The Foodsafetyportal. Online expert support for enforcement and risk assessment

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ABSTRACT

It is an obligation in the EU that a Member State's RASFF Contact Point notifies to the European Commission and the other Member States on a hazard of, among others, a chemical compound in food, within 48 hours. To conclude about the risk, an exposure assessment is needed. Following the concept of Risk Analysis of the Codex Alimentarius, the Contact Point is officially a risk manager. Being not a risk assessor, support might be needed. The foodsafetyportal (https://foodsafetyportal.eu) provides such support; a risk manager can now perform a rapid exposure assessment using calculators and data-sets presented in the portal. Furthermore, a risk assessor can find additional information in the portal, such as details about reference values and EFSA's approach of the Margin of Exposure. All tools in the portal are online; separate downloads or registration is not needed. The portal is also used in training programs; it is included in BTSF training sessions on the program On Risk Assessment (Course 1, Chemical risk assessment in food). To develop this portal and its tools it was needed to download various data-sets from EFSA and other providers. And, to create computer codes for the calculation tools. New concepts were developed for the selection of the most appropriate HBGV to evaluate consumers' intake, and for the implementation of EFSA's Margin of Exposure. Based on the experiences of acquiring the data-sets it is concluded that scientifically-based food safety needs better

harmonization of data sources' formats and relation schemes. And agreements on how to arrange updates. Besides EFSA is kindly requested to provide a public download of the FOODEX 2 codes, and to make existing data of consumption of individual consumers in the member states' surveys available for download.

INTRODUCTION

In the second half of the twentieth century, it became possible to export food, thanks to innovations in the agricultural production. Importing countries wanted to receive food that was safe for the consumers, and the countries set up the Codex Alimentarius under the supervision of the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO). The Codex Alimentarius develops food quality standards that are to be implemented in the national legislation of Codex Members. Here the concept of Risk Analysis is followed as described in the Procedural Manual of the Codex Alimentarius (FAO and WHO, 2023. Section 4). Risk Analysis exists of Risk Assessment, Risk Management, and Risk Communication. The conclusions of a Risk Assessment are input for risk managers who have to conclude on follow-up activities. To define "safe" foods the Codex Alimentarius uses different groups of experts such as the Joint (FAO/WHO) Expert Committee on Food Additives (JECFA) to evaluate health risks for consumers. These experts use as the principle of Risk Assessment, as described in the Procedural Manual.

Risk assessment in food safety is focused on the health risks of chemical compounds and microbiological agents in food. The process is divided in 4 steps. The first step is the hazard identification; it leads to the description of adverse health effects after exposure to the compound. The identification uses scientific studies with experimental animals or humans (WHO and FAO, 2009, chapter 4). The identification is then used for the second step: hazard characterization. In the hazard characterization the exposure levels that pose health risks are quantitatively defined. The result is a maximum value for permissible intake. These maximum values are better known as Health Based Guidance Values (HBGVs). Well known examples are the Acceptable Daily Intake (ADI) and Tolerable Daily Intake (TDI), and the Acute Reference Dose (ARfD) (WHO and FAO, 2009, chapter 5 update 2020). Nowadays the HBGVs are derived by panels of toxicological experts. EFSA is the organization setting HBGVs for the EU Member States (Regulation (EC) No 178/2002, chapter III), whereas HBGVs for the Codex Alimentarius Commission are derived by panels of JECFA. Other panels working on HBGVs are of the U.S. Environmental Protection Agency (US-EPA) and the Agency for Toxic Substances and Disease Registry (ATSDR). The HBGVs are used to evaluate potential health risks for consumers of chemical or microbiological compounds in food or feed. This is done in step three: (dietary) exposure assessment. The intake can be

determined using data on the consumption of food (or animal feed) in combination with the concentrations of the compound in the food commodities. The fourth step is the risk characterization, where the intake is compared with the HBGV. If the exposure exceeds the HBGV, then a possible health risk cannot be excluded and the food is considered to be not “safe”.

Food safety policy in the EU

The concept of Risk Analysis as defined by the Codex Alimentarius is copied into the EU legal system (Regulation (EC) No 178/2002, Article 6). In the EU the risk management is laid down in a legal framework. Risk assessment is assigned to EFSA (Regulation (EC) No 178/2002, Chapter III). It is an obligation for the Member States to copy the EU Regulations into their national legislation; doing so it leads to a harmonized structure using the same quality standards and food safety procedures within the EU. And, leads consequently to an internal market with free movement of food and feed (Council Regulation (EEC) No 315/93).

The EU food safety system also includes an obligation for the Member States of official control (Regulation (EU) 2017/625). One of the obligations for the official control authority of the EU Member States is to issue a Rapid Alert notification to the European Commission and the Member States when a hazard is found in food or feed. According to the IMSOC Regulation the notification is to be issued by a single contact point, on a 24/7 basis, within 48 hours (Commission Implementing Regulation (EU) 2019/1715, articles 13, 14, 17-20). That notification should include a conclusion whether the situation is causing a “serious” risk or not. Following the Risk Analysis approach it must be noted that a RASFF Contact Point is a risk Manager. The decision about the risk however can only be taken after a food safety risk assessment. That decision is officially outside the responsibility of the Official Control. So, who will decide about the risk detected by official control, to be notified to the European Commission and the Member States through RASFF?

At this moment EFSA is not involved in such evaluations. On a Member State’s level one can find national risk assessment organizations or councils, such as BfR in Germany (German Federal Institute for Risk Assessment, 2022), ANSES in France (Anses, 2022), and the Office for Risk Assessment and Research in the Netherlands (Office for Risk Assessment & Research). They can do such assessments on request of their national risk managers, but many other EU Member States lack such support. Consequently, it can be noticed that not a risk assessor but the national RASFF Contact Point decides on the risk. And, that questionable arguments are used for that decision: *e.g.* just exceeding an ML or MRL is considered similar to a serious health risk for consumers, or, all genotoxic chemicals are always considered to pose a serious risk. Whether this is true or not can only be concluded after an exposure assessment.

THE PORTAL

Based on the situation is was decided to develop calculations tools to help the risk managers with a (rapid) exposure assessment of chemical compounds in food. These tools evaluate the risk with a minimal input by the user. Additional expert information such as on genotoxic carcinogens and on EFSA's Margin of Exposure was added to these tools, to have the users better understand the calculations and their conclusions. The tools are coded in the programming language PHP, as this language provides excellent support on interactive online applications (Wikipedia, PHP). Relevant sources of information were copied from the Internet and converted into SQL databases. These databases provide the data needed for the calculations. The tools and their descriptive texts were then moved into a web portal, to offer an access point with food safety information for risk assessors and risk managers. The site officially started in 2018 as *https://portal.robtheelen.nl*, but was renamed in line with its function in 2020 into *https://foodsafetyportal.eu*.

The portal started with a first version of a rapid exposure assessment calculation tool (EAST), and a searchable implementation of Commission Regulation (EC) No 1881/2006 on contaminants in food, of the Directive 2002/32/EC on undesirable substances in animal feed, and of the Codex Alimentarius General Standard of Contaminants and Toxins in Food and Feed (GSCTFF), CXS 193-1995. Over time other topics were added including more calculation tools and databases, and with more descriptive texts to explain complicated issues. At present there are 16 topics, and various supporting pages.

As the portal does not save any data of users, there is no need for registration. The system is fully unaware of a user and its digital environment.

Data-sets and databases

At the start of the development it was clear that the tools need basic data; for an exposure assessment Health Based Guidance Values (HBGVs) and consumption quantities are needed. HBGVs were copied from EFSA's OpenFoodTox hazard database of February 2021 (EFSA, 2017). These data were downloaded as spreadsheets, and were converted into a SQL database (MariaDB). A problem encountered was that the definitions of various fields are not well described, so their meanings had to be guessed. Likewise, a relation scheme for the fields was also not available, thus making it complicated to connect the data in the various sheets. More toxicology data were imported from the IRIS database of US-EPA to Excel (EPA, 2018), as this database is more

focused on cancer related effects. Other databases on the Internet such as from WHO-JECFA and ATSDR also provide health based reference values, but their data sets cannot be downloaded.

For consumption quantities several EU data-sets were downloaded and converted into a SQL database. These are the EFSA PRIMo spreadsheets revision 3 and revision 3.1 (EFSA, PRIMo) and the Comprehensive European Food Consumption Database of EFSA (EFSA, 2022). PRIMo provides default food consumption data from EU Member States consumers and their associated body weights. The Comprehensive Database contains summaries of food consumption surveys of EU Member States, and shows median and higher percentiles for consumption quantities for different types of consumers (infants, toddlers, adolescents, and adults). It should be noted here, that a food consumption survey originally contains series of consumption quantities for individual consumers. EFSA's Comprehensive European Food Consumption Database must contain these data, but only summaries can be downloaded. It is not made clear why only summaries are provided, nor is it clear how to obtain data of individual consumers in the surveys.

Next to EFSA's PRIMo and the Comprehensive European Food Consumption Database it was possible to obtain a Dutch food consumption survey (RIVM, 2023), directly from the holder of this data-set. Another data-set with individual consumers was found on the Internet, coming from Cyprus. Here the consumption quantities are published in an Excel-based spreadsheet (ImproRisk Excel 1.3.4), and in a later version (ImproRisk Excel 2.0.6).

Calculation tools

EAST A first rapid exposure assessment calculation tools was built in 2018 following an informal request of some representatives of official control authorities of the EU Member States. In the ANNEX [1], [2], and [3] you will find the calculations that are used in these tools, to calculate intake and to define whether the commodity is "safe" or not for the consumer. All these tools consist of the same 4 functional steps:

1. User selection of the chemical compound to be evaluated from a list;
2. User selection of the commodity and the concentration of the chemical in that commodity from lists;
3. User selection of the "scenarios". This means the countries (survey), consumer type (child, adult, ..);
4. Systems calculations of intake and associated "risk", and output.

Ad 1. After the selection of a chemical, a list of HBGVs and/or BMDLs from the OpenFoodTox and IRIS database is shown. As most users of the calculations tools are not experts in the evaluation of risks of chemicals compounds it was decided that the system will select the maximal permissible intake level from that list. Therefore, a set of rules was developed, and implemented in computer code. The rules for selecting the reference value to use are:

i. Select a reference value from the IRIS database, only when no EFSA data is available;

ii. Select the most recent study.

For a series of values of the most recent study:

iii. Select a BMDL, only if no HBGVs are derived in the same study;

iv. Prefer BMDLs from human studies, above those of animal studies;

v. Prefer a BMDL01 above a BMDL05, and a BMDL05 above a BMDL10.

vi. The lowest value of a series of BMDLs of similar type.

As an example of this approach, see figure 1, where the selection for the reference value for lead is selected. The user has to confirm it. When a user has arguments to deviate from the system's selection, he can override the result by selecting another value.

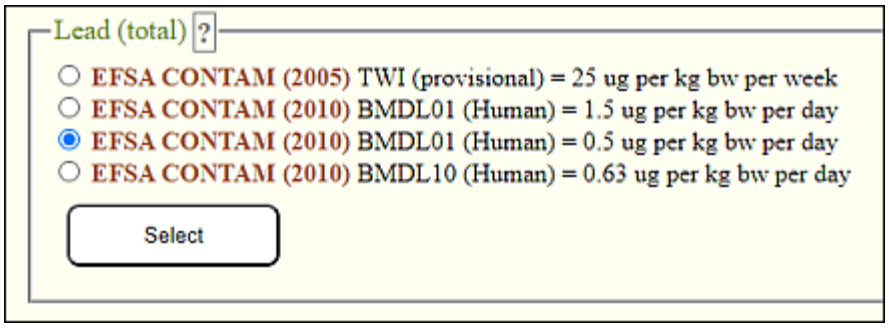

Figure 1: Selection of the reference value for lead in EAST

Another issue that needed to be resolved for an automated exposure assessment tool is that the reference value can be a BMDL. A BMDL is used following EFSA's Margin of Exposure (MoE) concept. Its implementation can be found in the ANNEX, algorithm [4]. In the underlying EFSA document (EFSA, 2012) it is stated that a BMDL10 from animals studies needs to have a MoE greater than 10,000 for genotoxic carcinogens. In some EFSA Opinions it can also be read that the MoE (of a BMDL10 from an animal study?) should be above 100 for non-genotoxic chemicals. This leaves the question what critical value for the MoE should be used, when selecting a BMDL of a human study, or a BMDL01 or BMDL05 of animal studies? To solve this issue a second procedure was developed. The first step of this procedure is answering the question whether a chemical is

genotoxic or not. Here an algorithm was developed that evaluates the conclusions of the genotoxicity studies in the databases. When the results indicate that the chemical compound is genotoxic, then the MoE needs to be above 10,000 to be "safe". For the non-genotoxic chemicals, the MoE is set on the basis of Safety Factors (SFs). A SF of 3 is used between the different BMDLs, and 10 between BMDLs of an animal study and a human study. This gives the margins as presented in table 1. The MoE value is used in the evaluation (ANNEX [4]: SF). See figure 2 for an example of the output. The user has to confirm the system's choice for the MoE. When a user has arguments to deviate from the system's selection, he can override the result by selecting another critical MoE from the list.

chemical	*BMDL*	*study*	*SF* *critical MoE*
genotoxic	all BMDLs	both animal and human	10,000
non-genotoxic	BMDL10	animal	100
		human	10
	BMDL05	animal	30
		human	3
	BMDL01	animal	10
		human	1

Table 1 Critical Safety Factors SF for the Margin of Exposure by different BMDLs

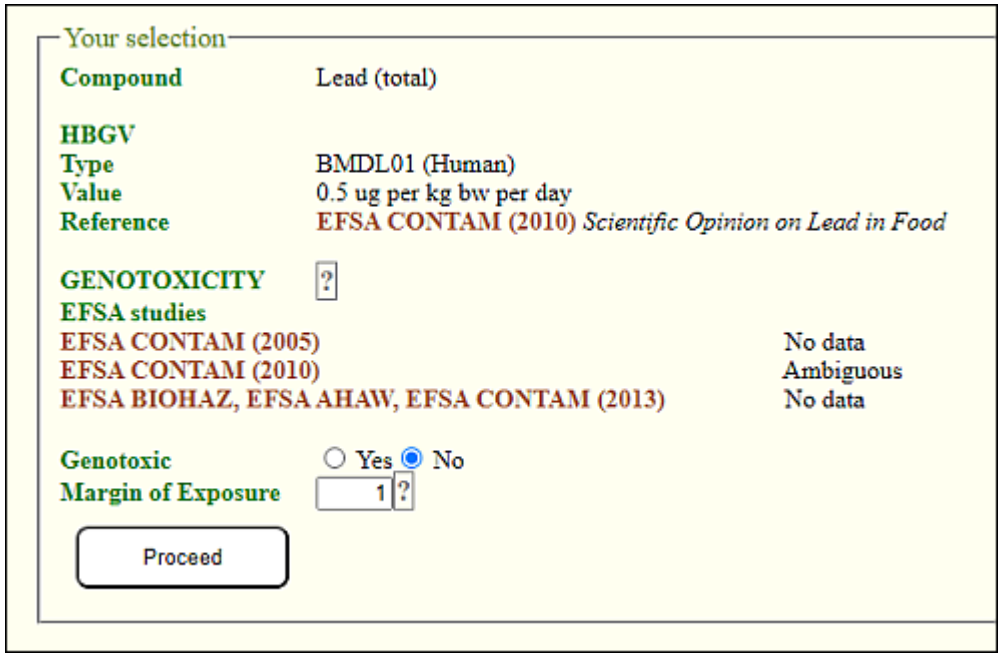

Figure 2: Selection of the critical MoE for lead in EAST

Ad 2. Next to the selection of the maximal permissible intake level, the system uses data on consumption for a large array of food commodities. As there are three different EU consumption data-sets reported by EFSA today, there are also three different calculators. The first implementation is using EFSA's PRIMo revision 3, and is called EAST (Exposure Assessment Tool); EAST2 uses the later PRIMo 3.1 data, and EAST3 is using the Comprehensive European Food Consumption Database. The user searches for a commodity in the database or selects the commodity from a list, and gives the concentration of the chemical in that commodity.

Ad 3. The system shows a list of countries and consumers. The user selects the scenarios that need to be used for the rate of consumption. If needed the user can add a private scenario; then, information about the consumer type and the consumption quantity must also be included.

Ad 4. Based on the input of the chemical, concentration, commodity, and scenario, the tool calculates the intake, and compares it with the HBGV or BMDL. The output is shown in a table and can be printed as a pdf file. For EAST3 the output can also be downloaded as a csv file for further analysis.

Two additional calculations are included. The first is "the Limit of Rejection" (LoR). Its algorithm is presented in ANNEX [5]. This value is the concentration of a chemical compound in a food when the HBGV is just exceeded or just below the critical Margin of Exposure. The result can be used by an Official Control authority to reject foods without a MRL or ML, according to Regulation (EC) No 178/2002, article 14. A similar type of calculation is the Maximum Consumption Quantity (MaCQ) (ANNEX [6]). This is the amount of food to be ingested to exceed the HBGV, or just below the MoE for a given concentration. That number can be used for a semi-quantitative exposure assessment, when detailed data on consumption quantities is lacking.

Monte Carlo calculations To use the individual consumers' data of The Netherlands and of Cyprus, another calculation tool was developed. The tool using the Dutch data is called "XI", and for Cyprus "ImproRisk". These applications calculate the individual consumer's intakes, and show basic statistics: the percentage of non-consumers, the number of consumers exceeding the maximal permissible intake level, and median and higher percentiles. The intake of individual consumers can be downloaded as *csv* files, for import in spreadsheets or statistical packages. Next to the input of one concentration, these tools offer the possibility to insert a series of concentrations. Now the application will randomly select a concentration from the series. In this way, both tools can be considered as a "Monte Carlo" type of evaluation, by combining the variation of consumption data with the variation of the concentrations data of the chemical in the food (Wikipedia, Monte Carlo method). So, these tools take the factual variation in consumption and concentrations into account; doing so they improve the quality of the exposure assessment.

RiskRanger The tool called "RiskRanger" is the online version of the tool with the same name, published on the Internet by the Australian Food Safety Centre of Excellence. It is used for risk ranking of microbiological risks. The concept was originally developed in 2002, and full details of this tool were published by Ross and Summer (2002). A spreadsheet is available for download (RiskRanger, 2023). Using the underlying formulae and data-sets as shown in the spreadsheet, the tool was converted into an online application in the foodsafetyportal, as an alternative for the spreadsheet.

RiskMerger The "RiskMerger" tool is a tool for semi-quantitative risk ranking that is under development by Mr. Jóźwiak (Jóźwiak, 2023). His tool weighs risks relative to each other, using weighing factors for human health, economic, and political risks. It is based on the RiskRanger tool with some modifications. His original spreadsheet was given to the author of this article. For the portal the spreadsheet was also converted into an online version.

Expert support

The rapid exposure assessment tools were used in BTSF training sessions (European Commission, 2023) for food safety personnel for EU Member States and non-EU countries. The tools will also be included in forthcoming BTSF sessions on Chemical Risk Assessment in Food in the period of 2023 to 2025. Based on the experiences in the BTSF sessions, the concept of the Margin of Exposure (EFSA, 2012) needed more attention. Additional web pages were added, describing the details of EFSA's Margin of Exposure, and how HBGVs and BMDLs are developed and must be understood.

For information about carcinogenicity a series of pages on genotoxicity and carcinogenicity was added, including descriptions of how to calculate the relative risk of genotoxic carcinogens quantitatively. The relative risk can be calculated with EAST when selecting “slope factors” from the IRIS database (EPA, 1992; Wikipedia, Cancer slope factor).

Other topics that are included in the portal are referring to the Codex Alimentarius, both on the structure of the organization and how standards are set, and on how to participate in the Committees meetings. Information is included on the relationship of chemicals in food and feed, and how to estimate concentrations in food on the basis of concentrations in animal feed. A more generic topic is included with information on food safety trainings, and on relevant sources of information on the Internet.

DISCUSSION AND CONCLUSIONS

Following downloading and copying data-sets it was noticed that spreadsheet files are the major source of public data. A spreadsheet provides a clear visual oversight of the data, although in two dimensions only. Its major disadvantage is that such an approach leads to a huge repetition of data. This is very error prone when changes are needed. For that reason a SQL related data-set is to be preferred, which is normalized according to Cod (1970). Another disadvantage is that not all Microsoft Excel versions and open source office applications are mutually interchangeable. So it is possible that a copy of a spreadsheet does not fully match the original. And, most spreadsheets operate by (MS Visual Basic) macros. Such macros are often used by hackers to infect your computer system (Lakshmanan, 2021).

With regard to the data-sets on HBGVs and consumption data it is noticed that there is no common harmonized format for these data. Also relation schemes are missing. Only a limited number of identical fields can be found both in EFSA’s OpenFoodTox database and US-EPA’s IRIS database. Various differences and sloppinesses were noticed in the description of units. As an example: it was noticed that “mg/kg” was used to refer to a concentration, but also for some BMDLs. When referring to the descriptors of food commodities it can be noted, that EFSA’s FOODEX 2 is a well-structured system. This data-set is however not yet readily available for download for third parties. To avoid discrepancies in the data-sets needed for exposure assessment it is therefore recommended that the risk assessors’ community agrees on a harmonized data format, relation schemes, and on a unified terminology. With regard to EFSA’s FOODEX 2 it is needed that the data-set is available for download. Only then it will be possible to develop a conversion tool for the different

existing national systems of food descriptors into one harmonized EU system.

It is important to update databases whenever possible. It was noted that new downloads with updates showed inconsistencies. For example: a download dated 2022 was still missing data from 2020. Another problem is that recent downloads contain old data plus the additional data. To include these data in your own databases one has to remove the full previous database and rework the spreadsheet again to be converted into a normalized database. Or, to filter the data to remove the old data before conversion. In an ideal world the updates should contain additional data only, without any copies of data from previous versions of the data-sets. Thus, it is recommended that the process of update should also be harmonized.

It is not clear why EFSA offers only data-sets with summarized consumption quantities in the Comprehensive European Food Consumption Database for download, and why third parties are not allowed to download consumption quantities of individual consumers. By doing so, EFSA blocks a better understanding of the variability of consumers' exposure to chemical compounds in food. It is strongly recommended that EFSA makes these data-sets available for the scientific community. Or, that risk assessors can obtain their national food consumption survey data directly (as in the Netherlands where everyone can request for a copy).

EPILOGUE

I would like to encourage risk assessors and others interested in food safety and risk assessment to use the information in the food safety portal (https://foodsafetyportal.eu) and provide feedback. Suggestions and ideas about additional topics t be included in the portal are highly appreciated. Contact information can be found in *https://foodsafetyportal.eu/footer/mypage.html*

DECLARATION OF INTEREST

The author declares that he has no competing financial interest that could have influenced the content of this paper.

ANNEX

[1] Intake [mg/day] = concentration [mg/kg] * consumption [kg/day]

The concentration might need a correction to derive the value “as consumed”, *e.g.* by means of a processing factor.

[2] Intake [mg/kg.day] = intake [mg/day] / body weight [kg]

To normalize the units it is needed to recalculate the intake using the body weight of the consumer.

[3] “Safe” = (intake [mg/kg.day] / HBGV [mg/kg.day] $\leq$ 1)

The intake is “safe” when it is equal to or less than the Health Based Guidance Value (HBGV).

[4] “Safe” = (BMDL [mg/kg.day] $\div$ intake [mg/kg.day] $\geq$ SF)

For chemicals without a HBGV, BMDLs are used as maximal permissible exposure levels. The critical factor SF are presented in table 1.

[5] LoR [mg/kg commodity] = HBGV [mg/kg bw.day] * body weight [kg] / consumption [kg/ day]

With: Limit of Rejection (LoR).

[6] MaCQ [kg/day] = HBGV resp. BMDL [mg/kg bw.day] * body weight [kg] / concentration [mg/kg].

With: Maximum Consumption Quantity (MaCQ).

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