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Results of multi-actor collaboration in risk analysis: a simplified risk assessment toolkit for rapid detection of emerging risks

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Abstract

The dynamic field of food safety faces continuous challenges, prompting stakeholders to develop collaborative actions for improved food safety systems. As part of these actions, the EU-FORA fellowship programme was dedicated to a multi-actor collaboration addressing risks of the unregulated mycotoxins T-2 and HT-2 toxins in oats. Critical gaps in risk assessment procedures were identified, leading to a joint effort to develop a strategy for rapid data collection and risk assessment, including the development of a risk assessment toolkit comprising of a training manual and two intuitive Microsoft® Excel files. The toolkit enables efficient data collection and processing, facilitating risk assessment calculations and rapid risk detection. Applying the toolkit to assess T-2 and HT-2 toxin risks in Belgian oats revealed minimal concerns, except for children aged 3–9 years, likely due to an overestimation. The toolkit is available on the FoodSafety4EU Platform and will be refined based on user feedback, promoting better risk assessment practices. This approach empowers stakeholders, from professionals to policymakers, fostering collaboration and enhancing food safety practices.

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Summary

The field of food safety is constantly evolving, with new challenges and emerging risks posing significant concerns for both public health and the food industry. As part of the EU-FORA programme of EFSA, a work programme was set up aiming to provide a comprehensive overview of the chemical risk assessment process, focusing on the harmonisation of enforcement practices and addressing unregulated hazards and emerging issues.

During the programme, the fellow was actively involved in the 'Food Safety Operational Lab' (FSOLab), a kind of living lab. This is a dynamic and collaborative environment where various stakeholders within the food safety system work together to diagnose current challenges, generate innovative ideas, implement pilot actions and evaluate the outcomes. This involvement allowed the fellow to contribute as a member of the Lab management team, alongside the project coordinator Dr. Veronica Lattanzio and other dedicated team members.

One of the key areas of focus within the FSOLab was the harmonisation of risk assessment strategies in relation to unregulated (i.e. no regulatory maximum limit) mycotoxins, particularly T-2 and HT-2 toxin. These mycotoxins, which can contaminate various food commodities such as oats, present a significant health risk to consumers. However, the current risk assessment procedures for these toxins suffer from several critical gaps that need to be addressed. Within the work programme, it was decided to focus on two issues: hindered analytical data sharing and the need for rapid risk assessment.

A strategy for rapid data collection and risk assessment was outlined, including the development of a simplified risk assessment toolkit comprising of a training manual and 2 intuitive Microsoft® Excel files. One file helps with rapid data collection and is based on the standard sample description format (SSD2) of EFSA and can be customised for specific contaminants and specific food matrices, while the other file contains spreadsheets to process the data and to perform the risk assessment, applying deterministic calculations.

The toolkit can be used for chemical contaminants and was tested to assess the risk of the sum of T-2 and HT-2 toxin in oats for the Belgian population. No risks were identified, except for the upper bound scenario in children between 3 and 9 years old. However, this is very likely an overestimation.

The toolkit is freely available on the Foodsafety4EU Platform (www.foodsafety4.eu) as a beta version, and will be further optimised based on user feedback.

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1. Introduction

The EU-FORA programme focused on identifying and improving issues in risk assessment using a multi-actor approach. The fellow was actively involved in the 'Food Safety Operational Lab' (FSOLab), which is a social living lab. This is a dynamic and collaborative environment where various stakeholders within the food safety system work together to diagnose current challenges, generate innovative ideas, implement pilot actions and evaluate the outcomes (Hossain et al., 2019).

In preparatory work executed before the start of the work programme, two multi-actor workshops were organised to bring together stakeholders from science, policy and society and discuss current constraints and challenges in risk assessment. Emerging and/or unregulated mycotoxins were identified as a main issue, and the group decided to zoom in on T-2 and HT-2 toxins in oats, as their occurrence is high in West, East and Northern Europe and oats are prone to contamination. The perceived challenges in risk assessment among stakeholders were: hindered data sharing, unclear communication between actors, complex risk assessment procedures and insufficient knowledge, changing dietary patterns and climate, unclear mycotoxin mitigation strategies, and lack of analytical capacity and human resources for control. Within the EU-FORA work programme, it was decided to dive deeper into the issues of data sharing and complexity of risk assessment.

Mycotoxins, which are fungal metabolites of low molecular weight, often play a critical role in plant pathogenesis and the spread of fungal infections. *Fusarium* species utilise various compounds, including specific trichothecene mycotoxins, as virulence factors to infect cereals like wheat and barley (Desjardins and Thomas, 1997). These two crops contribute to ~ 80% of small-grain production in Europe and can be heavily contaminated with trichothecenes (Bottalico and Perrone, 2002). T-2 and HT-2 toxin are type A trichothecenes produced under cool and moist conditions before harvest (Janik et al., 2021). Cereal grains, particularly oats, and their derivatives are the primary sources where T-2 and HT-2 toxin are predominantly found (EFSA, 2017a). Rapid deacetylation at the fourth carbon position is the primary metabolic pathway of T-2 toxin, leading to the formation of HT-2 toxin, regardless of the animal species involved (Nathanail et al., 2015). T-2 and HT-2, like many other trichothecenes, not only hinder protein synthesis and cell proliferation in plants but also induce acute or chronic intoxication in humans and animals. These toxins have various detrimental effects such as growth retardation, myelotoxicity, haematotoxicity, and the formation of necrotic lesions at contact sites (Rocha et al., 2005). Due to their toxic nature, EFSA has established a tolerable daily intake (TDI) value of 20 ng/kg body weight (bw) per day for the sum of T-2 and HT-2 (EFSA, 2017a). Additionally, the European Commission Recommendation 2013/165/EU provides indicative levels for the combined presence of these two toxins in cereals and cereal products, ranging from 15 μg/kg for cereal-based foods intended for infants and young children, up to 2,000 μg/kg for oat milling products (European Commission, 2013).

2. Description of the work programme

2.1. Aim

The overall aim was to generate solutions for identified needs in current emerging mycotoxin risk assessment procedures, focusing on a multi-actor approach. These needs included (among others) the lack of high-quality occurrence data of mycotoxins and the need for rapid assessment of (emerging) risks using risk assessment procedures, understandable for non-experts. To address these needs, following sub-goals were set:

1) To execute a small pilot to address the identified needs. This included the generation of a simplified data format to collect data and the development of a simplified risk assessment framework to make it accessible to non-experts and to rapidly detect emerging risks in the form of a toolkit.
2) To make the results of the pilot public for further exploitation on the digital FoodSafety4EU platform.

2.2. Activities

2.2.1. Pilot action to address specific needs in mycotoxin risk assessment

Development of a standard data collection format.

There is a lack of data on mycotoxins, including T-2 and HT-2 toxin and other emerging/ unregulated mycotoxins, as many stakeholders do not share acquired results, such as universities and

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industrial actors. While there are requests from EFSA to submit data using a standard format, not many institutes provide all data. The fellow studied the data collection process of EFSA and aimed to simplify the SSD2 format specifically for data collection of T-2 and HT-2 toxin in specific oat types, so that data providers do not need to go through the supplementary guidance files. A Microsoft® Excel file was created including the following fields: Sampler, Sample point, Sample country, Region/ province/department, Sampling year, Sample FoodEx code (Oat groats: A002Z; Oat bran: A003B; oat rolled grains: A00DH; Rolled oats, instant: A00DJ), Sample country of origin, Year of analysis, Lab accreditation, Code analyte (T-2 or HT-2), Method of analysis, Result unit, Result LOD, Result LOQ, Result value and result type (Appendix A.1). While this data format cannot be used for official data submission to EFSA, it allows researchers to rapidly collect data on a specific food contaminant in predefined matrices and perform preliminary risk assessments to rapidly detects potential risks.

Development of a simplified risk assessment toolkit and application to T-2 and HT-2 toxin in oats

A risk assessment toolkit was generated consisting of two Microsoft® Excel files. One file is the data collection format as described above for optional use, and the other file contains a template to perform a risk assessment step-by-step, including simple deterministic calculations (Appendix A.2). The template also includes a sheet for the input of contamination data, where lower and upper means of the concentrations are calculated, and a sheet to insert consumption data for acute and/or chronic consumers of interest. Finally, the toolkit also comes with a short manual, with instructions on how to use the template, with relevant resources.

Hazard identification – The toolkit starts with hazard identification, where the user needs to insert up-to-date information about the contaminant. For T-2 and HT-2 toxin, EFSA performed a hazard identification in 2011. Briefly, T-2 induces ribotoxic and oxidative stress and inhibits DNA, RNA and protein synthesis. T-2 has been shown to cause apoptosis and lipid peroxidation, affecting cell membrane integrity. Recent investigations also suggest that T-2/HT-2 induces anorexia/emesis via alteration of pro-inflammatory cytokines and satiety hormones (EFSA, 2011). The available information on the toxicokinetics of T-2 and HT-2 toxins is incomplete. T-2 toxin is rapidly metabolised to a large number of products, HT-2 toxin being a major metabolite. The metabolic pathways include hydrolysis, hydroxylation, de-epoxidation, glucuronidation and acetylation. Distribution and excretion of T-2 toxin and its metabolites are rapid. There are no significant data available on the toxicity of most metabolites. De-epoxidation is believed to be a detoxification process.

Hazard characterisation – Next, the user needs to find information on the hazard characterisation of the contaminants. The manual provides guidance and resources to search for genotoxicity, reference points (such as the benchmark dose lower confidence level ($BMDL_{10}$)) and health-based guidance values (HBGVs, for instance tolerable daily intake (TDI) and the acute reference dose (ARfD)) in the OpenFoodTox database.[1] There is also guidance for compounds for which no reference values have been identified. The manual helps to distinguish between genotoxic carcinogens and non-genotoxic compounds, as the risk assessment will be different for both classes. T-2 and HT-2 toxin are currently characterised as not genotoxic and carcinogenic. The EFSA Panel on Contaminants in the Food Chain (CONTAM) established a group TDI for T-2 and HT-2 toxin of 0.02 μg/kg bw per day based on an in vivo subchronic toxicity study in rats that confirmed that immune- and haematotoxicity are the critical effects of T-2 toxin and using a reduction in total leucocyte count as the critical endpoint. An ARfD of 0.3 μg for T-2 and HT-2 toxin/kg bw was established based on acute emetic events in mink.

Exposure assessment – The next step is to calculate the exposure to the contaminant in the population of interest. For this step, the additional sheets for contamination and consumption data need to be completed first. The user is guided through the steps.

Collection of T-2 and HT-2 toxin contamination data in oat bran

The data collection format was sent to partners of the project, and in total, 126 analytical results were received, of which 38 for oat bran specifically which could be used for further risk assessment. The sum of T-2 and HT-2 toxin was considered. Only two samples contained toxins in a concentration above the limit of quantification (LOQ). Strategies have been proposed to address these situations, considering the presence of so-called non-detects in calculations and accounting for the potential low concentration of the contaminant. It is therefore important to organise the data into different scenarios. When dealing with contamination data, this involves creating a lower bound scenario, where

[1] https://zenodo.org/record/3693783

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non-detects are assumed to be zero, and an upper bound scenario, where non-detects are replaced with the limit of quantification (LOQ) of the analytical method used (EFSA, 2010). The mean concentrations of the sum of T-2 and HT-2 toxin were 0.55 μg/kg and 7.79 μg/kg in the lower and upper bound scenario, respectively. The contamination levels and respective LOQs need to be filled in. The tool will calculate the mean for the lower and upper bound scenarios. These values appear automatically in the risk assessment sheet.

Collection of oat consumption data

Consulting the EFSA food consumption database,[2] statistical descriptors for oat bran were searched for Belgium, for all age categories. Oat bran was found to be classified in L4 as follows: Grain and grain-based products (L1) > Cereal grains and similar and primary derivatives thereof (L2) > Cereal bran (L3) > Oat bran (L4). Only the most recent data (i.e. from the Belgian food consumption survey of 2014) were used. There were only results available for 'other children' (36 months to 9 years), 'adolescents' (10 to 17 years) and 'adults' (18–65 years). The average and 95th percentile (P95) of acute and chronic consumption were used (see Table 1). In the consumption data sheet, the values found in databases for acute and chronic consumption need to be filled in, which will also appear automatically in the risk assessment sheet. The tool will then calculate the exposure for the populations for which consumption data were available and display the corresponding values. The calculated exposure values for T-2 and HT-2 toxin are presented in Table 2.

Table 1: Consumption of oat bran in Belgium

Population	Acute		Chronic	
	Mean (kg/kg bw per day)	P95 (kg/kg bw per day)	Mean (kg/kg bw per day)	P95 (kg/kg bw per day)
Other children (36 months-9 years)	0.0019	0.00397	0.00119	0.0028
Adolescents (10–17 years)	0.00073	0.00158	0.00039	0.00082
Adults (18–64 years)	0.00063	0.00132	0.00042	0.00102

bw: body weight.

Risk characterisation – Finally, the tool will calculate if there is a potential risk associated with the contaminant or not. For acute exposure, the outcome of the exposure assessment is compared with the ARfD. If the exposure exceeds this dose, there is a potential risk identified. The tool calculates the hazard quotient (HQ), which is the exposure value divided by the ARfD. If this is larger than 1, it means that the exposure value exceeds the ARfD, and a certain risk is identified. The tool generates a red colour when a risk is identified. A similar methodology is applied for chronic exposure to non-genotoxic compounds. The outcome of the exposure assessment is compared with the chronic HBGV. If the exposure exceeds this value, there is a potential risk identified. The tool calculates the HQ, which is the quotient of the chronic exposure value and the HBGV. If this is larger than 1, it means that the exposure value exceeds the HBGV, and a certain risk is identified. The tool generates a red colour when a risk is identified. For genotoxic carcinogens, it is recommended to work with margins of exposure (MOEs), rather than hazard quotients. The MOE is the ratio calculated by determining a level of exposure in which harm to human health is not expected to occur (e.g. $BMDL_{10}$), and then dividing that by an estimated level of human exposure (EFSA, 2017b). For genotoxic carcinogens, a value above 10,000 is considered as low risk. When the obtained value is smaller than 10,000, it means that the outcome lies too close to the level at which harm can occur and a potential risk is identified. The MOE is not a HBGV, i.e. it is not a safety threshold below which the daily intake is considered as safe. When there is evidence of harmful effects but not enough to confirm how much is safe, the MOE tells us if current intakes are likely to be harmful or not: a low MOE represents a greater risk than a higher MOE. For T-2 and HT-2 toxin, the risks after both acute and chronic consumption were characterised, using the ARfD and the group TDI. The acute exposure ranged between 0.0003 and 0.0309 μg/kg bw per day throughout all available age categories, consumption patterns and scenarios. At a first glance, it is already clear that no value exceeds the ARfD of 0.3 μg/kg bw per day. Therefore, no potential risk after acute exposure is identified with the available data. This is confirmed by the tool at the risk characterisation step, where no HQ of > 1 was calculated, hence no cell turned red for potential

[2] https://www.efsa.europa.eu/en/data-report/food-consumption-data

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risk indication. For chronic exposure, the calculations are similar, but now, the TDI is used. As T-2 and HT-2 toxin are not on the list of genotoxic carcinogens, the tool will not calculate the MOE, but a HQ. The chronic exposure ranges from 0.0002 to 0.0218 μg/kg bw per day. At the first glance, we see that in the category of 'other children', the TDI is exceeded in the upper bound scenario of high consumers. As 36 of 38 samples were below LOQ, this scenario is very likely an overestimation. However, this is a good illustration of how the tool can identify potential risks related to chemicals in food. The risk characterisation step of the tool confirms a HQ >1 for high-consuming children between 3 and 9 years old at the upper bound scenario, indicating a potential risk by turning red (Table 3).

Table 2: Exposure to the sum of T-2 and HT-2 toxin through consumption of oat bran in Belgium. LB: lower bound scenario, UB: upper bound scenario

Population	Acute exposure				Chronic exposure			
	LB scenario		UB scenario		LB scenario		UB scenario	
	Average consumers (kg/kg bw per day)	High consumers (kg/kg bw per day)	Average consumers (kg/kg bw per day)	High consumers (kg/kg bw per day)	Average consumers (kg/kg bw per day)	High consumers (kg/kg bw per day)	Average consumers (kg/kg bw per day)	High consumers (kg/kg bw per day)
Other children	0.0010	0.0022	0.0148	0.0309	0.0007	0.0015	0.0093	0.0218
Adolescents	0.0004	0.0009	0.0057	0.0123	0.0002	0.0004	0.0030	0.0064
Adults	0.0003	0.0007	0.0049	0.0103	0.0002	0.0006	0.0033	0.0079

bw: body weight.

Table 3: Risk characterisation of the sum of T-2 and HT-2 toxin in oats in the Belgian population expressed as hazard quotient. For acute exposure, this means the acute exposure divided by the acute reference dose. For chronic exposure, the hazard quotient is calculated as the quotient of the chronic exposure and the group tolerable daily intake

Population	Acute Risk (hazard quotient)				Chronic exposure (hazard quotient)			
	LB scenario		UB scenario		LB scenario		UB scenario	
	Average consumers	High consumers	Average consumers	High consumers	Average consumers	High consumers	Average consumers	High consumers
Other children	0.0035	0.0073	0.0493	0.1030	0.0372	0.077	0.4633	1.0902
Adolescents	0.0013	0.0028	0.0189	0.0410	0.0107	0.0225	0.1518	0.3192
Adults	0.0012	0.0024	0.0163	0.0343	0.0115	0.0281	0.1635	0.3971

LB: lower bound scenario, UB: upper bound scenario.

2.2.2. Feedback of users of the risk assessment toolkit and further steps

The toolkit was presented to the FSOLab members and demonstrated to be very efficient to perform preliminary risk assessments for emerging chemical contaminants, even by non-experts. The received feedback was overwhelmingly positive, underlining its potential as a valuable resource for researchers, students and individuals engaged in food safety environments.

A noteworthy aspect of the toolkit is its alignment with the EFSA's tool for rapid assessment of contaminant exposure (RACE tool), which is specifically designed to be accessible to non-experts. The toolkit shares a similar rationale, extending its applicability to a broader audience. Notably, the developed toolkit goes beyond its counterparts by offering a comprehensive template for rapidly collecting essential analytical data. This feature not only facilitates the risk assessment process but also ensures that a robust foundation of data is available for accurate evaluations. Additionally, the toolkit's ability to calculate lower and upper bound scenarios based on the provided analytical results further enhances its utility. This feature aids in understanding the potential range of risks associated with the analysed contaminants, allowing for a more comprehensive evaluation. A key advantage of the toolkit lies in its user-friendly interface, which guides the user through the four fundamental steps of risk assessment. This streamlined approach facilitates a basic understanding of risk assessment

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procedures, making it accessible to users with varying levels of expertise. Moreover, the toolkit promotes an insightful approach to risk assessment by encouraging users to seek and incorporate relevant reference values and consumption data. By doing so, users gain valuable insights into the underlying calculations and the basis for their risk assessments, enhancing the overall transparency and reliability of the results.

The toolkit is freely available on the Foodsafety4EU Platform (www.foodsafety4.eu) as a beta version, and will be further optimised based on user feedback. Besides the manual, further training videos will be provided to help users to efficiently apply the toolkit.

Lastly, it is intended to implement the toolkit in an upcoming European-African food safety project to spread awareness on the necessity of proper risk assessment methods. Many target groups such as students, food safety professionals, food business operators and policy makers will benefit from the toolkit and will have a basic understanding of chemical risk assessment.

2.2.3. Other activities during the EU-FORA fellowship

- **Side project on crisis communication**

Figure 1: Workshop invitation

While the EU-FORA project focused mainly on risk assessment, a few weeks of the programme were dedicated to risk communication, more specifically crisis communication. Ways to involve young students in the process of risk communication were explored. A workshop was organised at Ghent University (Figure 1), where students were challenged to come up with ideas on how to improve crisis communication, using *Salmonella* in chocolate crisis in Belgium as a model case (ECDC and EFSA, 2022). Three communication experts were also invited to the workshop and gave a short presentation on challenges they encountered during the *Salmonella* crisis. After the presentations, the students co-created solutions for communication challenges based on what they have heard during the talks of the experts. The results were presented by the fellow on the second pre-forum of FoodSafety4EU on 15 December in Brussels. These two activities led to a multi-actor policy brief entitled: 'Towards the EU Food Safety Forum: shaping together the new collaborative platform' FoodSafety4EU PRE-FORUM 2022 'The new sustainability regulation: how to integrate it into food safety?' (Ivanov et al., 2023).

- **Involvement in other FoodSafety4EU FSOLabs**
  The fellow was deeply involved in three other FSOLabs running during the FoodSafety4EU project, which were focused on preparing a strategic food safety research agenda, mapping food safety funding schemes in Europe and exploring ways for improved food safety communication to citizens.

- **Risk assessment training modules EU-FORA**
  The fellow attended all trainings modules organised within the EU-FORA training programme in September (Parma), November (online), March (online), June (Parma) and August (online).

- **EFSA webinars on the FoodEx2 classification system**
  The fellow followed all available webinars concerning the FoodEx2 classification system presented by EFSA to gain comprehensive knowledge on the use and implementation of the system.

- **Horizon Europe proposal writing including food safety and risk assessment strategies in African countries**
  The fellow was highly involved in writing a proposal for the call 'HORIZON-CL6-2023-FARM2FORK-01-20 – EU-Africa Union – food safety'. Both the hosting and sending institutes are main partners within this project proposal. As the project will focus on risk assessment and food policy, the expertise gained from the EU-FORA programme will be exploited substantially. The proposal was successful and is now in the grant agreement preparation phase.

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- **Organisation of the EU Food Safety Forum 2023**
  On 28 and 29 November 2023, the European Food Safety Forum will be organised for the first time in Brussels. The fellow will chair a session involving young students dedicated to different aspects in the food safety field.

3. Conclusion

Solutions were provided for a selection of the needs in current risk assessment procedures identified by a multi-actor team in the FSOLab. The selected needs were (a) hindered analytical data collection for specific emerging contaminants and (b) need for rapid risk assessment of emerging contaminants using simple processes. The developed risk assessment toolkit addresses both needs, as it provides a template for rapid data collection based on the SSD2 format but without the need to read supplementary guidance, and a spreadsheet where risk assessment calculations can be performed rapidly. The toolkit does not replace the current risk assessment procedures of EFSA, but serves as a tool to quickly assess risks of emerging or unregulated chemical contaminants by non-experts.

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Abbreviations

ARfD	acute reference dose
$BMDL_{10}$	benchmark dose lower confidence limit
bw	body weight
CONTAM	Panel on Contaminants in the Food Chain
FSOLab	Food Safety Operational Lab
HBGV	health-based guidance value
HQ	hazard quotient
LOQ	limit of quantification
MOE	margin of exposure

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P95	95th percentile
SSD2	Standard sample description version 2.0
TDI	tolerable daily intake

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Appendix A – The risk assessment toolkit

A.1. Data collection format

This is a condensed version of the Excel spreadsheet for illustration purposes. In the normal version, all entry parameters are ranked next to each other, from column A to column R.

	A	B	C
1	**Sampler**	**Sample point**	**Sample country**
2	Industry/official/industry AND official/HACCP or other checks/private/public/other	Which point of food chain: manufacturing, farm, transport, retail...	Where was sample taken
3			
4			
5	**Region/province/department**	**Sampling year**	**Sample FoodEx code**
6		When was sample taken	Search for the correct FoodEx2 code for the food matrix in the EFSA catalogue browser
7			
8			
9	**Sample country of origin**	**LOT number**	**Expiration date**
10	Where did the sample originate from	if available	if available
11			
12			
13	**Year of analysis**	**Lab accreditation**	**Code analyte**
14	When was sample analysed	Accredited/third party assessment/none	Assign a code to the analyte
15			
16			
17	**Method of analysis**	**Result unit**	**Result LOD**
18	LC-MS; GC-MS; ELISA ...	µg/kg; ng/kg ...	specify LOD
19			
20			
21	**Result LOQ**	**Result value**	**Result type**
22	specify LOQ	Numeric value expressed in specified unit	<LOD; <LOQ; > LOQ
23			

A.2. Risk assessment tool

This is a screenshot of the Excel spreadsheet for risk assessment for illustration purposes.

Q30

	A	B	C	D	E	F	G	H	I
1	**1. HAZARD IDENTIFICATION**								
2	Briefly describe the potential hazards to humans that the presence of a substance in food may pose								
3	**2. HAZARD CHARACTERISATION**								
4	*** Genotoxic carcinogen?**	**RP in µg/kg bw/day**	**Type**	**References**					
5	Find genotoxicity evaluation in File **Genotoxicity_KJ** and specify reference point (RP) from File **ReferencePoints_KJ** on the *OpenFoodTox database* (NOAEL, $BMDL_{10}$...):		$BMDL_{10}$						
6	https://zenodo.org/record/3693783								
7	If no RP: Use TTC of 0.0025 µg/kg bw/day								
8	*** NOT genotoxic?**								
9	**ACUTE**	**ARfD in µg/kg bw/day**	**Type**	**References**					
10	Specify the acute reference dose (ARfD) from File **ReferenceValues_KJ** on *OpenFoodTox database*		ARfD						
11	https://zenodo.org/record/3693783								
12									
13	**CHRONIC**	**HGBV in µg/kg bw/day**	**Type**	**References**					
14	Specify health-based guidance value (HBGV) from File **ReferenceValues_KJ** on *OpenFoodTox database* (TTC,								
15	TDI, ADI, TWI...):								
15	https://zenodo.org/record/3693783								
16	If no RV: Specify Cramer Class using *Toxtree*. Class I: use TTC of 30 µg/kg bw/day; Class II-III: use TTC of 1,5 µg/kg								
17	https://apps.ideaconsult.net/data/ui/toxtree								

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3. EXPOSURE ASSESSMENT

CONTAMINATION DATA

LB mean in µg/kg	UB mean in µg/kg
#DELING.DOOR.0!	#DELING.DOOR.0!

	ACUTE CONSUMPTION DATA		CHRONIC CONSUMPTION DATA	
	Average consumers in kg/kg bw/day	High consumers in kg/kg bw/day (95th percentile)	Average consumers in kg/kg bw/day	High consumers in kg/kg bw/day (95th percentile)
Infants 0-11 months				
Toddlers 12-35 months				
Other children 36 months-9 years				
Adolescents 10-17 years				
Adults 18-64 years				
Elderly 65-74years				
Very elderly 75 years and older				

	ACUTE EXPOSURE = CONTAMINATION X ACUTE CONSUMPTION				CHRONIC EXPOSURE = CONTAMINATION X CHRONIC CONSUMPTION			
	LB MEAN CONCENTRATION		UB mean CONCENTRATION		LB MEAN CONCENTRATION		UB mean CONCENTRATION	
	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)
Infants 0-11 months								
Toddlers 12-35 months								
Other children 36 months-9 years								
Adolescents 10-17 years								
Adults 18-64 years								
Elderly 65-74years								
Very elderly 75 years and older								

4. RISK CHARACTERIZATION

Non-genotoxic ACUTE HQ = Exposure/ARfD

	LB MEAN CONCENTRATION		UB mean CONCENTRATION	
	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)	Average consumers (µg/kg bw/day)	High consumers (µg/kg bw/day) (95th percentile)
Infants 0-11 months				
Toddlers 12-35 months				
Other children 36 months-9 years				
Adolescents 10-17 years				
Adults 18-64 years				
Elderly 65-74years				
Very elderly 75 years and older				

Genotoxic compounds MOE = RP/chronic exposure

	LB MEAN CONCENTRATION		UB MEAN CONCENTRATION	
	Average consumers	High consumers	Average consumers	High consumers
Infants 0-11 months				
Toddlers 12-35 months				
Other children 36 months-9 years				
Adolescents 10-17 years				
Adults 18-64 years				
Elderly 65-74years				
Very elderly 75 years and older				

Non-genotoxic compounds HQ = chronic exposure/HBGV

	LB MEAN CONCENTRATION		UB MEAN CONCENTRATION	
	Average consumers	High consumers	Average consumers	High consumers
Infants 0-11 months				
Toddlers 12-35 months				
Other children 36 months-9 years				
Adolescents 10-17 years				
Adults 18-64 years				
Elderly 65-74years				
Very elderly 75 years and older				

Instructions | Risk assessment tool | Contamination data | Consumption data

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