



The foodsafetyportal. Online expert support for enforcement and risk assessment

Rob Theelen

Foodsafetyportal, Molenstraat 31, 4132 VA Vianen, the Netherlands

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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 h. To determine the risk, an exposure assessment might be 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. The portal is used 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 also available for download.

1. Introduction

1.1. The Codex Alimentarius

In the second half of the twentieth century, it has become possible to export food, thanks to innovations in agricultural production. Importing countries wanted to receive food that is safe for the consumers, and the countries set up the Codex Alimentarius (FAO/WHO, 2023a) 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. For this the concept of Risk Analysis is used, as described in the Procedural Manual of the Codex Alimentarius (FAO/WHO, 2023b, Section 4). Risk Analysis consists of Risk Assessment, Risk Management, and Risk Communication. 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 follow procedures for the evaluation, as described in the Procedural Manual

(FAO/WHO, 2023c; Section IV). The conclusions of a Risk Assessment are input for risk managers who decide about follow-up activities.

1.2. Risk assessment

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 (WHO & FAO, 2009, chapter 4). The first step is the hazard identification. Its purpose is to identify the adverse health effects after exposure to the compound. The identification uses scientific studies with experimental animals or humans. 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), Tolerable Daily Intake (TDI), and Acute Reference Dose (ARfD) (WHO & FAO, 2009, chapter 5 update 2020). Nowadays, the HBGVs for chemical substances in food or feed are derived by panels of toxicological experts.

E-mail address: rob.theelen@gmail.com.

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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 (JECFA, 2023). Other well known panels working on HBGVs are those of the U.S. Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry. The HBGVs are used to evaluate potential health risks for consumers of chemical 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 chemical substances in the food commodities. The fourth step is the risk characterization, where the intake is compared with the HBGV, to conclude about the probability of the hazard causing negative health consequences.

1.3. 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. It is an obligation for the Member States to copy the EU Regulations into their national legislation. It leads to a harmonized structure using the same quality standards and food safety procedures within the EU, and consequently to an internal market with free movement of food and feed (Council Regulation (EEC) No 315/93). Risk assessment is assigned to EFSA (Regulation (EC) No 178/2002, Chapter III).

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 h (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 (Rapid Alert System for Food and Feed) Contact Point is a risk Manager. The decision about the risk, however, can only be taken after a 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), or the Office for Risk Assessment and Research in the Netherlands (Office for Risk Assessment & Research, 2023). They can do risk assessments upon request of their national risk managers, but many other EU Member States lack such support. Consequently, it can be noticed that mostly not a risk assessor but the national RASFF Contact Point decides on the risk. The notifications in the RASFF database demonstrate, that exceeding a MRL (Maximum Residue Limit) or a ML (Maximum Limit) is often considered synonymous to a “serious risk”. That conclusion is debatable. Whether this is true or not can only be stated after an exposure assessment.

2. The portal

2.1. Rapid exposure assessment

Based on the EU situation it was decided to develop calculations online tools to help risk managers with a (rapid) exposure assessment of chemical compounds in food. These tools evaluate the risk with a minimal input by the users. Additional expert information such as on genotoxic carcinogens and on EFSA’s Margin of Exposure was added to these tools, to help 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, 2023b). Relevant sources of information were copied from public sources on the Internet and converted into SQL databases. These databases provide the data that are 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 <http://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 database of Commission Regulation (EC) No 1881/2006 on contaminants in food. Besides a database was included with the limit values of 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 (FAO/WHO, 2023b). As the Regulation 1881 was recently replaced by Commission Regulation (EU) 2023/915/, that database is now under revision. Over time, other topics were added including more calculation tools and databases, and descriptive texts to explain various food safety topics. At present there are 16 topics, and 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.

2.2. 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, 2009–2023). 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 (EPA, 2018), as this database is more focused on cancer related effects. Other databases on the Internet such as from WHO-JECFA and from the Agency for Toxic Substances and Disease Registry (ATSDR, 2023) also provide health based reference values, but their data sets cannot yet be downloaded directly.

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, 2023) 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 that are used for the evaluation of pesticides. 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 these food consumption surveys originally contain consumption quantities of individual consumers. In EFSA’s Comprehensive European Food Consumption Database however, 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 of different EU member states. It was possible to obtain the Dutch food consumption surveys (RIVM, 2023), directly from the holder of this data-set. This data-set contains the consumption quantities of individual consumers in the Netherlands. Another data-set with individual consumers was found on the Internet, coming from Cyprus. These consumption quantities are published in two Excel-based spreadsheets: ImproRisk Excel 1.3.4, and the later version ImproRisk Excel 2.0.6 (ImproRisk, 2021).

2.3. Calculation tools

2.3.1. East

East is a rapid exposure assessment calculation tools following an informal request of representatives of official control authorities of the EU Member States. ANNEX [1], [2], and [3] contain the mathematical functions that are used in these tools, to calculate intake and to define whether the commodity is “safe” for the consumer. This tool consist of 4 functional steps:

1. User selection of the chemical substance to be evaluated;
2. User selection of a food stuff, and its concentration of the substance;
3. User selection of “scenarios”;
4. Systems calculations of intake and associated “risk”, and output.

2.3.1.1. Selection of the chemical compound. 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 for them. Therefore, a set of rules was developed, and implemented in computer code. The rules for selecting the reference value 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.

An example of this approach is shown in Fig. 1. There you see the selection of the reference value for lead. The user has to confirm it, or override the result by the selection of another value.

Another issue that needed to be resolved for an automated exposure assessment tool is that the reference value can be a BMDL when no HBGV is available. 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 published later, it can also be read that the MoE 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 or not a chemical is genotoxic. 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 extrapolation factors. A factor of 3 is used between the different BMDLs, and 10 between BMDLs of an animal study and a human study. This gives the critical Margins of Exposure as presented in Table 1. See Fig. 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 providing another value for the MoE.

2.3.1.2. Selection of the food stuff. Next to the selection of the maximal permissible intake level, the system uses data on consumption for a large array of food stuffs. As there were three different EU consumption datasets reported by EFSA, 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 (EFSA, 2023), and EAST3 is using the Comprehensive European Food Consumption Database (EFSA, 2022). 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.

2.3.1.3. Selection of a “scenario”. The system shows a list of countries and its consumers. The user selects the scenarios that need to be used. If needed, the user can add a private scenario; then, information about the consumer type and the consumption quantity must also be provided.

2.3.1.4. Calculation of intake and its associated risk. 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 (comma-separated values) file for further analysis.

2.3.1.5. Limit of Rejection and Maximum Consumption Quantity. Two

Table 1
Extrapolation factors for the critical Margin of Exposure of different BMDLs.

chemical	BMDL	study	extrapolation factor
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	

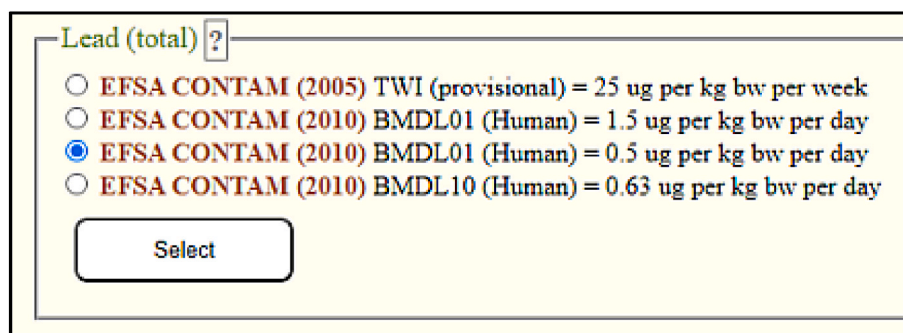


Fig. 1. Selection of the reference value for lead in EAST.

Your selection

Compound Lead (total)

HBGV

Type BMDL01 (Human)

Value 0.5 ug per kg bw per day

Reference EFSA CONTAM (2010) *Scientific Opinion on Lead in Food*

GENOTOXICITY ?

EFSA studies

EFSA CONTAM (2005)	No data
EFSA CONTAM (2010)	Ambiguous
EFSA BIOHAZ, EFSA AHAW, EFSA CONTAM (2013)	No data

Genotoxic Yes No

Margin of Exposure ?

Proceed

Fig. 2. Selection of the critical MoE for lead in EAST.

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.

2.3.2. 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 and 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, the tool 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, 2023a). So, these tools take the factual variation in consumption and concentrations into account; doing so they improve the quality of the exposure assessment.

2.3.3. 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.

2.3.4. RiskMerger

The “RiskMerger” tool is a tool for semi-quantitative risk ranking that is under development by Mr. Józwiak (Józwiak, 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 on request to the developer of the portal. For the portal the spreadsheet was then converted into an online version.

2.4. 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 portal will also be included in forthcoming BTSF sessions on Chemical Risk Assessment in Food in the period of 2023–2025. 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, 2022).

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, that can be used 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.

3. Discussion and conclusions

3.1. Data and databases

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. Next, 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.

It is important to update databases whenever possible. It was noted that new downloads presented on the Internet 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 the new data, one has to remove the full existing database and rework the spreadsheet again to be converted into a new normalized database. This might lead to differences between the previous and new data. Or, to filter the data to remove the old data before conversion. In an ideal world, the updates should contain new 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.

3.2. Calculation tools

The calculation tools provide an intuitive interface. This makes that they can be used without an extensive training or after reading a comprehensive manual. Based on the comments of people that use the tools, it can be noted that the tools meet the need of rapid exposure assessments of today. These persons can be identified as being both risk managers, and risk assessors. As the tools provide the users with all necessary data, more time can be spent on the exploration of the most appropriate scenario. Multiple scenarios can now easily be compared among themselves. An advantage of these tools is also, that they prevent from obvious errors of using different units (such as microgram per kilogram for a concentration, and gram per day for consumption quantities). Such errors can easily occur when performing the calculations with "pen and paper" or on pocket calculators. And, using a calculation tool leads to more consistency in input and output values, making different evaluations more comparable. Finally it is much appreciated that no registration is needed, in contrast to similar types of programs on the Internet.

4. 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 to be included in the portal are highly appreciated. Contact information can be found in <https://foodsafetyportal.eu/footer/mypage.html>.

5. ANNEX

$$[1] \text{ Intake [mg/day]} = \text{concentration [mg/kg]} * \text{consumption [kg/day]}$$

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

$$[2] \text{ Intake [mg/kg.day]} = \text{intake [mg/day]} / \text{body weight [kg]}$$

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

$$[3] \text{ "Safe"} = (\text{intake [mg/kg.day]} / \text{HBGV [mg/kg.day]} \leq 1)$$

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

$$[4] \text{ "Safe"} = (\text{BMDL [mg/kg.day]} / \text{intake [mg/kg.day]} \geq \text{EF})$$

For chemicals without a HBGV, BMDLs are used as maximal permissible exposure levels. The extrapolation factors (EF) are presented in Table 1.

$$[5] \text{ LoR [mg/kg commodity]} = \text{HBGV [mg/kg bw.day]} * \text{body weight [kg]} / \text{consumption [kg/day]}$$

With: Limit of Rejection (LoR).

$$[6] \text{ MaCQ [kg/day]} = \text{HBGV resp. BMDL [mg/kg bw.day]} * \text{body weight [kg]} / \text{concentration [mg/kg]}.$$

With: Maximum Consumption Quantity (MaCQ).

CRedit authorship contribution statement

Rob Theelen: Conceptualization, Methodology, Software, Validation, Resources, Data, Writing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

All data come from public sources.

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