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# Risk ranking and risk-based prioritisation of aflatoxin M<sub>1</sub> in milk and dairy products supporting risk-based monitoring and food safety governance

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## ABSTRACT

In Serbia, contamination of milk and dairy products with aflatoxin M<sub>1</sub> (AFM<sub>1</sub>) represents a recurrent food safety challenge, reflecting the dairy chain's susceptibility to climate extremes, feed contamination, and improper storage conditions. Protecting public health, particularly that of children, requires systematic approaches that move beyond descriptive monitoring towards structured risk prioritisation. The aim of this study was to apply the FAO (2020) and EFSA (2015) methodologies for risk ranking and prioritisation to AFM<sub>1</sub> in Serbia, thereby providing an evidence-based framework to guide risk-based monitoring and food safety governance. The analysis was based on data synthesised from peer-reviewed studies on AFM<sub>1</sub> occurrence, dietary exposure, and risk characterisation in different dairy product categories. Risk matrices were constructed by combining likelihood of contamination with severity of health outcomes, expressed through Margin of Exposure (MOE) values. In addition, binomial probability principles were applied to design optimised sampling strategies. Results showed that raw and pasteurised/UHT milk represent the highest-priority categories, reflecting both high contamination frequencies and dietary importance for children. Average MOE values exceeded the health-based threshold, but high consumers, particularly toddlers, were at risk of falling below safe levels. Probability-based sampling demonstrated how resources can be rationally allocated to maximise detection assurance. This study concludes that structured risk ranking and prioritisation provide a transparent foundation for proportionate AFM<sub>1</sub> monitoring and control.

## ARTICLE HISTORY

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## Introduction

Mycotoxins are toxic fungal secondary metabolites produced mainly by *Aspergillus*, *Fusarium*, and *Penicillium* species, which can contaminate crops and persist in the food chain despite processing (WHO 2015). Among them, aflatoxins pose a particular public health concern due to their genotoxic and carcinogenic adverse effects (IARC 2012). Aflatoxin M<sub>1</sub> (AFM<sub>1</sub>), the hydroxylated metabolite of aflatoxin B<sub>1</sub> (AFB<sub>1</sub>), is excreted in milk when dairy animals consume contaminated feed (Masri et al. 1974; Li et al. 2021). Due to its high thermal stability, AFM<sub>1</sub> can persist through pasteurisation and processing,

contaminating milk and dairy products consumed daily by broad population groups, including infants and young children, who are especially vulnerable due to their high intake-to-body-weight ratio (Muaz et al. 2022).

Global regulations on AFM<sub>1</sub> vary considerably. The United States, China, and Russia allow maximum levels of 0.5 µg/kg in milk (Jiménez Medina et al. 2021), while the European Union (EU) enforces the strictest standard at 0.05 µg/kg for raw and heat-treated milk, and 0.025 µg/kg for infant formulae (EC 2023). Serbia has faced recurrent aflatoxin crises since 2012, when severe drought and maize contamination forced authorities to temporarily increase the national AFM<sub>1</sub>

limit tenfold to 0.5 µg/kg. Although the limit was later reduced, Serbia's current threshold of 0.25 µg/kg (Jakšić et al. 2019), remains five times higher than the EU maximum, reflecting the challenges of balancing food safety with production realities and the implications for both consumer protection and international trade.

Since the 2012 crisis, numerous Serbian studies have documented the occurrence of AFM1 in milk and dairy products, revealing substantial seasonal and inter-annual variability (Milićević et al. 2020). Children have consistently been identified as the most vulnerable group, with higher estimated daily intakes (EDI) relative to body weight (Milićević et al. 2021). However, findings related to risk characterisation are often inconsistent across studies, spanning a wide range of risk estimates. While some deterministic and probabilistic exposure assessments indicate a relatively low carcinogenic risk—reflected in hepatocellular carcinoma (HCC) incidence estimates and margin of exposure (MOE) values exceeding the safety threshold of 10,000 (EFSA 2020)—other studies, conducted not only in children but also in the broader Serbian population, report scenarios where MOE values fall below this threshold, suggesting potential health concern (Đekić et al. 2020; Udovički et al. 2023). This divergence reflects differences in study design, exposure scenarios, and analytical sensitivity, underscoring the uncertainty that complicates risk management decisions. Collectively, these data demonstrate the recurrent and systemic nature of AFM1 risk in Serbia, tightly linked to climatic extremes, maize production, and feed storage practices, while also highlighting the urgent need for more consistent and harmonised approaches to exposure and risk assessment. In this context, competent authorities bear the responsibility to implement risk-based food control systems that optimise the use of inspection resources and to periodically review their performance to ensure effectiveness and adaptability (FAO & WHO, 2019).

Climatic variability is a critical upstream driver of mycotoxin risk in Serbia, with direct implications for AFM1 contamination in milk. The unprecedented drought of 2012 created optimal conditions for *Aspergillus flavus* proliferation in maize, triggering Serbia's first major aflatoxin

crisis and widespread exceedances of AFM1 in milk (Kos et al. 2024). In contrast, the extremely wet 2014 season, with rainfall at historical maxima, favoured *Fusarium* growth and resulted in co-occurrence of deoxynivalenol (DON), zearalenone (ZEN), and fumonisins (FUM), while aflatoxins were largely absent. This duality illustrates how hot, dry summers drive *Aspergillus* outbreaks, whereas prolonged humidity fosters *Fusarium* and multi-mycotoxin contamination (Milićević et al. 2020; Kudumija et al. 2025).

From 2015 to 2018, systematic surveillance of more than 20,000 raw milk samples revealed pronounced year-to-year variability in AFM1 prevalence. Peaks were consistently observed during late winter and early spring, reflecting both the seasonal feeding of stored maize and the carry-over of AFB1 into milk. Statistical analyses confirmed that AFM1 occurrence was positively correlated with higher temperatures and relative humidity, and inversely correlated with cumulative precipitation, underscoring the complex, non-linear influence of climate on contamination risk (Milićević et al. 2019).

These findings align with broader Serbian surveys linking alternating drought and flooding to shifting mycotoxin profiles, confirming Serbia as one of Europe's climate-vulnerable hotspots for food safety risks. Moreover, climate change not only alters fungal incidence but also modulates the expression of aflatoxin biosynthetic genes, thereby influencing toxin yields. The increasing frequency of extreme events such as drought, heat waves, and heavy rainfall, within the same production cycle amplifies risks by fostering overlapping contamination scenarios (Kos et al. 2024). Taken together, AFM1 contamination in milk serves as an indicator of Serbia's broader climate-induced vulnerabilities in the agri-food chain. Integrating climate-informed hazard analysis into food safety monitoring and control systems is therefore essential, with preventive measures such as rapid maize drying, controlled aeration, dew point monitoring, and improved storage hygiene forming critical adaptation strategies (Milićević et al. 2019).

Despite extensive monitoring of AFM1 in Serbia and numerous exposure studies, a structured risk-ranking and prioritisation framework is still

missing. The Food and Agricultural Organisation of the United Nations (FAO) Guide to Ranking Food Safety Risks (FAO 2020) and the European Food Safety Authority's critical review of risk ranking methodologies (EFSA 2015) both provide structured approaches for systematically evaluating hazards by combining likelihood of exposure and severity of outcomes, followed by prioritisation that also considers feasibility, costs, and societal context. Applying such a framework to AFM1 in Serbia can support proportionate, evidence-based decisions on monitoring, optimal allocation of resources, and targeted interventions in the dairy chain (Kerekes et al. 2016). International approaches to chemical contaminant ranking—such as decision-tree models for infant foods, semi-quantitative risk ranking for contaminants, and feed ingredient prioritisation models—demonstrate the value of structured ranking tools for enhancing food safety governance. This approach is consistent with the FAO Strategic Framework 2022–31, which promotes evidence-based and data-driven governance as a foundation for more efficient, resilient, and sustainable agrifood systems (FAO 2021).

The objective of this study is to perform a structured risk ranking and prioritisation of AFM1 in milk and dairy products in Serbia, using the FAO (2020) and EFSA (2015) methodologies as a guiding framework. By synthesising national occurrence and exposure evidence with risk-ranking principles, this study aimed to propose a prioritisation model that not only informs risk-based monitoring and control strategies but also strengthens the overall food safety system in Serbia, thereby enhancing public health protection, improving alignment with international food safety standards, and safeguarding vulnerable consumer groups.

## Materials and methods

### Data sources

This study is based on a systematic literature review of research conducted between 2014 and 2024 on the occurrence, exposure, and risk assessment of AFM1 in milk and dairy products in Serbia. The data were collected in May 2025 through comprehensive searches of indexed databases (Scopus, Web of Science, PubMed) and

relevant national repositories to ensure completeness and reliability. Evidence was drawn primarily from peer-reviewed articles authored by the present research team and collaborators. These studies encompassed large-scale monitoring of AFM1 in raw and processed milk, dietary exposure and risk assessment investigations in different population groups—particularly children and young adults—as well as evaluations of seasonal and inter-annual variability in AFM1 concentrations under climatic extremes. All referenced studies were conducted in accredited laboratories and applied validated, quality-assured methods for AFM1 determination. Screening analyses were performed using enzyme-linked immunosorbent assay (ELISA), while samples exceeding the maximum permitted level were confirmed by liquid chromatography coupled with tandem mass spectrometry (LC–MS/MS), in accordance with ISO 14501:2022 and Commission Regulation (EU) 2023/915. The detection limit of the ELISA method was 0.005 µg/kg with 100% specificity, whereas for LC–MS/MS analysis it was 0.02 µg/kg, as reported in the referenced studies (Milićević et al. 2017, 2019, 2021). Analytical quality assurance was verified through participation in an international proficiency testing scheme, which confirmed the reliability and comparability of the analytical results. These methodological criteria ensured that only analytically verified and internationally comparable datasets were included in the present evaluation.

Dietary intake data of milk and dairy product groups for toddlers (1–3 years) and children (3–9 years) were obtained from previously published national dietary surveys (Milićević et al. 2021) and served as the basis for risk characterisation in this study. Consumption values were stratified by age group and product category to enable the calculation of estimated daily intake (EDI) and subsequent margin of exposure (MOE) values (EFSA 2020). These data were further complemented by analyses of regulatory developments and food safety implications in Serbia.

### Analytical approach

To ensure methodological consistency, the study relied on international frameworks, notably the FAO Guide to Ranking Food Safety Risks (FAO

2020) and the EFSA critical review of risk ranking methods (2015). Building on these references, the analytical framework followed the three-step methodology proposed by FAO (2020). First, the systematic review and data extraction focused on quantitative data regarding AFM1 occurrence, dietary intake, and risk characterisation outcomes such as EDI and MOE. Outcomes were classified according to target population groups, with particular emphasis on toddlers and children, and compared with regulatory thresholds (EU: 0.05 µg/kg; Serbia: 0.25 µg/kg).

In the second step, evidence was synthesised within a risk ranking framework using risk matrices that combine likelihood of occurrence with severity of consequences, as recommended by EFSA (2015) and FAO (2020) and further supported by methodological reviews highlighting their applicability for food-related hazards (van der Fels-Klerx et al. 2018). Likelihood classes were defined according to the probability of AFM1 occurrence: rare (<5%), unlikely (5–15%), possible (16–30%), likely (31–60%), and almost certain (>60%). Severity was classified on the basis of MOE values, which serve as internationally recognised risk indicators (EFSA 2020): values above 20,000 were considered negligible, between 15,000 and 20,000 low (close to the safety zone), between 10,000 and 15,000 moderate (threshold zone), between 5,000 and 10,000 high, and below 5,000 very high or critical. This structured approach enabled the risk ranking and risk-based prioritisation of AFM1 in milk and dairy products, providing a systematic basis for identifying hazards of greatest public health concern.

### **Probability of contamination and sampling strategy**

The third step addressed the design of monitoring strategies, focusing on the probability of contamination and its implications for sampling plans. The probability of detecting at least one violative sample in a given number of randomly selected units was modelled using binomial probability principles, following the USDA Food Safety and Inspection Service (FSIS) methodology (2018). The general formula applied was (1)

$$n = \frac{\log(1-p)}{\log(1-v)} \quad (1)$$

where  $p$  is the probability of detection,  $v$  the violation rate in the population, and  $n$  the sample size. This statistical principle, incorporated into the U.S. National Residue Program ('Blue Book'), provides the basis for calculating the minimum number of samples required to ensure detection with a predefined confidence level (e.g. 90%, 95%, or 99%). Applied to AFM1 monitoring in the Serbian dairy sector, this model supports the development of optimised sampling strategies that balance statistical reliability with practical feasibility. The synthesis was translated into a proposed prioritisation model that informs risk-based monitoring, guides control strategies, and supports the alignment of national programs with international food safety standards, thereby reinforcing the scientific foundation of AFM1 surveillance in Serbia and contributing to its harmonisation with globally recognised best practices in residue control.

### **Results**

The results of this investigation are presented in the following tables and figures, covering three main aspects: (i) the synthesis of published data on the occurrence of AFM1 in milk and dairy products, (ii) the assessment of dietary intake in children, and (iii) the subsequent risk characterisation and prioritisation. Specifically, Table 1 summarises the incidence, mean levels, and distribution of AFM1 concentrations across different dairy product categories based on collected data from the literature, while Table 2 reports the calculated MOE values for toddlers (1–3 years) and children (3–9 years). Figures 1 and 2 provide a visual representation of the risk ranking of dairy products according to MOE values. In addition, a sampling plan based on statistical assurance is proposed and presented in Table 3, which translates observed violation rates into the number of analytical units required for 95% detection probability, thereby supporting risk prioritisation in practical monitoring programs.

**Table 1.** Aflatoxin M1 contamination in milk and dairy products: incidence, mean levels, and concentration range.

Food products	N	n (%)	Mean ± Sd	Lower 95% CI	Upper 95% CI	Median P50	P95	IQR (Q1-Q3)	Range (min-max)	Above EU MLs, N (%)	n95 (p=95%)
Fermented milk products	775	158 (20.3)	13.56 ± 0.02	12.18	14.95	5.0	56.3	0	5.0-174.0	53 (6.84)	43
Pasteurised and UHT milk	725	574 (79)	22.87 ± 0.02	21.56	24.18	22.0	52.8	21	2.5-132.0	41 (5.66)	52
Milk beverages	714	145 (20)	8.20 ± 0.01	7.4	9.0	5.0	22.3	0	5.0-117.0	9 (1.26)	237
Cheese	404	7 (2)	6.28 ± 0.01	4.87	7.68	5.0	5.0	0	5.0-276.0	3 (0.74)	402
Milk powder	201	67 (33)	12.46 ± 0.02	9.72	15.2	5.0	47.0	4.0	5.0-155.0	13 (6.47)	45
Butter	143	14 (10)	9.70 ± 0.01	7.2	12.2	5.0	46.7	0	5.0-92.0	5 (3.50)	85
Sour cream	132	19 (14)	11.18 ± 0.02	8.22	14.14	5.0	48.0	0	5.0-103.0	6 (4.55)	65
Infant formula	92	14 (15.2)	5.88 ± 0.004	5.41	6.35	5.0	12.0	0	5.0-14.0	0 (0)	3
Whey liquid	90	13 (14)	19.11 ± 0.05	8.51	29.69	5.0	74.4	0	5.0-278.0	8 (8.89)	33
Raw milk	29711	21214 (71.4)	44.75 ± 0.10	43.6	45.89	12.0	207.0	33.5	2.5-1400.0	5649 (19.0)	15

N = number of analysed samples; n = number of positive samples (AFM1 > LOD); % = percentage of positive samples; The limit of detection (LOD) for AFM1 is 5.0 ng kg<sup>-1</sup>; IQR (interquartile range) = Q3 - Q1; (Q3 - 75. percentile) and (Q1 - 25. percentile), EU maximum levels (MLs) 50 ng kg<sup>-1</sup>.

**Table 2.** Margin of exposure (MOE) values for aflatoxin M1 across different dairy products, stratified by age group.

Food products	MOE					
	Toddlers, 1-3 Years			Children, 3-9 Years		
	Male and Female			Male and Female		
	LB	UB	P95	LB	UB	P95
Fermented milk products	45354	32042	7623	65979	46614	11089
Pasteurised and UHT milk	22570	21548	9513	44543	42525	18775
Milk beverages	57773	29732	10600	108450	55812	19898
Cheese	1698542	367837	462052	2637988	571286	717535
Butter	2046801	1097254	226455	2312071	1239461	255803
Sour cream	486222	300083	69894	881800	544224	126758
Infant formula	1081089	294174	138379			
Whey liquid				25911	22642	20105
Average	776907	306096	132074	868106	360366	167137

MOE calculations were based on benchmark dose (BMDL<sub>10</sub>) for AFB1 of 0.4 µg kg<sup>-1</sup> bw day<sup>-1</sup> and potency factor for AFM1 of 0.1 (30EFSA 2020). Lower bound (LB) = assuming that the not detected results are equal to 0 (ND = 0). Middle bound (MB) = assuming that the not detected results correspond to half the LOD (ND = 2.5 ng kg<sup>-1</sup>). Upper bound (UB) = assuming that the not detected results correspond to the LOD (ND = 5.0 ng kg<sup>-1</sup>). P95 = 95th percentile.

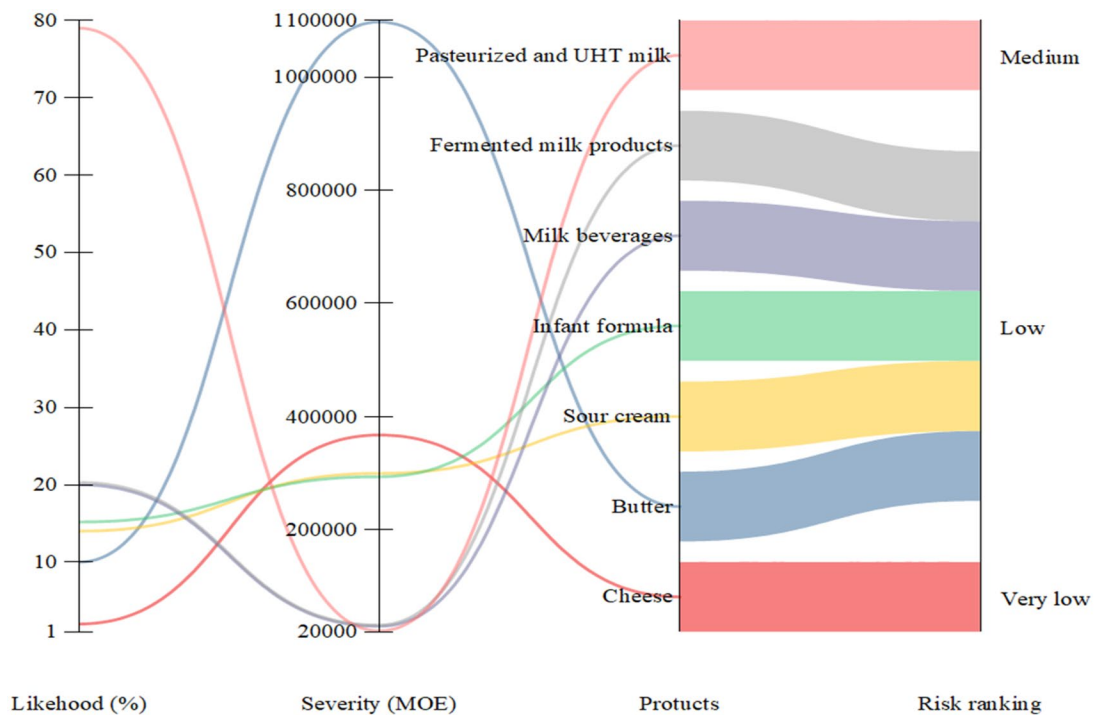
### Occurrence of AFM1 in milk and dairy products

Based on collected data from the literature, analysis of 32,987 samples of raw milk and dairy products (Milićević et al. 2017, 2019, 2021) revealed substantial variability in AFM1 contamination levels (Table 1). The highest incidence of AFM1 above the limit of quantification was reported in pasteurised and UHT milk (79%), followed by raw milk (71.4%). Milk powder

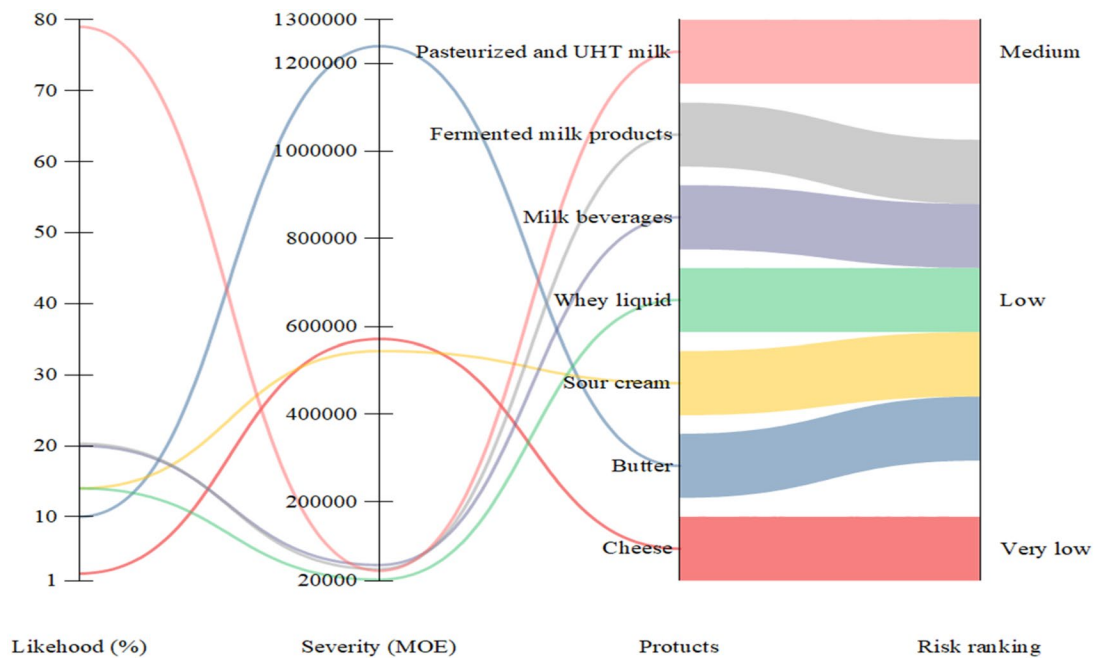
(33%), fermented milk products (20.3%), and milk beverages (20%) showed moderate levels of occurrence, while butter (10%) and cheese (2%) had the lowest detection rates. In addition, published studies reported notable differences in the average concentration of AFM1 across dairy products, as well as in the frequency of samples exceeding the EU maximum permitted level.

According to compiled literature data, the highest mean concentration of AFM1 was reported in raw milk (44.75 ng/kg), followed by pasteurised/UHT milk (22.87 ng/kg), whey liquid (19.11 ng/kg), fermented milk products (13.56 ng/kg), milk powder (12.46 ng/kg), sour cream (11.18 ng/kg), butter (9.70 ng/kg), milk beverages (8.20 ng/kg), and cheese (6.28 ng/kg). Infant formula consistently showed the lowest mean concentration (5.88 ng/kg). The maximum AFM1 concentration was documented in one raw milk sample (1400 ng/kg), representing the highest contamination potential among all dairy products. Other high maximum values were reported for whey liquid (278 ng/kg), cheese (276 ng/kg), fermented milk products (174 ng/kg), milk powder (155 ng/kg), and pasteurised/UHT milk (132 ng/kg). Moderate maximum levels were observed in sour cream (103 ng/kg) and butter (92 ng/kg), while infant formula presented the lowest maximum (14 ng/kg).

Published evidence also shows that in most dairy products the median (P50) concentration



**Figure 1.** Risk ranking of dairy products for toddlers (1–3 years) using scoring matrices. Likelihood: Rare: <5% · Unlikely: 5–15% · Possible: 16–30% · Likely: 31–60% · Almost certain: >60%, Severity: MOE > 20.000—Insignificant, MOE 15–20.000—Minor, MOE 10–15.000—Moderate, MOE 5–10.000—Major (below of thresholds), MOE < 5.000—Severe



**Figure 2.** Risk ranking of dairy products for children (3–9 years) using scoring matrices. Likelihood: Rare: <5% · Unlikely: 5–15% · Possible: 16–30% · Likely: 31–60% · Almost certain: >60%, Severity: MOE > 20.000—Insignificant, MOE 15–20.000—Minor, MOE 10–15.000—Moderate, MOE 5–10.000—Major (below of thresholds), MOE < 5.000—Severe

was 0 ng/kg, reflecting a predominance of non-detect samples. However, in raw milk, the P75 concentration reached 36 ng/kg while P95 reached 207 ng/kg, revealing a considerable subgroup of

highly contaminated samples. In pasteurised/UHT milk, the median (P50) was 22 ng/kg and the P95 was 52.8 ng/kg, indicating consistently higher contamination compared to other dairy

**Table 3.** Proposed structure of a practical sampling framework for dairy products based on risk prioritisation, required sample size (n95) for 95% detection probability, and recommended monitoring frequency.

Food products	Above EU MLs, N (%)	n95 (95% detection)	Risk category	Recommended frequency
Raw milk	5649 (19.0)	15	Medium	Daily (high-volume systems) / Weekly (small-scale)
Whey liquid	8 (8.89)	33	Low	Monthly to quarterly
Fermented milk products	53 (6.84)	43	Low	Monthly to quarterly
Milk powder	13 (6.47)	45	Low	Monthly to quarterly
Pasteurised and UHT milk	41 (5.66)	52	Medium	Daily (high-volume systems) / Weekly (small-scale)
Sour cream	6 (4.55)	65	Low	Monthly to quarterly
Butter	5 (3.50)	85	Low	Monthly to quarterly
Milk beverages	9 (1.26)	237	Low	Monthly to quarterly
Cheese	3 (0.74)	402	Very low	Quarterly to semi-annual
Infant formula*	0 (0)	3	Very low	Quarterly to semi-annual (sentinel for infant formula)

Legend: n95 represents the minimum number of samples required to detect at least one violation with 95% confidence, based on the binomial distribution (USDA-FSIS, 2018). For infant formula, the calculated value of  $n_{95}=3$  is a statistical artefact resulting from the absence of positive samples and does not indicate a real prevalence.

categories. Fermented milk products, milk beverages, and milk powder exhibited P95 values ranging from 47 to 56 ng/kg, while cheese, butter, and sour cream remained substantially lower. Infant formula once again showed minimal contamination, with a P95 of only 12 ng/kg. In addition, the variability of AFM1 concentrations was described using the interquartile range ( $IQR = Q3 - Q1$ ), which further confirmed that in most products the median value was 0 ng/kg due to the predominance of non-detects. For the purposes of risk ranking, these zero values were substituted with the validated LOD, in line with EFSA (European Food Safety Authority) (2010) recommendations. When examining regulatory compliance, the highest frequency of samples exceeding the EU maximum permitted level of 0.05 µg/kg was identified in raw milk, where 5649 samples (19%) were non-compliant. Among processed products, notable exceedances were recorded in whey liquid (8.9%), fermented milk (6.8%), milk powder

(6.5%), pasteurised/UHT milk (5.7%), sour cream (4.6%), and butter (3.5%). Cheese showed very limited exceedances (0.7%), while no infant formula samples surpassed the regulatory threshold. These occurrence data provide the empirical foundation for defining the likelihood component in the risk ranking framework, directly informing the likelihood axis of the risk matrix.

### **Probability of contamination and sampling outcomes**

Applying the USDA binomial sampling model (2018) to the observed violation rates (above MPL, the maximum permitted level), we estimated the minimum number of samples required to detect non-compliant units (exceeding the MPL of 0.05 µg/kg) with predefined levels of statistical assurance. Applied to our dataset, the required sample sizes varied markedly across product categories (Table 1). Raw milk, with a 19% non-compliance rate, required only 15 samples to provide 95% assurance of detecting at least one violative unit. Whey liquid (8.9%) required 33 samples, fermented milk products (6.8%) 43 samples, and milk powder (6.5%) 45 samples. Pasteurised and UHT milk (5.7%) required 52 samples, while sour cream (4.6%), butter (3.5%), and milk beverages (1.3%) required 65, 85, and 237 samples, respectively. Cheese, with only 0.7% of samples exceeding the maximum permitted level, required 402 samples for the same confidence. Infant formula showed no violations; nevertheless, sentinel monitoring is recommended due to the sensitivity of its consumer group.

It is important to emphasise that in this context, n represents the number of independent analytical units required to achieve the defined level of confidence. In practical terms, one analytical unit corresponds to a production batch/lot for processed dairy products, a bulk-tank collection for raw milk, or a retail package for consumer-ready products. Thus, the calculated sample size should not be interpreted as the total number of packages in production, but as the minimum number of representative test units that must be drawn from distinct lots or series to provide statistically reliable assurance.

### MOE-based risk characterization

MOE values for AFM1 were calculated for toddlers (1–3 years) and children (3–9 years), under lower bound (LB), upper bound (UB), and high exposure (P95) scenarios (Table 2).

For toddlers, MOE values ranged from 22,570 for pasteurised/UHT milk to over 2,046,801 for butter. In children, MOE values extended from 44,543 for pasteurised/UHT milk to more than 2,312,071 for butter. These average values are well above the health-based reference threshold of 10,000, indicating no appreciable health concern for the general child population. However, at the 95th percentile of intake (P95), several products yielded MOE values close to or below the safety threshold (EFSA 2020). In toddlers, this included pasteurised/UHT milk (9,513), fermented milk products (7,623), and sour cream (6,984), while in children, fermented milk products (11,089) and sour cream (12,675) approached the critical range. These findings suggest that although the general population of children is not at risk, high consumers of fluid milk, fermented products, and whey-based beverages may face potential health concerns. Overall, the MOE analysis confirms that AFM1 exposure from milk and dairy products is unlikely to pose a risk for average consumers, but it highlights the importance of targeted monitoring and risk management for high-consuming subgroups of children.

### Risk ranking

Based on the data presented in Tables 1 and 2, risk ranking of milk and dairy products was performed using a semi-quantitative approach (EFSA 2015; van der Fels-Klerx et al. 2018; FAO 2020). Semi-quantitative methods, such as scoring matrices, integrate likelihood (probability of AFM1 contamination, expressed as %) and severity (potential health impact, expressed through MOE values). According to the risk matrix approach, products were categorised as very low, low, or medium concern, as shown in Figures 1 and 2.

For toddlers (1–3 years), pasteurised/UHT milk was classified as a medium concern (M), reflecting its high incidence of contamination and regular consumption. Fermented milk products and milk beverages were categorised as low concern

(L), while sour cream, butter, and infant formula also fell into the low concern (L) group, given their lower incidence and consistently high MOE values (EFSA 2020). By contrast, cheese was placed in the very low concern (VL) category, reflecting its negligible contribution to overall AFM1 exposure. Under the high-consumer (P95) scenario, pasteurised/UHT milk and fermented milk products were classified as critical concerns, reflecting their high incidence of contamination and the lowest MOE values observed at this intake level. Milk beverages were categorised as a medium concern, since occasional high intakes may approach risk-relevant thresholds.

For children (3–9 years), the ranking followed a similar pattern as for toddlers. Pasteurised/UHT milk was identified as a medium concern, reflecting its high incidence of contamination and relevance in daily consumption. Milk beverages were classified as low concern, since MOE values for average consumers remained above the safety threshold (EFSA 2020). Under the high-consumer (P95) scenario, fermented milk products shifted into the medium-risk category, indicating potential concern for this subgroup. Cheese was consistently ranked as very low risk, underscoring its negligible role in AFM1 exposure, while butter, sour cream, whey liquid, and infant formula were all categorised as low risk. Taken together, these findings confirm that pasteurised/UHT milk and fermented milk products are the most relevant categories for targeted monitoring and control in this age group, whereas the remaining dairy products contribute only marginally to AFM1 exposure. This ranking forms the analytical basis for the proposed monitoring frequencies and practical sampling framework (Table 4), where risk categories are directly linked to statistical assurance ( $n_{95}$  values; number of samples from the population required to detect at least one violation with a probability ( $p$ ) of 95%).

Raw milk (71.4%, almost certain) and milk powder (33%, likely) were not included in the MOE-based ranking (Table 2 and Figures 1 and 2) because they are not directly consumed by the population, making exposure-based assessment inappropriate. Nevertheless, their contamination levels are critical for downstream safety. Raw milk serves as the primary determinant of AFM1

**Table 4.** Regulatory levels for AFM1 in milk and milk products in different countries (adapted from Milićević et al. 2017).

Jurisdiction	Food category	MPL for AFM1 ( $\mu\text{g kg}^{-1}$ )
European Union	Milk (raw milk, heat-treated milk and milk intended for the manufacture of milk-based products)	0.05
	Infant formulae, follow-on formulae and young-child formulae (ready to use or after reconstitution as instructed)	0.025
United States (FDA)	Whole Milk, Low fat Milk, Skim Milk	0.5
Codex Alimentarius	Milks	0.5
China	Milk and dairy products	0.5
EAEU / Russia	Milk and dairy products	0.5
Serbia	Milk (raw, heat-treated, and milk intended for manufacture of milk-based products)	0.25 (current)*; 0.05 announced from 1 Dec 2025
Switzerland	Milk (Milch / lait)	0.05
	Cheese (Käse / fromage)	0.25

Note: EU values have been updated according to Commission Regulation (EU) 2023/915.

\*Serbian Regulation, OG RS 73/2024, 90/2024, 47/2025, 61/2025.

transfer into processed milk and dairy products, while milk powder, used as an ingredient in various foods, can also act as a source of exposure. For this reason, risk evaluation for these categories was based on incidence data and violation rates, which justify targeted and frequent sampling at collection points and in processing facilities.

### Practical sampling framework

Table 3 presents a practical sampling framework that integrates statistical assurance ( $n_{95}$  values) and monitoring frequency for different dairy products (Table 1) with risk ranking (Figures 1 and 2). The required number of samples to ensure a 95% probability of detecting at least one violative unit varied widely across product categories, reflecting differences in violation rates and exposure relevance.

Products with the lowest  $n_{95}$  values, such as raw milk (15), whey liquid (33), fermented milk products (43), milk powder (45), and pasteurised/UHT milk (52), require relatively few samples to ensure statistical confidence of  $n_{95}$ . However, given their categorisation as medium concern (pasteurised/UHT milk) or low concern (fermented products, whey, milk powder), these

products demand more frequent monitoring (daily to weekly in high-volume systems, monthly in smaller-scale settings) to manage their contribution to overall AFM1 exposure. Products with intermediate  $n_{95}$  values, including sour cream (65) and butter (85), were consistently ranked as very low concern, as their MOE values (EFSA 2020) remain high and the likelihood of violations is low. For these categories, quarterly monitoring is sufficient to maintain assurance without disproportionate use of resources.

Finally, products with the highest  $n_{95}$  values, such as milk beverages (237) and cheese (402), also fall into the low or very low concern categories, respectively. Their negligible contribution to AFM1 exposure supports sentinel-type monitoring on a quarterly to semi-annual basis. Although infant formula showed no violations in this dataset, its sensitivity as a product for vulnerable consumers justifies occasional targeted testing, aligning it with the low-concern group.

In summary although some product groups (e.g. fermented milk products and milk powder) showed  $n_{95}$  values comparable to pasteurised/UHT milk, their overall contribution to AFM1 exposure is considerably lower due to reduced consumption levels and higher MOE values. Consequently, monitoring frequencies were aligned with risk ranking outcomes rather than  $n_{95}$  values alone. Such a tiered approach ensures that resources are directed proportionally to the actual AFM1 risk across dairy product categories.

### Discussion

The aflatoxin crisis of 2012 represented a turning point for food safety in Serbia. Extreme drought led to unprecedented contamination of maize and the subsequent carry-over of aflatoxin B1 into milk, with an exceptionally high proportion of samples exceeding the EU maximum level (EC 2023). While the crisis caused considerable economic and public health consequences, it also catalysed research efforts and methodological improvements (Đekić et al. 2020; Milićević et al. 2021; Udovički et al. 2023).

This study represents the first application of the FAO (2020) and EFSA (2015) risk-ranking methodologies to AFM1 in milk and dairy products in

Serbia. By adapting these internationally recognised frameworks to a nationally relevant hazard–food combination, the study provides a structured and transparent approach to risk prioritisation that had not previously been implemented in the Serbian context. Given the recurrent aflatoxin crises and their significance not only in Serbia but also across the wider Balkan region (Milićević and Pleadin 2023), this work highlights the broader applicability of structured risk-ranking methodologies to address persistent food safety challenges.

The main findings confirm that raw and pasteurised/UHT milk are the product categories of greatest concern, combining high occurrence rates with dietary relevance, particularly among children. This result was expected and is consistent with both national monitoring data and the applied methodological framework, which integrates occurrence, exposure, and severity dimensions into a risk matrix (Jajić et al. 2019; Jauković et al. 2024; Kos et al. 2024). Average MOE values across most dairy products exceeded the health-based reference threshold of 10,000 (EFSA 2020), confirming limited concern for the general population. However, at the P95 intake level, MOE values for toddlers fell close to or below the threshold for pasteurised/UHT milk, fermented milk products, and sour cream, indicating that high consumers in this age group may be at risk (Udovički et al. 2019; Đekić et al. 2020; Udovički et al. 2023). These results align with EFSA's broader assessments, which emphasise children as the most vulnerable group under high-consumption scenarios EFSA (2020). Although raw milk was excluded from the MOE-based ranking due to the absence of direct consumer exposure, its contamination plays a dual role within the dairy chain. On one side, raw milk serves as the main entry point for AFM1 transfer into processed dairy products, since technological treatment does not significantly reduce its concentration. On the other hand, monitoring of raw milk provides a backward signal of AFB1 contamination of animal feed, reflecting the effectiveness of on-farm practices and storage conditions. In this sense, raw milk should be considered an indicator matrix of both dairy chain safety and upstream feed management, emphasising the need for systematic

and frequent sampling at collection and processing stages as part of self-control plans (Polovinski Horvatić et al. 2018; Jauković et al. 2024).

The probability-based sampling model further reinforced these insights by linking violation rates with sample-size requirements for statistical assurance. Using the observed violation rates in our dataset (see Tables 1 and 3), the binomial model indicated that raw milk required  $\approx 15$  samples to provide 95% confidence of detecting at least one violation, whereas cheese required  $>400$  samples due to its very low violation rate. These findings illustrate the practical utility of integrating binomial probability principles into monitoring design—enabling more efficient allocation of resources while maintaining food-safety assurance (FSIS 2018; Farkas et al. 2014). The consistency between observed violation rates and required sample sizes demonstrates that the applied model is both logical and applicable in practice, and aligns with AFM1 implementations reported for dairy self-control systems (Farkas et al. 2014). To further optimise risk-based monitoring, recent advances in digitalisation and machine learning (ML) offer a data-driven layer that complements FAO/EFSA risk-ranking. Systematic reviews show that ML models (Wang et al. 2022a,2022b) can combine monitoring, weather, supply-chain and contextual data to forecast safety events and target sampling where the likelihood of non-compliance is highest. This aligns with EU risk-based control principles and strengthens the transparency of risk prioritisation.

Over more than a decade, research in Serbia has consistently demonstrated that AFM1 is a recurrent and climate-sensitive hazard. Following the 2012 crisis, early investigations documented extremely high prevalence rates in raw and fluid milk, with strong seasonal variation characterised by peaks in late winter and early spring (Kos et al. 2014; Tomašević et al. 2015; Miočinović et al. 2017). These seasonal peaks were causally linked to the use of stored and improperly ensiled feed, underscoring the vulnerability of the dairy chain during periods of feed scarcity. Subsequent studies broadened the analytical perspective, confirming that climatic extremes (droughts, heat waves, floods) were key drivers of maize contamination with aflatoxin B1, which translated into

elevated AFM1 levels in milk (Milićević et al. 2019). At the same time, infrastructural and technological factors—poor storage conditions, inadequate silage management, and gaps in preventive on-farm practices—were repeatedly identified as significant contributors (Polovinski Horvatović et al. 2018; Jajić et al. 2019; Ivetić et al. 2025). Over time, research moved beyond descriptive prevalence studies towards more advanced dietary exposure assessments and, most recently, probabilistic and climate-informed modelling approaches. This progressive methodological shift reflects a broader trend of modernising AFM1 research in Serbia, aligning it with international risk assessment practices and providing the scientific basis for the present study (Đekić et al. 2020; Milićević et al. 2021; Udovički et al. 2023).

Comparable results have been reported in neighbouring countries. Studies from Croatia and Bosnia and Herzegovina (Bilandžić et al. 2016, 2025) also identified raw and fluid milk as the primary sources of AFM1 exposure and highlighted children as the most at-risk group. Seasonal patterns, with higher contamination levels in late winter and early spring due to reliance on stored maize, were consistent across the region. In Hungary, deterministic exposure models identified borderline risk levels for young children, while probabilistic approaches yielded lower estimates but confirmed the susceptibility of high-consuming subgroups (Kerekes et al. 2021; Farkas et al. 2022). In Albania, AFM1 contamination was documented in raw milk, and researchers stressed the importance of including all dairy products and climate-related scenarios in risk assessments (Topi et al. 2022). In the Czech Republic, stricter EU regulatory limits (50 ng/kg) were associated with lower exceedance rates, underscoring the importance of harmonised regulatory frameworks and effective monitoring systems (Hasoňová et al. 2025).

From a regulatory perspective, maximum permitted levels (MPLs) for aflatoxin M1 (AFM1) in milk differ considerably among countries. Table 4 summarises the acceptable limits defined by key international and national authorities, highlighting the variation in safety thresholds and the need for harmonisation of food safety standards.

As shown, the EU (EC 2023) has adopted the most stringent limit (0.05 µg/kg for milk and 0.025 µg/kg for infant formula), whereas Serbia currently applies a transitional limit of 0.25 µg/kg, five times higher than the EU value (Serbian Regulation, OG RS 73/2024, 90/2024, 47/2025, 61/2025). This difference continues to influence national monitoring outcomes and risk characterisation results. Aligning Serbian regulations with EU standards remains a key step towards harmonised food safety governance and risk-based monitoring. These differences in regulatory stringency influence both the frequency of non-compliance and the interpretation of risk, underscoring the importance of aligning national legislation with EU and Codex Alimentarius standards.

Regulatory disparities are reflected in regional contamination and compliance trends across the Mediterranean basin, as further confirmed by the systematic review of Malissiova et al. (2024), which analysed two decades of data from Mediterranean countries. The review found AFM1 in 40% of milk and dairy product samples, with southeastern Mediterranean countries (including Serbia, Turkey, Egypt, and Lebanon) showing the highest exceedance rates and Hazard Index values. In contrast, western Mediterranean countries such as Spain, Italy, and France generally reported lower prevalence, attributed to stricter regulation and stronger monitoring systems. Importantly, raw and thermally processed milk were consistently contaminated due to the thermal stability of AFM1, while cheese emerged as the most affected category, confirming earlier findings from Serbia and other Balkan states. The review also emphasised the role of climate stressors—drought, heat, and humidity during storage—as decisive factors in AFM1 contamination, fully consistent with the Serbian experience where contamination peaks have coincided with hot and dry years. Moreover, children were once again identified as the most vulnerable group, reinforcing national and regional findings, while the authors highlighted the need for climate-informed predictive models to anticipate and manage AFM1 risks. This recommendation dovetails with the present study's emphasis on structured, probabilistic, and risk-based monitoring.

Evidence from ML applications demonstrates tangible gains for aflatoxins (Focker et al. 2019; Wang et al. 2020; Wang et al. 2022). In feed, supervised models reliably identify high-risk batches and, when embedded in monitoring design, can sharply reduce total costs (sampling, analysis, recalls) without sacrificing assurance. In dairy chains, risk-based optimisation frameworks allocate sampling budgets across nodes (farm, truck, plant) and across chemicals (AFB1/M1 vs. dioxins) to maximise reductions in Disability-Adjusted Life Years (DALYs)—widely recognised as the gold standard for risk ranking by leading international public health institutions. Under such constraints, AFM1 control is typically favoured when the reduction in disease burden per unit cost is higher compared to other contaminants. Similar optimisation along the maize supply chain shows where to test and replace to minimise end-of-chain aflatoxin levels at least cost (Focker et al. 2019). Together, these approaches convert violation probabilities into actionable portfolio decisions for monitoring intensity and placement. Beyond cost and placement, climate-aware ML forecasts at regional scale reinforce our discussion on climate sensitivity (Wang et al. 2022). Such predictors can be adapted to AFM1 through the feed-to-milk pathway, enhancing early warning during hot, dry years that historically coincide with AFM1 peaks in Serbia and the Mediterranean.

The present study is consistent with and extends these findings. By systematically linking occurrence data to risk matrices through FAO/EFSA frameworks, it moves beyond descriptive analysis and demonstrates how likelihood of occurrence and severity of health impact can be combined into transparent prioritisation tools. In addition, the application of a probability-based sampling model provides a rational foundation for optimising monitoring intensity, which is particularly important in resource-limited settings. While some limitations remain, such as reliance on deterministic intake data and indirect consideration of climate factors, the study offers a significant step towards evidence-based prioritisation of AFM1 monitoring and control. Taken together, the convergence of national, regional, and Mediterranean evidence underscores the need for Serbia to adopt structured, risk-based monitoring as part of a

broader, harmonised regional response to recurrent aflatoxin challenges. This approach resonates with the FAO risk-categorisation framework (Quessy et al. 2026) and the ‘fit-for-purpose’ principle articulated by Dearfield et al. (2014), both emphasising that inspection and control systems should be guided by measurable risk factors rather than routine scheduling—an approach directly reflected in our AFM1 prioritisation framework.

## Conclusion

By integrating data published in peer-reviewed studies on AFM1 occurrence, dietary exposure, and risk characterisation, raw and pasteurised/UHT milk were identified as the product categories of greatest concern. The application of a probability-based sampling model further demonstrated the practical value of linking violation rates to statistically assured sampling strategies, ensuring that monitoring intensity can be rationally allocated across dairy product categories. Together, these approaches provide a structured foundation for risk-based monitoring and food safety governance in Serbia. Importantly, the results confirm that risk ranking and prioritisation can guide proportionate and cost-effective interventions, focusing resources where the likelihood and consequences of AFM1 exposure are greatest.

Future research should focus on: (i) developing climate-informed predictive models that anticipate AFM1 peaks under extreme weather conditions; (ii) integrating machine learning algorithms with peer-review evidence and national monitoring databases to enable real-time risk forecasting; (iii) expanding probabilistic dietary exposure assessments across broader consumer groups; and (iv) testing pilot workflows that combine digital early-warning tools with FAO/EFSA risk-ranking frameworks. Such advances would not only enhance national food safety governance but also contribute to regional harmonisation and resilience in managing aflatoxin risks under changing climatic conditions.

## Disclosure statement

The authors declare that there are no conflicts of interest. This study used published data from peer-reviewed journals and therefore did not require ethical approval.

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