EFSA's open-science principles and the FAIR data movement (Findable, Accessible, Interoperable, Reusable).

Today's computational landscape includes both regulatory-grade platforms—developed or validated in collaboration with EFSA—and open-source statistical environments that allow researchers to implement or refine models for specific contaminants, including mycotoxins. Together, these tools define the methodological capacity of the field.

3.2 EFSA and EU-regulated platforms

3.2.1 DietEx: deterministic engine for baseline exposure

The DietEx tool represents EFSA's primary instrument for deterministic (point-estimate) exposure assessment. Built to operate on harmonised datasets from the *Comprehensive European Food Consumption Database* and mapped through the *FoodEx2* classification, DietEx enables users to compute chronic dietary exposure under the EFSA framework for contaminants, nutrients, and additives.

DietEx provides standardised algorithms to combine mean or median occurrence values with mean consumption for defined population groups, outputting exposure in µg/kg bw/day. It supports multi-scenario computation (lower-, middle-, upper-bound) to reflect LC uncertainty, ensuring alignment with EFSA's 2010 guidance on censored data[1].

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Strengths:

- Full harmonisation with EFSA data structures (FoodEx2, body-weight, age categories).
- Transparent, reproducible deterministic calculations.
- Ideal for baseline or regulatory exposure estimations.

Limitations:

- No probabilistic capability or uncertainty propagation beyond scenario analysis.
- Restricted to chronic exposure; acute and mixture scenarios require external tools.
- Limited flexibility for integrating national or experimental datasets not formatted in EFSA structures.

Despite these limitations, DietEx functions as the *regulatory benchmark*, ensuring that all EFSA opinions and Member-State submissions share a common computational baseline.

3.2.2 MCRA: probabilistic and cumulative exposure platform

The MCRA platform is the cornerstone of probabilistic and mixture exposure modelling within the EU. Supported and co-governed by EFSA, MCRA implements Monte Carlo simulations to model variability and uncertainty in exposure across individuals and populations.

MCRA supports deterministic and probabilistic modelling of both chronic and acute exposure scenarios and includes functionalities for handling left-censored data using either substitution-based or parametric approaches. It enables the integration of correlated food consumption and occurrence data and provides dedicated modules for CRA based on the Hazard Index and RPF methodologies. Interoperability with EFSA datasets is ensured through

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compatibility with the FoodEx2 classification system, and uncertainty can be further explored through bootstrapping and Bayesian re-sampling options.

MCRA uses large-scale Monte Carlo simulations to generate population exposure distributions from raw individual data. Its probabilistic engine can combine multiple contaminants (e.g., DON, ZEN, T-2/HT-2) using dose addition principles, and compute the probability of exceeding toxicological reference values. The system includes uncertainty quantification via re-sampling, supporting EFSA's 2018 *Guidance on Uncertainty*[11].

Advantages:

- Full compliance with EFSA methodologies for probabilistic and cumulative assessments.
- User-friendly web-based interface, accessible under registration for research and regulatory institutions.
- Built-in visualisation tools for exposure distributions, uncertainty ranges, and source attribution (food contributions).

Limitations:

- Closed-source; while accessible, internal algorithms are not fully open for modification.
- Computationally intensive for high-resolution data.
- Requires harmonised microdata; aggregated consumption data cannot exploit full probabilistic capacity.

MCRA's prominence is such that EFSA references it in nearly all cumulative and probabilistic exposure reports published after 2016. It operationalises the transition from deterministic to distributional risk assessment and is progressively being adapted to align with FAIR data infrastructures under Horizon Europe projects.

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3.3 Open-source and research software ecosystems

3.3.1 R environment for statistical exposure modelling

The R programming environment is central to academic and advanced regulatory research on exposure assessment. Its flexibility allows the construction of custom deterministic, probabilistic, or censored-data models aligned with EFSA protocols.

Key packages include:

- *NADA / NADA2*: provide functions for handling left-censored data via regression on order statistics (ROS), Kaplan–Meier estimators, and parametric (MLE) methods. These are directly applicable to mycotoxin occurrence data with moderate-to-high nondetect fractions.
- *censReg* and *survival::survreg*: implement censored regression (Tobit-type) models suitable for occurrence data with variable LOD/LOQ thresholds and covariates (matrix, year, lab).
- *mc2d*: allows two-dimensional Monte Carlo simulations separating variability and uncertainty—useful for probabilistic exposure models when data sources are aggregated.
- *fitdistrplus*: fits and compares statistical distributions (lognormal, gamma, Weibull) for parameterisation prior to simulation.
- *rstanarm / brms*: provide Bayesian frameworks for hierarchical censored models, allowing explicit uncertainty propagation and inclusion of prior knowledge (e.g., from similar toxins).

Using R for exposure modelling offers transparency, replicability, and integration with reproducible workflows (RMarkdown, Git versioning).

- Advantages:

- Fully open-source and extensible.
- Allows customisation to specific contaminants or national datasets.
- Enables publication-quality uncertainty and sensitivity analyses.

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Limitations:

- Requires advanced statistical and coding expertise.
- No direct EFSA-endorsed template; outputs must be benchmarked against DietEx or MCRA for regulatory comparability.

In practice, R serves as the *methodological testbed* where new approaches (e.g., Bayesian imputation of censored values or climate-adjusted occurrence models) are developed before possible translation into institutional tools.

3.3.2 Python and other analytical environments

Python-based libraries such as *NumPy, SciPy, Pandas*, and *PyMC3* (Bayesian inference) are increasingly used in data preprocessing, probabilistic simulation, and machine-learning-driven exposure modelling. However, Python's adoption in the mycotoxin exposure domain remains limited compared to R, due to fewer domain-specific packages for censored environmental data.

Other analytical platforms include *@RISK*, *Crystal Ball*, and *OpenTURNS*, which offer Monte Carlo and uncertainty analysis but are primarily used in industrial or environmental contexts. Their utility for food contaminant exposure is secondary and often requires bespoke adaptation.

A comparative description of the available tools is reported in Table 2.

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Table : *Overview and comparison of software tools and analytical environments used for dietary exposure assessment, highlighting modelling approach, key functionalities, degree of alignment with EFSA methodologies, and main strengths and limitations.*

Tool	Type	Key functions	EFSA alignment	Strengths	Limitations
DietEx (EFSA)	Deterministic	Chronic exposure (LB/MB/UB); FoodEx2 integration	Full	Transparent, regulatory benchmark	No probabilistic/ mixture capability
MCRA (WUR/RIVM)	Probabilistic / cumulative	Monte Carlo simulation, CRA (HI/RPF), uncertainty propagation	Full	State-of-art, cumulative exposure modelling	Requires microdata, closed codebase
R packages (NADA, censReg, mc2d, etc.)	Research-grade open-source	LC data modelling, parametric fitting, probabilistic simulation	Partial	Flexible, transparent, reproducible	Requires coding; not officially validated
Python / PyMC3 / OpenTURNS	Analytical / research	Bayesian simulation, data integration	Experimental	Machine-learning and Bayesian capacity	Sparse domain-specific support
EPA ProUCL	Environmental statistics	Censored data, UCL computation	None	Robust for ND-heavy data	Non-food oriented; limited EU compliance

3.3.3 Interoperability and FAIR principles

A key development in EU food-risk science is the progressive alignment of software with FAIR principles. EFSA's data strategy (2023–2027) emphasises reproducibility through open metadata, shared ontologies (FoodEx2, CHEBI, EFSA Biological Ontology), and traceable data provenance[15–17].

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Tools like DietEx and MCRA are being progressively linked to EFSA's Knowledge Junction on Zenodo, enabling versioned public documentation of workflows and parameters. Meanwhile, R-based pipelines are increasingly integrated into FAIR repositories under projects such as FNS-Cloud (https://www.fns-cloud.eu) and PARC (https://www.eu-parc.eu), enabling community-based refinement of exposure algorithms.

The future regulatory landscape will likely involve hybrid workflows—where deterministic DietEx baselines are complemented by open-source probabilistic modules (e.g., R scripts) submitted alongside EFSA datasets for peer verification.

3.3.4 Implications for reproducibility and transparency

The coexistence of official (DietEx, MCRA) and open (R, Python) tools reflects the dual imperative of regulatory robustness and scientific innovation. For regulatory dossiers, the use of validated EFSA-aligned software ensures traceability; for research and method development, open-source environments provide flexibility and the ability to test emerging concepts such as machine-learning-aided imputation or climate-adjusted exposure forecasting.

To achieve full transparency and comparability, exposure studies should:

- Document software versions, parameters, and data transformations;
- Publish reproducible scripts or workflows (RMarkdown, Jupyter);
- Benchmark open-source results against EFSA tool outputs;
- Archive outputs and metadata under open repositories following FAIR guidelines.

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4. Dietary Consumption database currently available in the EU

Dietary exposure assessment at the European level relies on a limited number of harmonised consumption data sources, complemented by national dietary surveys with heterogeneous designs and temporal coverage, as summarised in Table 3.

For EU risk assessment, dietary consumption data used in food-exposure assessments are drawn mainly from the EFSA Comprehensive European Food Consumption Database[9], complemented by the newer EU-MENU programme[18]. These datasets together represent the most extensive attempt to harmonise individual consumption data across Member States for use in chemical-exposure and nutritional risk assessment.

The EFSA database compiles national dietary surveys submitted voluntarily by Member States under a common framework. Each dataset records individual-level daily food intakes, expressed in grams per person per day and classified according to FoodEx2, EFSA's hierarchical food classification and description system. Surveys differ in method—typically two non-consecutive 24-hour recalls or 3–7-day food diaries—but are re-coded into a uniform structure for integration. The database currently holds more than thirty national surveys representing roughly 70 000 individuals across 22 countries, covering infants, children, adolescents, adults, and the elderly. Updates since 2022 have added new surveys from Poland, Croatia, and Montenegro, and further EU-MENU surveys are progressively replacing legacy data.

In exposure assessment, these consumption distributions are combined with contaminant occurrence data to estimate dietary intake per kg bw. EFSA uses them in its deterministic (DietEx) and probabilistic (MCRA) exposure models, while Member States and researchers employ them for both nutrient and contaminant analyses.

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***Table 2**: Overview of the main dietary consumption databases and survey frameworks supporting dietary exposure assessment in the European Union, including coverage, timeframe, and population groups.*

Survey/Database	Timeframe / Notes	Countries covered	Age groups
EFSA Comprehensive European Food Consumption Database	Collection of national surveys across EU states; update 15 Dec 2022 noted.	Multiple EU / pre-accession countries (22+ states at earlier stage)	Infants → elderly (various)
EU-MENU (Pan-European dietary survey initiative)	Methodological guidance published December 2014.	Intended all EU Member States (children + adults)	From 3 months to 74 years (guidance)
Specific national surveys (various)	Surveys vary years, size, methodology; example: Balkan region 2017-2023.	Umbrella region example	Children 3 months-9 yrs, adults 10-74 yrs in example paper

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5. Current Baseline Scenario for Mycotoxin Exposure in Europe

5.1 Present understanding of exposure levels

According to the European Food Safety Authority (EFSA), the most commonly assessed mycotoxins in the European food chain include AF, OTA, DON and other *Fusarium* toxins, FUM and ZEN.

For several of these toxins, EFSA's assessments indicate that while average chronic exposure is in many cases below the respective HBGVs, specific population groups (notably infants, toddlers and children) remain at higher relative risk due to higher food intake per kg bw and more frequent consumption of relevant food categories (e.g., cereal-based products). For example, the HBM4EU assessment (via the European Environment Agency) indicates that about 14 % of adults in Europe may have internal exposure levels to DON that "may harm health"[19].

EFSA and EU monitoring currently confirm the presence of mycotoxins in a wide range of commodities - cereals and cereal products, nuts, dried fruits, spices, coffee, cocoa and derived foods - but also emphasise that contamination levels and prevalence vary markedly between years, regions, commodities and climate conditions (e.g., storage, drought stress).

5.2 Recent regulatory context and implications for the baseline

The European Commission's contaminants catalogue lists additional mycotoxins under monitoring (sterigmatocystin, ergot alkaloids, phomopsins, citrinin, *Alternaria* toxins) beyond the earlier "core" set[20]. This expansion implies that the past baseline scenario - focused on a narrower set of toxins - must now evolve to include these emerging contaminants.

EFSA's recent project MYCOBOOST highlights data-quality challenges (including LC, variable LOQs, heterogeneous occurrence datasets) and calls for improved occurrence data to refine exposure estimates[21]. Because these data-

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quality issues directly affect the baseline scenario, they must be acknowledged in any assessment of current exposure.

5.3 Key features of the baseline scenario

The current baseline scenario for dietary exposure to mycotoxins in Europe reveals a landscape characterised by marked heterogeneity, persistent uncertainty, incomplete toxicological characterisation for emerging mycotoxins, and pronounced temporal dynamics in occurrence and exposure patterns. Figure 1 provides a conceptual overview of this heterogeneity by positioning selected mycotoxins according to data availability and regulatory/toxicological maturity. Well-characterised, regulated mycotoxins occupy the upper quadrants of the matrix, reflecting both extensive occurrence data and established toxicological reference frameworks. In contrast, emerging or less-characterised compounds, including *Alternaria* mycotoxins and enniatins/beauvericin (ENNs/BEA), are located in areas indicative of more limited data support and lower regulatory maturity.

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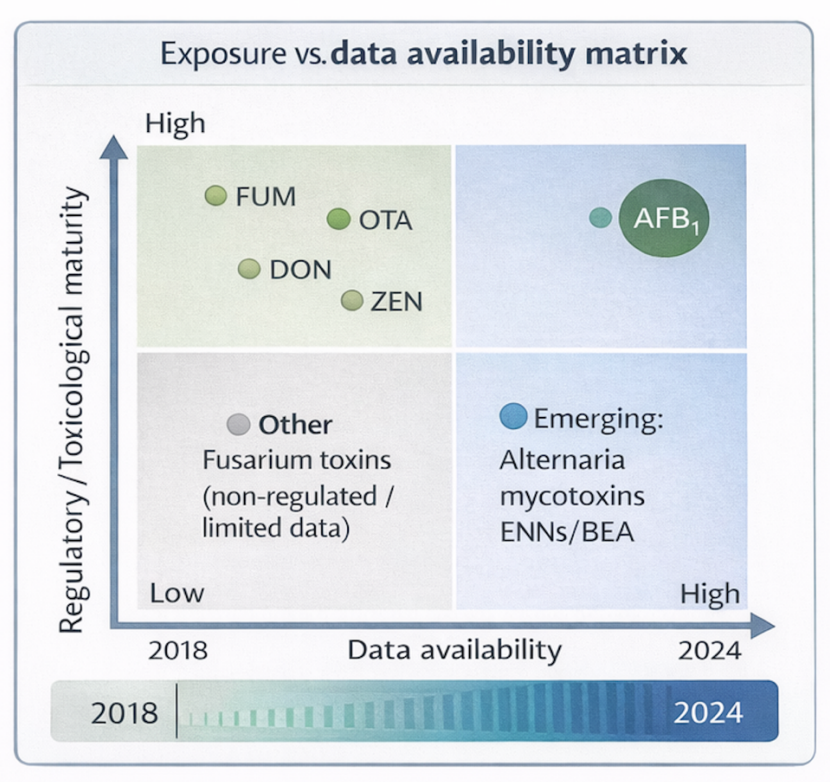

Figure 1: Conceptual positioning of selected mycotoxins by data availability and regulatory/toxicological maturity.

Exposure distributions across European populations are therefore far from uniform. While average exposures for many consumers fall below HBGVs, substantial variability emerges between population groups, dietary patterns, food matrices, and regions. Infants and young children consistently appear as the most exposed demographic groups, largely because of their higher food intake per kg/bw and their consumption patterns dominated by cereal-based foods—the commodities most frequently contaminated by *Fusarium* mycotoxins. Geographic diversity compounds this variation: southern European regions, with warmer climates and greater reliance on maize and nuts, tend to show higher AF and FUM exposure, whereas northern areas exhibit a prevalence of trichothecene-type toxins[22,23].

Uncertainty remains one of the dominant characteristics of the baseline scenario. The heavy presence of left-censored data in occurrence datasets,

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variable LOQs among national laboratories, and the scarcity of robust co-occurrence information all contribute to wide uncertainty bands[24]. EFSA's standard LB/MB/UB scenarios often produce broad exposure intervals that can span an order of magnitude, especially in commodities with a high proportion of non-detects. This lack of precision translates into reduced confidence in high-end exposure percentiles (such as the 95th percentile), which are critical for assessing risk in vulnerable sub-populations. The uncertainty is structural, not merely statistical: inconsistent sampling, divergent analytical methods, and incomplete metadata on processing and storage conditions collectively undermine comparability across Member States and survey years.

A further limitation of the existing baseline is its narrow chemical scope. It continues to reflect primarily the "classical" mycotoxins - AF, OTA, DON, FUM, ZEN, and the T-2/HT-2 toxins[21]. For emerging toxins such as *Alternaria* metabolites, ENNs, BEA, or moniliformin, exposure data remain too sparse and heterogeneous for comprehensive modelling. Consequently, mixture and cumulative exposure assessments, though conceptually advanced within EFSA's methodological framework, cannot yet be implemented at scale. This under-representation distorts the apparent risk profile, since simultaneous low-level exposure to multiple toxins may lead to additive or synergistic effects unreflected in current single-compound baselines.

Finally, the baseline is not static: it is already being reshaped by environmental and economic forces. Climate change has begun to modify fungal ecology and toxin occurrence patterns—warmer and drier conditions in central and southern Europe increasingly favour aflatoxin-producing *Aspergillus* species that were once restricted to subtropical regions[22,25]. Altered trade flows, intensified importation of commodities from high-risk regions, and shifts in agricultural practices all act as dynamic modifiers of contamination and exposure. In effect, today's "baseline" represents a moving average of an evolving system.

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Given the characteristics described above, the baseline exposure scenario for mycotoxins in Europe must be regarded not as a fixed, fully reliable estimate, but rather as a reference point - a scientifically grounded starting line against which future data and scenario refinements can be compared. In practical terms, this means that the baseline scenario supports regulatory decision-making by highlighting which food categories and population groups are potentially of concern, especially where exposure approaches or exceeds HBGVs. It delineates the contours of the problem: for example, pointing to cereal-based foods for young children, nuts and dried fruit in certain regions, or age cohorts with elevated per-kg body weight food intake.

At the same time, the baseline scenario signals where methodological and data-refinement efforts are most needed. For instance, it draws attention to the need for improved occurrence data specifically calibrated to children's foods, expansion of monitoring of emerging mycotoxins and their modified forms, and development of mixture modelling to account for co-exposure to multiple toxins[21].

Moreover, the baseline scenario underpins the modelling of alternative futures: climate change, shifting dietary patterns, changing trade flows and processing technologies become meaningful only when they are mapped relative to a defined "state of exposure"[26]. In this way the baseline becomes the hinge on which scenario-analysis swings - whether interpreting the effect of warmer growing seasons on aflatoxin risk, or the rising consumption of novel cereals on exposure.

However, this framing also demands that uncertainty be communicated transparently. The exposure estimates - especially those at the high end (percentiles like the 95th) or for children - carry greater levels of uncertainty. This uncertainty arises from methodological issues (such as LC occurrence data, variable LOQs, incomplete consumption data) and from external dynamics (like shifting supply chains and emerging toxins)[24].

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Dietary habits are represented through existing consumption surveys; explicit modelling of emerging or alternative dietary patterns is outside the scope of the present baseline and addressed in subsequent MYMATCH work packages.

5.4 Integration of curated occurrence datasets for scenario-based exposure modelling: the HOLiFOOD-CHEFS database

Figure 1 provides a conceptual overview of how the current EU regulatory exposure baseline can be transitioned toward scenario-ready exposure assessment within the MYMATCH framework. While EFSA-aligned baselines ensure harmonisation, transparency, and regulatory comparability, their direct extension to predictive, cumulative, and climate-informed scenarios is constrained by structural data limitations, including left-censored occurrence data, legacy dietary surveys, and limited information on co-occurrence and processing factors. Targeted data curation and readiness assessment—illustrated here through the integration of the HOLiFOOD-CHEFS database—address these constraints by strengthening occurrence data density, consistency, and usability for probabilistic modelling. At the same time, the framework explicitly recognises that toxicological and epidemiological gaps remain the primary limiting factors for cumulative risk and burden-of-disease applications beyond aflatoxin B_1. In this context, HOLiFOOD-CHEFS functions as an enabling data layer supporting the progression from WP4 baseline characterisation toward advanced exposure forecasting in WP7 and emerging toxin and mixture assessment in WP8.

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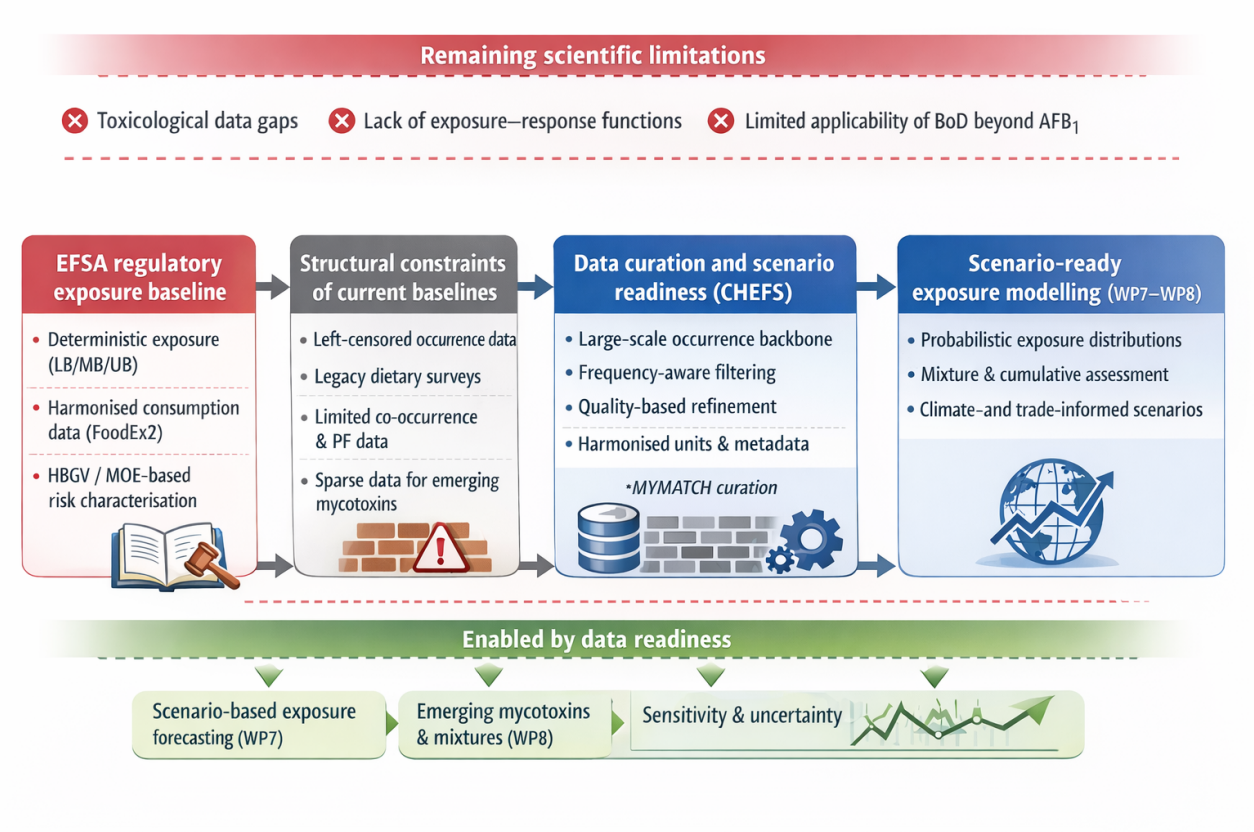

Figure 2: Conceptual framework illustrating the transition from the current EU regulatory exposure baselines to scenario-ready exposure assessment within MYMATCH. The figure highlights how targeted data curation and readiness assessment (exemplified by HOLiFOOD-CHEFS database) enable scenario-based exposure modelling, while toxicological and epidemiological gaps remain the main limiting factors for cumulative risk and burden-of-disease applications.

To enable scenario-based exposure modelling, baseline assessments must be supported by occurrence datasets that are not only large-scale, but also structured, queryable, and reproducible. In this context, MYMATCH has adopted and operationalised the CompreHensive European Food Safety (HOLIFOOD-CHEFS) database[27], an open infrastructure developed within the Horizon Europe ecosystem with explicit contributions from the Horizon Europe *HOLiFOOD project* (https://holifoodproject.eu) toward building and disseminating HOLIFOOD-CHEFS as an accessible platform for EU food safety monitoring data.

HOLIFOOD-CHEFS consolidates official food safety monitoring data submitted by EU Member States to EFSA and published on Zenodo into a unified

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relational database designed for large-scale analytics and AI-enabled trend detection. The accompanying HOLIFOOD-CHEFS publication describes a resource comprising 392 million analytical results derived from >15.2 million samples, spanning >4,000 food product types, and covering monitoring activities across 2000–2024. The database integrates three major analytical domains - chemical contaminants, pesticide residues, and veterinary medicinal product residues - in a common data model, thereby enabling cross-domain querying and consistent longitudinal analyses that are difficult to perform when data remain distributed across hundreds/thousands of heterogeneous files.

From an implementation perspective, the HOLIFOOD-CHEFS GitHub repository (https://github.com/WFSRDataScience/CHEFS) provides an end-to-end pipeline to build a local HOLIFOOD-CHEFS instance, including: (i) database setup (PostgreSQL schemas and tables), (ii) automated download of EFSA Zenodo data files, (iii) conversion and preprocessing routines, (iv) import into database tables/views, and (v) query and visualisation examples (Python notebooks) demonstrating typical analytical workflows. The repository structure explicitly anticipates extensibility (e.g., folders reserved for microbiological prevalence, AMR and zoonosis data), and includes EFSA catalogues required for harmonised metadata handling and classification support.

5.4.1 Cross-project alignment: HOLiFOOD ↔ CHEFS ↔ MYMATCH.

HOLiFOOD positions CHEFS as a European research infrastructure enabling advanced modelling, trend analysis and early-warning capabilities, consistent with HOLiFOOD's broader objective of leveraging AI and big data for proactive food safety risk analysis. Embedding HOLIFOOD-CHEFS within MYMATCH therefore represents a concrete cross-project interoperability pathway: HOLiFOOD contributes to the creation and dissemination of the infrastructure,

while MYMATCH reuses and curates it to support mycotoxin exposure scenario design under changing climate and dietary conditions.

MYMATCH will contribute in the curation, scenario-readiness, and upstream code improvement. Within WP4, MYMATCH has (1) downloaded the full HOLIFOOD-CHEFS data relevant to chemical contaminants, (2) performed systematic organisation, cleaning, and restructuring steps to ensure suitability for downstream exposure assessment and scenario modelling, and (3) conducted targeted quality control to identify and resolve inconsistencies affecting modelling fitness.

This work goes beyond passive reuse: it converts an open monitoring infrastructure into a scenario-ready occurrence backbone aligned with exposure-model input requirements (e.g., coherent units, consistent matrix descriptors, robust metadata for linking with consumption categories and model stratifications).

During this process, MYMATCH also identified errors within the original HOLIFOOD-CHEFS processing scripts that could affect reproducibility and correctness of the generated local database. These issues were corrected and communicated back through direct contributions to the HOLIFOOD-CHEFS codebase, strengthening the overall robustness of the shared European infrastructure. This is a practical example of bidirectional knowledge exchange between Horizon Europe projects, where improvements generated in one project propagate to enhance reusability by others, reducing duplication and increasing trust in shared data pipelines.

5.4.2 Role in MYMATCH: from baseline to scenarios.

In MYMATCH, HOLIFOOD-CHEFS does not replace EFSA-aligned baseline exposure estimates described in this deliverable; rather, it provides the scalable data layer needed to extend baseline characterisation toward alternative and forward-looking scenarios. Specifically, the curated HOLIFOOD-CHEFS - derived occurrence dataset enables: (i) scenario generation that modifies

contamination distributions (rather than relying only on historical point estimates), (ii) consistency checks across countries/time periods and food matrices, and (iii) improved support for probabilistic modelling and sensitivity analyses when combined with consumption data. In this sense, HOLIFOOD-CHEFS acts as the operational bridge between WP4 baseline framing and the scenario-based modelling activities planned in subsequent MYMATCH work packages.

5.4.3 Structural characterisation and methodological curation of the HOLIFOOD-CHEFS database for MYMATCH scenario modelling

The integration of the HOLIFOOD-CHEFS database within MYMATCH was accompanied by a systematic structural and exploratory analysis aimed at assessing its suitability as an occurrence-data backbone for exposure and scenario modelling. Given the scale and heterogeneity of HOLIFOOD-CHEFS, this step was considered essential to ensure that downstream modelling activities would be grounded in statistically and methodologically robust inputs rather than relying on the database "as is".

- *Overall structure and data density*

The HOLIFOOD-CHEFS dataset analysed within MYMATCH comprises *4,344,679 analytical records*, of which *1,421,119 (32.7%)* correspond to positive samples (non left-censored). This relatively high proportion of quantified results is a critical feature, as it indicates that the dataset is not dominated by left-censored observations and therefore retains substantial information content for modelling purposes.

The database includes *897 unique analytical parameters* (contaminants), reflecting the breadth of EU food safety monitoring activities. From a food-chain perspective, the dataset covers over *3,000 distinct food products* and

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approximately 200 countries of origin, providing wide coverage across matrices and geographical contexts.

Further exploratory analysis confirmed the high internal heterogeneity of the HOLIFOOD-CHEFS dataset, including wide temporal coverage (1998–2024), a large number of analytical parameters with highly skewed frequency distributions, and substantial variation in metadata completeness (e.g. origin country, analytical units). These characteristics reinforce the need for frequency-aware filtering and targeted curation prior to exposure and scenario modelling.

These characteristics confirm that HOLIFOOD-CHEFS represents a genuinely large-scale and diverse occurrence dataset, suitable for both descriptive and model-based analyses.

- *Frequency distribution of contaminants and information filtering*

An initial frequency analysis of analytical parameters revealed a highly skewed distribution of contaminant occurrence. Most parameters (725 out of 897) appeared fewer than 5,000 times, while a smaller subset showed substantially higher frequencies.

To ensure statistical robustness and avoid instability driven by sparse data, MYMATCH adopted a frequency-aware filtering strategy, retaining only parameters with more than 5,000 occurrences. This threshold reduced the dataset to 3,612,571 records while preserving the contaminants most relevant for exposure modelling at population scale. Importantly, this selection was driven by data density considerations rather than toxicological prioritisation, ensuring methodological neutrality at this stage.

- *Quality-based refinement: programmes and laboratory accreditation*

A further refinement step focused on data quality and regulatory relevance. By restricting the dataset to:

- official monitoring programmes, and
- analyses performed by accredited laboratories,

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The dataset was reduced to *3,072,013 records, of which 1,192,611 (38.8%)* were positive. This step increased the proportion of quantified results and strengthened confidence in analytical comparability across countries and years.

Following this refinement, the curated dataset comprised:

- 172 contaminants,
- 3,042 food products, and
- approximately 200 origin countries.

Records with unknown country of origin accounted for a substantial fraction of samples, including around 160,000 positives. Given their limited added value for exposure stratification and scenario modelling, these records were considered removable without materially affecting model robustness.

- *Construction of a scenario-ready analytical dataset*

Based on the structural and quality analyses, a reduced and purpose-built dataset (*t_mymatch_filtered*) was generated, retaining only variables essential for exposure and scenario modelling. These included identifiers, programme type, laboratory accreditation, sampling point, temporal variables, food descriptors, contaminant identifiers, quantitative results, limits of quantification, and evaluation codes.

This step transformed HOLIFOOD-CHEFS from a general-purpose monitoring repository into a scenario-ready occurrence dataset, optimised for integration with exposure models while preserving traceability to EFSA-aligned metadata.

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- *Preliminary modelling exploration as proof-of-concept*

To assess whether the curated dataset retained sufficient structure and information for predictive applications, a preliminary modelling exercise was conducted on a reduced subset of the data. Using a Bayesian Network approach applied to approximately 33,000 observations covering 28 contaminants with intermediate frequencies, the model achieved an accuracy of approximately 82% when considering the top three predicted parameters.
While this exercise is not intended as a formal validation or final modelling result, it serves as a proof-of-concept, demonstrating that the curated HOLIFOOD-CHEFS -derived dataset preserves meaningful statistical dependencies between variables and is suitable for advanced modelling approaches. These preliminary findings support the use of HOLIFOOD-CHEFS as a foundational data layer for the development of exposure scenarios and predictive models in subsequent MYMATCH work packages.

To support the structural characterisation of the HOLIFOOD-CHEFS database and to assess its relevance for mycotoxin exposure assessment, the frequency of occurrence of mycotoxin-related analytical parameters was systematically evaluated. This analysis aimed to quantify the representation of individual mycotoxins and mycotoxin groups within the curated HOLIFOOD-CHEFS dataset, thereby providing an empirical basis for selecting contaminants suitable for baseline description and scenario-based modelling.
Table 4 reports the frequency of analytical results associated with major regulated mycotoxins, their modified forms, and selected emerging mycotoxins. Frequencies reflect the number of analytical records per parameter and are used here as a proxy for data density rather than as an indicator of exposure magnitude or risk. This distinction is critical, as high parameter frequency supports statistical robustness and modelling feasibility,

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while toxicological relevance and risk characterisation are addressed separately within the exposure assessment framework.

Together, these data demonstrate that key mycotoxins of regulatory and public health relevance - such as AF, OTA, DON, ZEN, FUM, and T-2/HT-2 toxins - are among the most densely represented contaminants in the HOLIFOOD-CHEFS database. At the same time, the presence of modified and emerging mycotoxins, albeit at lower frequencies, confirms the suitability of HOLIFOOD-CHEFS as a forward-looking data resource for exploratory analyses and scenario development under evolving climatic and dietary conditions.

While HOLIFOOD-CHEFS substantially improves occurrence data density and scenario-readiness, it does not eliminate toxicological and epidemiological uncertainties, which remain the primary limiting factors for cumulative risk and burden-of-disease assessments.

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Table 3: Frequency of mycotoxin-related analytical parameters in the HOLIFOOD-CHEFS database after initial structural analysis

Mycotoxin	Frequency (n)
AFB1	78,134
OTA	70,061
AFG1	67,395
AFG2	66,535
AFB2	66,445
DON	47,364
Total AF (sum of B1, B2, G1, G2)	44,088
ZEN	42,196
FB1	29,663
FB2	28,354
Total FUM (FB1 +F B2)	18,079
T-2	17,105
HT-2	16,241
AFM1	9,949
15-AcetylDON	9,246
ENN A	4,513
FB3	4,474
DON-3-glucoside	4,362
Sterigmatocystin	3,448
3- and 15-AcetylDON (sum)	2,660
DOM-1	2,649
Ergotamine + ergotaminine (sum)	2,417
Total ergot alkaloids (ine + inine forms)	1,030
Ergot sclerotia	914
OTB	368
ZEN and derivatives	103

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5.5 Baseline scenario for risk assessment

The baseline scenario for risk assessment presented below is derived from published EFSA scientific opinions and supporting reports and represents the current regulatory reference for dietary exposure to major mycotoxins in Europe. The values summarised in Table 5 are not newly calculated within MYMATCH but compile EFSA-reported exposure estimates, stratified by population group where available, together with the corresponding HBGVs or toxicological benchmarks applied in EFSA risk characterisation.
Overall, the table defines the baseline regulatory exposure landscape against which MYMATCH scenario-based modelling and future refinements should be interpreted, highlighting both established areas of concern and persisting data gaps.

The current European baseline for dietary exposure to mycotoxins reflects both substantial progress and persistent uncertainty. For DON, EFSA data show that children's mean exposures in many European surveys approach the TDI, with 95th-percentile estimates often exceeding this threshold. This pattern highlights the vulnerability of younger populations, whose cereal-based diets and higher food intake per kg/bw result in proportionally greater exposure.
For OTA, overall exposure levels are low in absolute terms, expressed in ng/kg bw/day, but the toxicological benchmark differs fundamentally from that of DON. Owing to its genotoxic and carcinogenic properties, EFSA replaced the former TWI with a MOE approach. Under this framework, some population groups—particularly children—exhibit MOE values below levels considered protective, indicating potential health concern even at low exposure levels.

The situation is even more pronounced for T-2 and HT-2 toxins. Chronic upper-bound exposure estimates for infants and toddlers exceed the group TDI (20 ng/kg bw/day) by several fold, with 95th-percentile values far above this limit.

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These findings identify early-life stages as priority targets for risk mitigation and confirm that certain mycotoxins pose disproportionate risks to specific age groups.

In contrast, the baseline picture is far less defined for emerging or masked mycotoxins, for which occurrence data remain sparse, fragmented, or inconsistent. EFSA opinions rarely provide harmonised EU-wide mean and high-percentile exposure values for these compounds, leaving the baseline scenario incomplete and requiring cautious interpretation. Much of the available evidence relies on upper-bound substitution approaches for left-censored data, which preserve public-health conservatism but tend to overestimate true exposure. In addition, reliance on legacy monitoring datasets - many collected between 2007 and 2014 - limits temporal relevance, particularly considering climate-driven changes in fungal ecology and evolving trade patterns.

To ensure transparency and reproducibility, it is therefore essential to document survey years, age groups, and consumption databases underpinning each exposure estimate, and to highlight heterogeneity in analytical methods, detection limits, and food classification systems. Such annotation prevents baseline exposure values from being misinterpreted as static or fully comparable metrics and instead frames them as evolving constructs with embedded uncertainty.

Within this context, AF and OTA represent key benchmarks for the genotoxic–carcinogenic class of mycotoxins. EFSA's 2020 Scientific Opinion on aflatoxins[28] remains the most comprehensive assessment to date, incorporating over 200,000 occurrence results and identifying AFB_1 as the most potent compound. Using a $BMDL_{10}$ of 0.4 µg/kg bw/day, EFSA derived MOE values ranging from approximately 5,000 to 29 for AFB_1 and from 100,000 to 508 for AFM_1, well below the threshold of 10,000 generally considered of low concern. Consequently, EFSA reaffirmed that exposure should be kept as low as

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reasonably achievable (ALARA) and did not establish a TDI. However, the lack of detailed age-stratified exposure tables across Member States limits the resolution of aflatoxin baseline modelling.

A comparable paradigm shift occurred for OTA with EFSA's 2020 re-evaluation[29,30], which withdrew the former TWI of 120 ng/kg bw/week in favour of an MOE approach. Mean OTA exposures across Europe typically range from 0.6 to 17.8 ng/kg bw/day, with 95th-percentile values between approximately 2.4 and 51.7 ng/kg bw/day. While these estimates suggest that some high-consumption groups, especially children, may approach or exceed levels of health concern, interpretation is again constrained by incomplete age-specific data.

Taken together, the evidence indicates that baseline exposures to AF and OTA are not negligible. Even when central estimates remain low, high-percentile consumers and younger populations may experience exposures near toxicologically relevant levels. Benchmark margins are often narrow, implying that relatively small changes in contamination patterns or dietary habits - driven by climate change, novel foods, or processing practices - could substantially alter the risk profile. The European baseline therefore describes a risk spectrum rather than a safety plateau, underscoring the need for explicit communication of uncertainty, careful attention to high-exposure subgroups, and continued refinement of data collection to support more precise and dynamic exposure modelling.

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***Table 4**: EFSA-derived baseline dietary exposure estimates for major mycotoxins in Europe, by population group, including mean and high-percentile exposure levels where available, together with the corresponding HBGVs or toxicological benchmarks used for risk characterisation.*

Mycotoxin	Population group (age)	Mean chronic exposure	95th percentile exposure	HBGV / Toxicological benchmark
DON (incl. 3-Ac-DON, 15-Ac-DON, DON-3-Glc in group TDI)	0.22–1.02 µg/kg bw/day	0.43–1.86 µg/kg bw/day	Group TDI = 1 µg/kg bw/day (DON + 3-Ac-DON + 15-Ac-DON + DON-3-Glc)	DON (incl. 3-Ac-DON, 15-Ac-DON, DON-3-Glc in group TDI)
T-2/HT-2 (group)	survey means reported per age class; UB typically ~4× LB; infant/toddler means often closest to TDI	up to 146 ng/kg bw/day (infants, UB)	Group TDI = 20 ng/kg bw/day; group ARfD = 100 ng/kg bw	T-2/HT-2 toxins (group)
ZEN (group incl. modified forms expressed as ZEN-eq)	Adults (chronic, LB–UB): 4.4–64 ng/kg bw/day; Toddlers: up to ~100 ng/kg bw/day (UB) reported in older EFSA material	Adults: 11–117 ng/kg bw/day; Toddlers: up to 280 ng/kg bw/day (UB)	Group TDI = 0.25 µg/kg bw/day (250 ng/kg bw/day) (ZEN-eq)	ZEN (group incl. modified forms expressed as ZEN-eq)
FUM (FB1–FB4) (group)	EU-wide mean & P95 not consistently tabulated by	EU-wide P95 not consistently tabulated in public summaries	Group TDI = 1 µg/kg bw/day (sum FB1–FB4; often communicated	FUM (FB1–FB4) (group)

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	EFSA in a single public summary table for humans (values are per-survey/age in the opinions)		for FB1 with read-across)	
OTA	0.6–17.8 ng/kg bw/day (means across age groups/surveys)	2.4–51.7 ng/kg bw/day	No TDI/TWI; MOE approach applied in 2020 re-evaluation (earlier 2006 TWI 120 ng/kg bw/week rescinded as genotoxic/carcinogenic concerns prevailed)	OTA
AFB1, AFB2, AFG1, AFG2, AFM1	EU-wide mean & P95 values by age are not systematically published in the public summary; EFSA assessed cancer risk via MOE and potency factors using >200,000 occurrence results	Not systematically published in public summary	No TDI; MOE framework (e.g., BMDL10 for AFB1 = 0.4 µg/kg bw/day used for MOE)	AFB1, AFB2, AFG1, AFG2, AFM1
Ergot alkaloids	Toddlers/other children (UB means): up to	Toddlers (UB P95): up to 0.86 µg/kg bw/day	Group TDI = 0.6 µg/kg bw/day; group ARfD = 1 µg/kg bw (human	Ergot alkaloids (sum of 12–14 EAs)

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(sum of 12–14 EAs)	0.47 µg/kg bw/day		HBGVs; EFSA 2012/2017)	
Patulin	EFSA public summaries do not provide an EU-wide, age-stratified mean/P95 table; national assessments exist	Not consistently tabulated at EU level in public summaries	TDI = 0.4 µg/kg bw/day (EFSA/JECFA)	Patulin
Phomopsins (lupin)	No harmonised EU-wide public table of mean/P95 human dietary exposure	—	MLs exist for lupin products; no EFSA human TDI established (human exposure generally considered low with current MLs) — (no single EFSA human exposure table to cite)	Phomopsins (lupin)
Citrinin (food supplements, red yeast rice)	No harmonised EU-wide public table of mean/P95 exposure	—	EFSA (2012) identified nephrotoxicity; no TDI due to genotoxicity concern; risk characterised via MOE (not an exposure table). —	Citrinin (food supplements, red yeast rice)

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6. Data Gaps and Limitations in Mycotoxin Exposure Assessment

6.1 Limitations in Occurrence Data

Although decades of surveillance, academic studies, and national monitoring programmes have generated extensive mycotoxin datasets, this apparent abundance conceals a series of structural weaknesses. Most literature-based data lack key parameters - sampling design, analytical uncertainty, censoring thresholds, and harmonised food categorisation - essential for quantitative exposure modelling. As a result, the empirical basis of many exposure assessments remains fragmented, inconsistent, and often outdated.

Representativeness and sampling bias are persistent concerns. Many occurrence datasets originate from targeted surveillance, enforcement testing, or research projects rather than statistically representative sampling schemes. Such data are often biased towards noncompliant or high-risk commodities, specific geographic regions, or contamination peaks following known outbreaks. When aggregated without critical weighting, they tend to overestimate population-level exposure and distort temporal trends.

Heterogeneity in analytical reporting further reduces comparability. Studies differ in units (dry vs. fresh weight), analytical methods (HPLC-FLD vs. LC-MS/MS), and treatment of censored results. Detection limits (LOD/LOQ) and recovery rates are frequently absent, precluding application of EFSA's LB/MB/UB methodology. Many publications report only summary statistics (mean ± SD), omitting distributional data necessary for probabilistic exposure modelling. Consequently, literature data capture only central tendencies, not the variability that defines risk.

A high proportion of **left-censored results** also weakens reliability. In matrices such as baby foods or processed cereals, non-detect fractions may exceed 80–90 %. In the absence of raw data, substitution with assumed LOQ values inflates

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uncertainty and widens LB–UB intervals, producing unstable exposure estimates.

Mixture and co-occurrence data remain sparse. Most studies analyse single mycotoxin classes (e.g., trichothecenes) without quantifying concurrent contamination by other compounds. This absence of joint-distribution data forces exposure modellers to assume independence between toxins, likely underestimating cumulative exposure. It also impedes the development of RPFs (RPFs) and cumulative assessment groups (CAGs) required for mixture risk assessment.

Processing and transformation factors (PFs) are incompletely characterised. Mycotoxin levels can change substantially through milling, fermentation, roasting, or cooking, but PF data remain scarce and inconsistent. Without standardised PF databases, exposure models often default to PF = 1, introducing systematic bias.

Finally, **temporal and geographic disparities** affect the interpretability of occurrence data. Southern and Eastern European datasets are sparser than those from Western and Northern countries, yet commodities circulate freely within the single market. The combination of incomplete spatial coverage, differing analytical capacities, and publication lags of two to four years means that exposure estimates often lag behind the actual contamination landscape, particularly in the context of climate-driven changes in fungal ecology.

6.2 Gaps in Dietary Consumption Data

The European dietary survey infrastructure - centred on EFSA's Comprehensive Food Consumption Database and the EU-MENU initiative - provides an indispensable but imperfect foundation for dietary exposure modelling. The database supports harmonised assessments across Member States, yet several structural limitations constrain its accuracy, temporal validity, and comparability.

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Temporal representativeness is the most critical issue. Many national surveys included in the EFSA database were conducted between 2003 and 2015, predating major shifts in food production, processing, and import patterns. Consumption data may therefore not reflect current European diets characterised by increased intake of processed foods, plant-based products, and imported commodities. Although recent updates have added surveys from Poland, Croatia, and Montenegro, most countries still rely on legacy datasets.

Methodological inconsistency across national surveys introduces additional uncertainty. Despite EFSA's harmonisation efforts under the EU-MENU programme, differences in recall method (24-hour vs. diary), number of recall days, sampling design, and portion-size estimation persist. EFSA itself acknowledges that such methodological variability limits the comparability of country-to-country data and complicates EU-wide analyses.

Population coverage is incomplete. While most age classes are represented, specific subgroups—pregnant and lactating women, vegetarians, and high consumers of niche commodities—are under-sampled. Data for infants and toddlers, who are typically the most exposed groups per kilogram body weight, are limited and statistically weak, resulting in large uncertainty at high consumption percentiles.

Commodity detail and processing information are often insufficient for contaminant-specific assessments. Foods are frequently aggregated into broad categories (e.g., "cereals and cereal products"), with limited indication of product type or processing state. Because processing alters mycotoxin levels, this lack of resolution weakens the link between occurrence and consumption data and hampers the derivation of realistic exposure estimates.

Geographical coverage remains uneven. Western and Northern European countries are well represented, while Eastern and Balkan regions are under-

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sampled or rely on older methodologies, creating regional gaps in exposure mapping.

High-percentile consumption estimates - critical for defining upper-bound exposure - are often unreliable due to small sample sizes and limited recall days. This compromises the assessment of extreme consumers, which are key to defining health-based exceedance probabilities.

Metadata transparency is also variable. Information on survey year, sampling design, weighting factors, or recall distribution is not consistently available. This limits reproducibility and prevents full uncertainty quantification.

Finally, **mismatch between consumption and occurrence datasets** further undermines representativeness. Consumption surveys and occurrence monitoring are rarely contemporaneous, leading to potential bias when pairing older consumption data with newer contamination results.

6.3 Implications for Exposure Assessment

For quantitative modelling, EFSA's datasets should be regarded as approximations of dietary patterns rather than direct reflections of present-day behaviour. Temporal and methodological variability in the consumption data, combined with uneven representativeness in occurrence datasets, introduces structural uncertainty that must be explicitly acknowledged in all exposure analyses.

Model developers should:

- Record survey metadata (year, population group, methodology, recall days) for each dataset used.
- Conduct sensitivity analyses to evaluate how alternative consumption or occurrence assumptions influence exposure outcomes.
- Supplement EFSA data with national statistics (e.g., household budget or market sales data) to update or validate consumption levels for high-risk commodities.

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- Assess the direction and magnitude of temporal bias when consumption and occurrence datasets refer to different years.
- Report uncertainty ranges for both mean and high-percentile estimates, indicating confidence levels and primary data limitations.

Until systematic renewal of dietary surveys and complete transparency of metadata are achieved, EFSA's consumption data and literature-derived occurrence datasets should be considered suitable for baseline and comparative modelling, but not definitive indicators of current exposure. Harmonised survey renewal, improved process-level data, and enhanced access to microdata will be essential to reduce uncertainty and improve the predictive accuracy of future European mycotoxin exposure assessments.

7. Burden of disease

The burden of disease (BoD) provides a quantitative measure of the impact of health risks or conditions on populations[31]. It integrates mortality and morbidity into a single metric, the Disability-Adjusted Life Year (DALY), which reflects the total number of healthy life years lost due to premature death and disease-related disability. One DALY corresponds to one lost year of "healthy" life. DALYs are the sum of Years of Life Lost (YLL) due to premature mortality and Years Lived with Disability (YLD) associated with non-fatal outcomes. This unified framework enables consistent comparison of diverse health outcomes and risk factors, including those arising from foodborne contaminants such as mycotoxins.

For risk assessment purposes, the DALY metric captures both the severity and duration of the health outcomes attributable to exposure. The YLL component is derived from the number of deaths and the standard life expectancy at the age of death, whereas the YLD component quantifies the non-fatal health loss as the product of disease prevalence (or incidence × duration) and a *disability*

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weight. The latter expresses the magnitude of functional health loss on a scale from 0 (full health) to 1 (death).

Applying the BoD framework to chemical exposures requires estimation of the population-attributable fraction (PAF)—the proportion of disease burden attributable to the specific exposure. For food contaminants, this involves linking dietary exposure data with validated exposure–response relationships for defined health outcomes (e.g., AFB_1 and hepatocellular carcinoma). The PAF is then applied to observed disease incidence or mortality data to estimate the number of attributable cases, deaths, and DALYs.

This approach offers several advantages for food safety and risk management. It provides a common measure that allows comparison of different hazards on the same scale, thus supporting prioritisation of regulatory actions. It also enables integration of health impact into cost-effectiveness and risk–benefit analyses. Moreover, BoD metrics explicitly incorporate age and population structure, identifying subgroups at higher risk, such as children or individuals with specific dietary patterns.

In the context of mycotoxin risk assessment[32], the DALY framework allows translation of exposure levels - typically expressed in µg/kg bw/day - into measurable public health impact. While EFSA currently expresses risk for genotoxic carcinogens using the MOE approach, DALY modelling provides complementary insight by quantifying the potential number of life years lost due to the exposure. For mycotoxins with well-established dose–response relationships, such as AFB_1, DALY estimation represents a key instrument for understanding the comparative significance of these contaminants within the wider burden of foodborne disease in Europe[33].

7.1 Methodology

The methodology applied for quantifying disease burden follows the structure developed by the WHO[31], the Foodborne Disease Burden Epidemiology

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Reference Group (FERG - https://www.foodbornediseaseburden.org/ferg), and the Global Burden of Disease (GBD) framework (https://www.healthdata.org/research-analysis/gbd). It is designed to ensure consistency and transparency in estimating health loss attributable to mycotoxin exposure.

The process comprises three main stages: (1) definition of causal risk–outcome pairs; (2) estimation of population-attributable incidence and mortality; and (3) calculation of DALYs by summing YLL and YLD.

- *Definition of causal relationships.*

Only mycotoxin–disease pairs supported by robust causal evidence are included. For AFB_1, this corresponds to the association with hepatocellular carcinoma (HCC), for which quantitative risk models exist. Other mycotoxins (e.g., OTA, FUM, trichothecenes) currently lack validated exposure–response functions suitable for burden modelling and are therefore excluded from DALY quantification.

- *Data sources.*

Exposure distributions are derived from EFSA dietary exposure assessments, disaggregated by age, sex, and region, and expressed as LB/MB/UB scenarios to account for LC. Epidemiological data on incidence, prevalence, and mortality for the target disease are sourced from WHO or GBD datasets. Effect sizes are taken from established dose–response relationships (e.g., cancer potency factors for AFB_1) and adjusted for co-factors such as hepatitis B virus prevalence, which modifies cancer risk.

Disability weights and disease durations follow the GBD standardised health-state definitions. Life expectancy values are drawn from the GBD normative life tables for the YLL calculation.

- *Calculation of the population-attributable fraction (PAF).*

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For continuous exposures, the PAF is derived by integrating over the exposure distribution and relative risk function:

$$\text{PAF} = \frac{\int P(x)\,[RR(x) - 1]\,dx}{\int P(x)\,RR(x)\,dx}$$

where:

PAF is the Population Attributable Fraction, i.e. the proportion of disease cases (or burden) in the population attributable to the exposure;

P(x) is the probability density function of the population exposure distribution, where x denotes the level of exposure;

RR(x) is the relative risk associated with exposure level x, derived from the exposure–response relationship;

x represents the continuous exposure metric (e.g. µg/kg bw/day);

the integrals are evaluated over the full range of population exposure.

- *Computation of DALYs.*

Attributable disease cases and deaths are multiplied by standard life expectancies and disability weights to estimate YLL and YLD respectively:

$$\text{YLL} = D_{a,s} \times L_{a,s}$$
$$\text{YLD} = I_{a,s} \times DW \times \text{duration}$$

where:

YLL is the Years of Life Lost due to premature mortality and YLD is the Years Lived with Disability

$D_{a,s}$ is the number of deaths and $I_{a,s}$ the number of incident cases attributable to the exposure in the age group **a** and sex **s**;

$L_{a,s}$ is the remaining life expectancy at the age of death for age group **a** and sex **s**, derived from standard life tables (years);

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DW is the disability weight associated with the specific health outcome (dimensionless, ranging from 0 = full health to 1 = death);
duration is the average duration of the health outcome (years).
Total DALYs are the sum of these two components. Rates per 100,000 population are calculated for comparability across countries and age groups.

This methodology aligns with current WHO and EFSA guidance on health impact quantification. It ensures transparency and reproducibility while maintaining scientific rigour in linking mycotoxin exposure with measurable public health outcomes. Within the MYMATCH framework, it provides the analytical basis for integrating exposure assessment with health impact evaluation, enabling prioritisation of control measures according to their estimated contribution to the total burden of foodborne disease in Europe.

7.2 Application to mycotoxin exposure in Europe

At present, quantitative BoD estimation is feasible only for AFB_1, while for other regulated mycotoxins the scientific evidence and data infrastructure – as largely reported in this deliverable - are still insufficient to support reliable modelling[34].
AF represent the only mycotoxin group for which the full chain of evidence - causal link, quantitative dose–response, and global epidemiology - is sufficiently developed for BoD modelling. Aflatoxin B_1 is a potent genotoxic carcinogen causing HCC, with risk modified by chronic hepatitis B virus (HBV) infection.
The Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a cancer potency factor of approximately 0.01 cancers per year per 100 000 persons per ng/kg bw/day of AFB_1 exposure for HBV-negative populations, and about 30-fold higher for HBV-positive individuals. EFSA (2020) adopted this model for European risk assessment using a $BMDL_{10}$ of 0.4 µg/kg bw/day[28].

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Global and regional burden estimates have been produced within the WHO Foodborne Disease Burden Epidemiology Reference Group (FERG) framework. WHO's 2015 global assessment attributed roughly 20 000 HCC deaths and 0.7 million DALYs annually to aflatoxin exposure worldwide, with the highest burdens in regions of high HBV prevalence and maize- or groundnut-based diets[31].

Within Europe, the burden is comparatively low but measurable: literature applying EFSA exposure data to the WHO model[35] estimated 0.3–1.1 DALYs per 100,000 population, with variability linked to dietary exposure and HBV prevalence. Although absolute numbers are small, these figures demonstrate that chronic low-level aflatoxin exposure contributes a quantifiable health burden in the European population.

For reference, the following table summarise the peer-literature studies so far available providing BoD for AF.

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***Table 5**: Summary of published burden-of-disease (DALY) estimates for aflatoxin exposure, including global, regional, and national assessments based on different exposure metrics and modelling frameworks.*

Study (year)	Geography / population	Exposure source	Outcome model	DALYs (as reported)	Notes / Key parameters
WHO/FERG (2015)[31]	Global and regional	FAO/WHO food data + JECFA exposure distributions	HCC (HBV ± potency model)	≈ 0.7 million DALYs globally per year	Standard reference for all later models; uses global HBV prevalence, WHO life tables, YLL-dominated burden.
Martins et al. (2021)[35]	19 EU countries (adults)	EFSA (2020) occurrence + exposure data	HCC	0.3 – 1.1 DALYs / 100 000 pop.	First EU-wide application; used JECFA potency; uncertainty not published; HBV 0.5 – 1 %.
Kimanya et al. (2021)[36]	Tanzania (national)	Biomarker (AF-albumin)	HCC	≈ 56 248 total DALYs	High exposure context; assumes HCC CFR ≈ 0.9; YLL dominant; sensitivity to HBV prevalence > 8 %.
Rasheed et al. (2021)[37]	4 African countries (children < 5 y)	AF-albumin biomarkers	Stunting (YLD + YLL)	≈ 49 000 DALYs / 100 000 children	Non-cancer outcome; very high AF exposure; prevalence-based DALYs; not comparable to HCC models.
Qin et al. (2023)[38]	Chongqing, China	Dietary exposure (grain, nuts, spices)	HCC DALY (FDA-iRISK)	6.47–40.72 DALYs / 100 000 person-years	Lifetime average exposure 2.40–8.25 ng/kg bw/day (mean) and 9.51–15.10 ng/kg bw/day (P95); PAF 1.68–10.60% (HCC burden)
Chen et al. (2022)[39]	China (national)	Dietary intake (peanuts, corn, peanut oil)	HCC DALY	1.53 DALYs / 100 000 population	Total intake ~4.02 ng/kg bw/day; DALYs highest in coastal regions; national consumption survey used

Across the studies summarised in Table 6, the estimated BoD attributable to aflatoxin exposure shows marked geographical variability. In Europe, DALY estimates below 1 per 100,000 population reflect the combined effect of relatively low dietary exposure levels and low HBV prevalence. In contrast, studies from Asia and Africa report substantially higher burdens, typically in the range of 10–50 DALYs per 100,000 population in settings where HBV prevalence is higher (approximately 6–10%) and reaching orders of magnitude higher values in high-exposure contexts, particularly among young children.

At the global level, the WHO/FERG assessment provides a reference estimate of approximately 0.7 million DALYs per year attributable to aflatoxin exposure, with the burden overwhelmingly dominated by YLL due to fatal HCC.

Despite differences in exposure assessment methods and geographical scope, a strong convergence is observed in the underlying modelling approaches for HCC-related outcomes. Most studies rely on JECFA/WHO cancer potency factors, standard WHO life tables, and assume high HCC case-fatality rates (>90%), resulting in YLL contributing far more to total DALYs than YLD. Differences in DALY estimates across regions therefore primarily reflect variation in dietary exposure levels and HBV prevalence rather than methodological divergence.

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BoD estimation requires three essential components: a validated risk–outcome pair establishing a causal link between exposure and a specific health effect, a quantitative exposure–response function, and population-level data on disease incidence and mortality. For most mycotoxins - such as OTA, FUM, DON (DON), ZEN, and the T-2/HT-2 - these prerequisites are currently not fulfilled.

First, validated exposure–response relationships suitable for BoD modelling are lacking. While EFSA and WHO evaluations identify critical effects and establish HBGVs, they do not provide quantitative dose–response functions that can be used to estimate population-attributable fractions of disease. For OTA, risk characterisation relies on the MOE approach rather than a cancer-slope or continuous risk model. For FUM and trichothecenes, the identified adverse effects are predominantly subacute and non-specific - such as growth impairment or immunotoxicity - and do not translate into a clearly defined disease endpoint with an established exposure–response relationship.

Second, epidemiological endpoints linking chronic dietary exposure to measurable disease outcomes are largely absent. Reliable incidence or mortality data that can be causally attributed to long-term exposure to these mycotoxins are not available. For example, suggested associations between FUM exposure and neural tube defects have not been confirmed in European populations and therefore cannot support quantitative burden estimation.

Third, the absence of recognised clinical case definitions, disability weights, and disease durations prevents conversion of potential health effects into YLD or DALYs. Without these elements, even well-characterised toxicological effects cannot be translated into BoD metrics.

Finally, substantial heterogeneity in exposure data further undermines BoD applicability. High proportions of left-censored results, lack of harmonised LOQs, and temporal mismatches between consumption and occurrence datasets introduce structural uncertainty that would propagate through any burden calculation and compromise interpretability.

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8. Conclusion remarks

Deliverable D4.2 consolidates the current European state of knowledge on dietary exposure to mycotoxins and defines the methodological baseline for subsequent predictive and cumulative risk-modelling activities within MYMATCH. Anchored in EFSA guidance and supported by comprehensive European food consumption databases, the framework described provides a robust and harmonised foundation for exposure assessment. At the same time, it highlights structural limitations related to uneven data quality, the age of several dietary surveys, and the still limited coverage of emerging and modified mycotoxins.

The analysis confirms that baseline exposure levels for major regulated mycotoxins are generally below HBGVs for most consumers. However, for specific population groups—most notably infants and toddlers—exposure may approach or exceed toxicological reference values, underlining persistent vulnerability linked to dietary patterns and higher intake per kilogram body weight. Deterministic exposure models, implemented through tools such as DietEx, therefore remain the regulatory reference for harmonised baseline estimates, while probabilistic approaches, exemplified by MCRA, offer a more detailed characterisation of variability and uncertainty when sufficiently harmonised microdata are available.

Across contaminants and datasets, the treatment of left-censored data remains a critical methodological constraint. Continued progress towards model-based approaches and statistically robust imputation methods is essential to improve the accuracy, comparability, and interpretability of exposure estimates. In parallel, persistent gaps in dietary consumption data—particularly for emerging dietary patterns, regional heterogeneity, and high-risk or underrepresented population groups—limit the representativeness of current exposure models and require targeted improvement.

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Finally, the influence of climate change and global trade dynamics on mycotoxin occurrence is increasingly evident, reinforcing the need to move beyond static baseline descriptions. Adaptive, climate-informed exposure baselines and continuous data updating are required to ensure that risk assessment remains relevant under evolving environmental and food-system conditions.

In this context, Deliverable D4.2 functions as the methodological hinge linking data collection, baseline exposure characterisation, and advanced modelling within MYMATCH. It provides the validated reference point for WP7 (advanced exposure forecasting), WP8 (emerging toxins and mixture assessment), and WP10 (policy integration and risk communication). Strengthening European data stewardship, interoperability, and modelling coherence will be essential to transform baseline exposure estimates into a dynamic and climate-resilient framework for mycotoxin risk assessment.

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Annex A - Overview of National Dietary Surveys Included in the EFSA Comprehensive European Food Consumption Database

Country	Survey name / acronym	Survey years (fieldwork)	Age groups covered	Method / recall days	Approx. sample size
Austria	ASNS / Nutrition Survey	2005–2007	Adults (18–64)	2 × 24 h recall	~2,000
Belgium	NVS II / BNFCS	2004, 2014–2015	Children, adults	2 × 24 h recall + FFQ	~3,000
Bulgaria	National Food Survey	2008–2010	Adults	24 h recall	~2,500
Croatia	Cro-Nutrition	2014–2015, 2022 update	Children, adults	2 × 24 h recall	1,400
Cyprus	CY Menu	2008–2010	Children, adults	2 × 24 h recall	1,200
Czech Republic	SISP04	2003–2004	Adults	2 × 24 h recall	2,600
Denmark	DANSDA	2005–2008, 2011–2013	4–75 yrs	7-day diary	3,000–4,000
Estonia	NVS	1997–1999, 2014	Adults	24 h recall	1,000
Finland	FINDIET	2007, 2012	25–74 yrs	2 × 24 h recall	2,000
France	INCA2 / INCA3	2006–2007, 2014–2015	3–79 yrs	7-day record	4,000–5,000
Germany	NVS II	2005–2007	14–80 yrs	2 × 24 h recall	20,000
Greece	Hellenic Nutrition Survey	2013–2015	All ages	2 × 24 h recall	3,000

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Hungary	NNS	2009	Adults	24 h recall	2,000
Ireland	NANS / NPNS	2008–2010	5–90 yrs	4 × 24 h recall	1,500
Italy	INRAN-SCAI	2005–2006	0.1–97 yrs	7-day record	3,300
Latvia	EFSA EU-Menu pilot	2012–2013	Adults	24 h recall	1,200
Lithuania	NNS	2007–2009	Adults	24 h recall	1,500
Netherlands	DNFCS	2007–2010, 2012–2016	7–69 yrs	2 × 24 h recall	3,800
Poland	WOBASZ / EFSA EU-Menu	2000–2011, 2022 update	Children, adults	24 h recall	3,000
Portugal	IAN-AF	2015–2016	3 m–84 yrs	2 × 24 h recall	6,000
Spain	ENIDE / ANIBES	2009–2011, 2013	9–75 yrs	3 × 24 h recall	3,000
Sweden	Riksmaten	2010–2011	Adults, adolescents	4-day diary	2,000
United Kingdom	NDNS	Ongoing (2008–present, rolling)	1.5–94 yrs	4-day diary	1,000 / yr
Norway (EEA)	Norkost3	2010–2011	18–70 yrs	2 × 24 h recall	1,700
Italy	IV SCAI (Adults)	2018–2020 (published 2022–2024)	10–74 y (separate children survey 3 mo–9 y)	Two non-consecutive 24-h recalls (GloboDiet); FPQ; FoodEx2	~1,969
Poland	National Dietary Survey on the adult	2019– 2020 (released 2024)	10–≥75 y (adolescents, adults, elderly); plus	EU-MENU protocol; (two non-consecutive 24-h recalls + FPQ	2,432 core participants; +300 vegetarians;

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	population (EU-MENU)		ad-hoc vegetarians & pregnant	typical for EU-MENU)	+150 pregnant women invited as ad-hoc groups
Netherlands	DNFCS 2019–2021	2019–2021	1–79 y	Two non-consecutive 24-h recalls (GloboDiet) + FPQ; all days/seasons balanced	3,570
Ireland	NANS II (National Adult Nutrition Survey II)	Apr 2021–Aug 2022	≥19 y	Two telephone 24-h recalls (≥7 days apart) + FPQ; brand-level detail	= 1,000 adults
Belgium	FCS 2022–2023	2022–2023	≥3 y	Two non-consecutive 24-h recalls; food diary for children; FPQ	3,777

(Compiled from EFSA Journal 9(3):2097 – "Use of the EFSA Comprehensive European Food Consumption Database", updates 2022–2024 on EFSA portal.)

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