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Review article

European Food Safety Authority open access tools to estimate dietary exposure to food chemicals

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ABSTRACT

The European Food Safety Authority (EFSA) has developed a suite of open access tools to estimate dietary exposure to food-borne chemical hazards. The tools are tailored to several regulatory domains within EFSA's remit (e.g. food and feed additives, pesticide residues, contaminants and food enzymes) and are intended for use by EFSA experts, industry applicants of regulatory product dossiers, researchers or any stakeholder with an interest in estimating dietary exposure using European food consumption data. The majority of the tools are based on FoodEx2, EFSA's food classification and description system as well as the EFSA Comprehensive European food consumption database. This paper provides an overview of these open access tools, the regulatory framework in which they were developed as well as data sources used.

1. Introduction

The European Food Safety Authority (EFSA) provides independent scientific advice on risks associated with the food chain. EFSA's scientific advice helps to protect consumers, animals and the environment from food related risks by informing EU risk management measures.

Dietary exposure to hazards is a key component of the food chemical risk assessment paradigm (WHO/IPCS, 2009). Dietary exposure to food chemicals is estimated by combining data on food consumption with the concentration (occurrence) of chemicals in food for a population of interest. Dietary exposure can be assessed for a chemical before it has been approved for use (e.g. pre-market), after it has been approved for use and in the food supply (post-market) or where a chemical is naturally present in food (e.g. certain contaminants). The approach used to combine data on food consumption and chemical occurrence differs depending on the chemical, the purpose of the assessment and available data. Exposure estimates are compared with health-based guidance values (hazard characterisation) to estimate risk.

The outcome of the hazard characterisation step, which may relate to an acute or chronic toxicological end point, drives the type of dietary exposure assessment (e.g. acute versus chronic dietary exposure) (Kroes et al., 2002). In the case of pesticide residues, where acute toxicological effects are observed, acute dietary exposure is typically estimated whereas for other hazards such as food additives chronic exposure is estimated. Chronic exposure estimates are based on individual average consumption over a survey duration whereas for acute exposure intakes per day are typically estimated (EFSA, 2011c). Dietary exposure can be estimated for single chemicals or multiple chemicals with the same mode of action or target organ (cumulative exposure).

EFSA estimates dietary exposure to intentionally added food chemicals (e.g. food and feed additives, flavourings, pesticide residues, novel foods, enzymes) as well as contaminants, both naturally occurring (e.g.

Abbreviations: ADI, Acceptable Daily Intake; API, Application Programming Interface; ARfD, Acute reference dose; CEF Panel, Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids; CRA, Cumulative Risk Assessment; EMA, European Medicines Agency; FACE, Feed Additives Consumer Exposure; FAIM, Food Additives Intake Model; FAIR, Findable, Accessible, Interoperable, Reusable; FEEDAP Panel, Panel on Additives and Products or Substances used in Animal Feed; FEIM, Food Enzyme Intake Model; FAO, Food and Agricultural Organisation of the United Nations; GDD, Global Dietary Database; GEMs, Global Environment Monitoring System; GIFT, Global Individual Food Consumption Data Tool; GNPD, Global New Products Database; IESTI, International Estimate of Short Term Intake; MCRA, Monte Carlo Risk Assessment; MRL, Maximum Residue Level; NEDI, National Estimated Dietary Intake; PFAS, Polyfluoroalkyl substances; RAC, Raw Agricultural Commodity; PRIMo, Pesticide Residue Intake Model; RACE, Rapid Assessment of Contaminant Exposure; RASFF, Rapid Alert System for Food and Feed; RPC, Raw Primary Commodity; TMDI, Theoretical Maximum Daily Intake; ToS, Total Organic Solids; WHO, World Health Organisation.

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mycotoxins) and contaminants present as a result of processing in the food chain (e.g. dioxins, PFAS) (Ahrens et al., 2019). Food consumption and food chemical concentration data are mainly collected from competent authorities in European countries in a structured format with defined quality criteria and metadata that are necessary to produce fit for purpose exposure assessments (EFSA, 2014, 2020). EFSA also works with the food industry to collect data on levels of chemicals present in or added to food according to the same standards required from competent authorities in European countries. Some 35 million records of food consumption and chemical monitoring data from European countries are stored annually in EFSA's scientific data warehouse for use in scientific assessments.

In the general scientific arena, there is a shift towards more openness and sharing of scientific research data to increase transparency and facilitate knowledge generation and innovation through re-use of data (Murphy, 2018; The Royal Society, 2012). Infrastructures such as the European Open Science Cloud (European Commission, 2016) have been established to facilitate this. A key element of EFSA's 2020 strategy is to increase transparency of its scientific assessments by providing access to the data and models on which they are based (Cavalli et al., 2019; EFSA, 2016). In addition, Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain places an even greater ownness on EFSA for more transparency in its scientific assessments (European Commission, 2019) by providing access to scientific studies on which risk assessment decisions are based.

EFSA adopted a stepwise approach to increase the openness of exposure data used in its scientific assessments. As a first step, EFSA provided public access to aggregated food consumption and chemical monitoring data in its scientific data warehouse (EFSA, 2015a). Adopting FAIR principles (Wilkinson et al., 2016), EFSA subsequently started to pro-actively publish chemical monitoring data with accompanying metadata at the lowest level of granularity in its open access hub (Knowledge Junction) on the Zenodo platform (EFSA, 2019b; EFSA, 2019a). Analysis and re-use of open datasets at the lowest level of granularity often necessitates access to statistical software programs as well as some degree of data literacy. To facilitate the needs of different stakeholders to estimate food chemical dietary exposure, EFSA has developed a suite of open access user friendly dietary exposure tools. The tools are tailored to regulatory domains within EFSA's remit and are intended for use by EFSA experts, applicants of regulatory product dossiers, researchers or any stakeholder with an interest in estimating dietary exposure to food chemicals using European food consumption data. The present paper provides an overview of these dietary exposure tools in the regulatory context in which they were developed. As food consumption data from the EFSA Comprehensive Food Consumption Database[1] (Comprehensive database) coded using the FoodEx2 food classification and description system is the foundation on which several dietary exposure tools were built, an overview of the Comprehensive database and FoodEx2 is also provided.

2. Comprehensive European food consumption database

A common feature of almost all EFSA dietary exposure assessment tools is the generation of dietary exposure estimates using individual level food consumption data at the lowest level of granularity from the EFSA Comprehensive database. Harmonised food consumption data are the basis for assessing human exposure to potential risks in the food chain. EFSA has been collecting harmonised European food consumption data at an increased level of detail since 2010. These data are used to populate the Comprehensive database (EFSA, 2011c). This database is updated periodically and contains primarily nationally representative dietary information for 25 European countries (Fig. 1) collected at individual level with a 24-hour recall or dietary record method for different population groups. Since 2010, there were three updates of this database, containing more recent data from countries already included in the database or from new European countries. The Comprehensive database is used for EFSA dietary exposure assessments in different domains such as food additives (EFSA, 2018a; EFSA, 2018b), contaminants (EFSA et al., 2020d), nutrients (EFSA, 2017) and genetically modified organisms (EFSA, 2015c). Food consumption data in the Comprehensive database are divided by country, survey, category of food, age class, population group (infants to adults aged of 75 years old or older) and gender. Information on the body weight of each individual is also available.

Important differences affect the level of detail in each dietary survey in the Comprehensive database such as different dietary assessment methods (24 h recall or dietary record) used to collect data, the number of days per subject, the sampling design and the quantification of portion sizes. In addition, it is important to keep the Comprehensive database up to date with the most recent standardised information on what people eat across the EU. To address both needs, in 2011 EFSA launched the EU Menu project to obtain more harmonised and up to date food consumption data suitable for exposure assessment. Within the frame of the EU Menu project, 32 surveys in 21 European countries for different age groups were (part)-funded by EFSA (Ioannidou et al., 2020). These surveys follow the EFSA guidance on the EU Menu methodology (EFSA, 2014). Once these surveys are concluded and the data are submitted to EFSA, they are incorporated in the Comprehensive database in order to maintain the most recent data for a given country and population group. With the most recent release in February 2020 the database contains data from 48 dietary surveys containing ~8 million eating occasions as detailed in Table 1 and in Supplementary Information Table S1

3. Open access tools to estimate dietary exposure to food-borne chemicals

An overview of the open access tools for dietary exposure assessment of food-borne chemicals developed by EFSA is described below together with the regulatory context in which they were developed. A summary of the tools, including their location, is shown in Table 2. The tools provide the functionality to estimate acute and/or chronic exposure dietary exposure to single chemicals.

3.1. Food Additives Intake Model (FAIM)

FAIM (Food Additives Intake Model) (Table 2) is an online tool primarily developed for the estimation of chronic dietary exposure to food additives according to the food categories (Annex II part D) of Regulation (EU) No 1129/2011 (European Commission, 2011d). FAIM can be used for the estimation of exposure for the total population to a new food additive or exposure resulting from new uses of an already authorised food additive. FAIM can be used in the dietary exposure assessment process by applicants, risk assessors and scientists (Van Loco et al., 2015). The current description refers to version 2 of the FAIM tool that was released in 2017.

For the authorisation of a new food additive or a modification of use of an authorised food additive, applicants are required in accordance with Regulation (EC) 1331/2008 to submit an application to the European Commission (European Commission, 2008b) that requests an opinion from EFSA (for a new food additive). Administrative and scientific data requirements of a food additive application are described in Commission Regulation (EU) No 234/2011 (European Commission, 2011c). An application must include, among others, the food additive chemistry and specifications, toxicological characterization and exposure assessment (EFSA ANS Panel, 2012). The assessment of exposure to the food additive in question should be based on known or anticipated dietary uses to the proposed additive or toxicologically relevant components of the additive from food, and

[1] https://www.efsa.europa.eu/en/microstrategy/foodex2-level-7.

Fig. 1. Map of European countries providing individual food consumption data in the EFSA Comprehensive database.

any other potential dietary sources (EFSA ANS Panel, 2012). Applicants are recommended to use FAIM to estimate dietary exposure (EFSA ANS Panel, 2012; EFSA FAF Panel et al., 2020).

After registering for an account in MicroStrategy[2], the user can input food additive levels (in mg/kg) in pre-defined food categories (according to the food additive legislation) and run the exposure calculation. FAIM estimates chronic dietary exposure (in mg/per kg of body weight per day) to a food additive for each individual in the Comprehensive database (EFSA, 2011c) by multiplying, for each food category, the concentration levels inputted by the user with the respective amount of food consumed. FAIM contains an in-built mapping between the food classification defined in Annex II part D of Regulation (EU) No 1129/2011(European Commission, 2011d) and FoodEx[3] (the EFSA food classification) (see Section 4)) used in the Comprehensive database where this was possible. Most common food categories are included with reasonably good coverage.

The exposure per food category is subsequently added to derive an individual total exposure per day. The exposure estimates are then averaged over the number of survey days, resulting in an individual average exposure per day. Dietary surveys with only one day per subject are excluded as they are considered as not adequate to

[2] Microstrategy is a business intelligence analysis tool (software).

[3] FoodEx is an earlier and less detailed version of FoodEx2 (EFSA, 2011a)–the mapping is currently being updated to FoodEx2.

Table 1
Details on EFSA's Comprehensive European Food Consumption database.

EFSA Comprehensive European Food Consumption Database	
Number of countries	25
Number of surveys	48
Number of subjects	134,929
Number of eating occasions	8,151,421
Population groups	infants (0–11 months) toddlers (1 to < 3 years old) other children (3 to < 10 years old) adolescents (10 to < 18 years old) adults (18 to < 65 years old) elderly (65 to < 75 years old) very elderly (≥75 years old) pregnant women lactating women

to download summary results and descriptive statistics as an Excel file. A webinar on the use of the FAIM tool was organised by EFSA in 2018 and it can be accessed via the web[4].

FAIM can also be used to estimate anticipated chronic intakes of novel foods or traditional foods from third countries regulated under Regulation (EU) 2015/2283 (European Commission, 2015) where the food categories match reasonably well the food categories included in FAIM (Ververis et al., 2020). Under this legislation, applicants that intend to place a novel or traditional food in the EU market need to submit an application dossier (novel food) or a notification (traditional food from third countries) to the European Commission, and EFSA is responsible for carrying out a pre-market risk assessment. Administrative and scientific requirements are outlined in Commission Implementing Regulation (EU) 2017/2469 (European Commission, 2017b) and Commission Implementing Regulation (EU) 2017/2468 (European Commission, 2017a). In addition, EFSA developed a guidance for the preparation and presentation of applications for authorisation of novel foods (EFSA NDA Panel et al., 2016) and on the preparation and presentation of a notification and application for authorisation of traditional foods from third countries (EFSA NDA Panel et al., 2016). Applicants should specify the intended target population, e.g. adults. Moreover, they must specify form of uses, the food categories in which the novel food is proposed to be used, the proposed maximum amount in food product(s) as consumed and the estimated average and maximum daily intakes for different age groups. As a domain specific dietary exposure tool for novel foods was not developed for applicants, FAIM was proposed to be used.

In case a novel or traditional food is intended to be used in food categories not matching food categories in FAIM, the applicant can make

Table 2
EFSA open access tools for dietary exposure assessment of food-borne chemicals.

Tool*	Domain/Regulation	Chronic/acute exposure	Food consumption data source	Latest version (Date)	Location/Type of tool	User registration
FAIM	Food additives/Regulation (EU) 1129/2011, Novel foods/Regulation (EU) 2015/2283	Chronic	Comprehensive database (individual data)	2.0 (October 2017)	EFSA website[a]/web application	Yes
RACE	Contaminants/Regulation (EU) 16/2011	Chronic/acute	Comprehensive database (individual data)	1 (April 2019)	EFSA website[b]/web application	Yes
FACE	Feed additives/Regulation (EC) 1831/2003	Chronic/acute	Comprehensive database (individual data) RPC (raw primary commodity) model	1.1 (January 2019)	EFSA website[c]/web application	Yes
FEIM FEIM baking	Food enzymes/Regulation (EU) 562/2012	Chronic	Comprehensive database (summary statistics)	1 (June 2018)	Zenodo platform[d]/Excel	No
FEIM brewing		Chronic		1 (January 2018)		
FEIM cereal based processes		Chronic		1 (December 2019)		
PRIMo	Pesticide residues/Regulation (EC) 396/2005 & Regulation (EU) 1107/2009	Chronic/acute	Aggregated consumption data for food commodities, for which pesticide MRLs (maximum residue levels) are established	3.1 (March 2019)	EFSA website; Zenodo platform[e]/Excel	No

* FAIM, Food Additive Intake Model; PRIMo, Pesticide Residue Intake Model; RACE, Rapid Assessment of Contaminant Exposure; FACE, Feed Additives Consumer Exposure calculator; RPC model, Raw Primary Commodity Model; FEIM, Food Enzymes Intake Model.
[a] https://www.efsa.europa.eu/sites/default/files/applications/FAIM-instructions.pdf.
[b] https://www.efsa.europa.eu/en/microstrategy/race.
[c] https://dwh.efsa.europa.eu/bi/asp/Main.aspx?rwtrep=FACE.
[d] https://zenodo.org/record/1297333#.X2EO5mgzbD4, https://zenodo.org/record/1299219#.X2EPxGgzbD4, https://zenodo.org/record/3560578#.X2EQEmgzbD4.
[e] https://www.efsa.europa.eu/sites/default/files/applications/EFSA_PRIMo_rev3.1.xlsm.

assess chronic exposure.

The exposure is estimated for every single individual resulting in distributions of individual exposure for each population group (from infants to the elderly) in each dietary survey. The mean and 95th percentile of exposure are then calculated per population group in each survey. The 95th percentile of exposure is only calculated for those population groups with a sufficiently large sample size (EFSA, 2011c).

Results are presented (in mg/kg body weight per day) in different interactive tabs as summary statistics and graphics per country and population group (of which an example can be found in Fig. 2) both for mean and P95th percentile. FAIM also provides information on the percentage contribution of each food group to the total mean exposure per population group, survey and country. Although individual results for each subject of the survey are not accessible, FAIM allows the user

[4] https://www.youtube.com/watch?v=0XCAfrrdpYg&feature=youtu.be.

Fig. 2. Example of exposure assessment results obtained using FAIM which is illustrative of several exposure tools with a MicroStrategy user interface. Results can be browsed by the user using different tabs. 'Exposure summary' graphs present the minimum and maximum exposure Mean (top left side) and 95th Percentile (top-right side) calculated from distributions (for population groups per survey for each country) of individual chronic exposure to the given food additive. Under the tab 'Exposure Results' (not shown here) the numerical results for mean and P95th exposure per population group and country can be browsed as well. FAIM also provides information on the percentage contribution to overall exposure of each food group to the total mean exposure per population group, survey and country under the tab called 'Exposure sources' (on the bottom).

use of the more detailed food categorization present in the summary food consumption statistics of the EFSA Comprehensive database openly available in the EFSA's scientific data warehouse (EFSA, 2015a). In this case anticipated daily intakes can be calculated by combining the intended use level in each food category with mean and high consumption values from the Comprehensive database to estimate exposure for average and high consumers, respectively.

EFSA has recently developed a new tool tailored to estimate dietary exposure to novel foods which is currently for internal use. It is envisaged that the tool will be added to the existing suite of EFSA's open access tools to estimate dietary exposure in the future.

3.2. Rapid Assessment of Contaminant Exposure (RACE)

RACE (Rapid Assessment of Contaminant Exposure) (Table 2) is an online tool developed by EFSA to provide a simplified risk evaluation of chemical contaminants in food within the frame of the European Commission's Rapid Alert System for Food and Feed (RASFF) (European Commission, 2011a). RASFF is a tool (information system) for the notification by control authorities of risks to human health deriving from food or feed.

When a chemical contaminant of potential concern is identified (e.g. exceedance of a legal limit at a border inspection) the relevant authority needs to evaluate and classify the risk to human health prior to issuing a notification in RASFF. The European Commission asked EFSA to develop a methodology (guidance) to allow a risk-based classification of RASFF notifications on chemical contaminants to ensure a rapid and consistent evaluation of risks (Fürst et al., 2019). RACE was developed to facilitate a rapid evaluation of risk based on an assessment of toxicological properties and dietary exposure.

RACE estimates acute and/or chronic dietary exposure to a food contaminant using food consumption data at the level of individuals from the Comprehensive database classified according to FoodEx2 (Table 2).

After registering for an account in MicroStrategy by sending a request to EFSA, the user is prompted to insert a new analysis, select the contaminant (e.g. arsenic) for which he/she wants to run the analysis as well as a single food (e.g. rice grain) from the exposure hierarchy of the FoodEx2 classification system (Section 4) corresponding to the foodstuff where the contaminant of potential concern has been identified. The user must then insert an analytical value for the contaminant and its corresponding reference point (e.g. Acute Reference Dose or a Benchmark Dose Level). Reference points can be retrieved from external resources linked in the tool e.g. EFSA's OpenFoodTox database (Dorne, 2021). The tool generates Excel spreadsheets with risk evaluation details, which include a summary of the assessment as well as individual tables with both acute and chronic exposure estimates (mean and 95th percentile) for the total population and consumers only, and a comparison of exposure estimates with toxicological reference points.

As in the case of the FAIM, the tool calculates exposure by multiplying the concentration level of the contaminant inputted by the user with the respective amount of the selected food consumed. The outcome is the individual total exposure per day expressed in mg/kg body weight. Chronic dietary exposure is calculated for each individual as an average of exposure over the number of survey days, resulting in an individual average exposure per day. Acute dietary exposure is calculated for each individual at the level of single reporting days. A distribution of individual exposures is calculated for each survey and population group from which mean and high percentile exposure are derived.

RACE is primarily intended for use by competent authorities in the Member States to provide a rapid evaluation of risk associated with a chemical contaminant of potential concern and to decide whether to issue a notification in RASFF based on a set of criteria developed by EFSA (Fürst et al., 2019), increasing also the harmonization in the evaluation process in Europe. A RACE user manual is described in Appendix J of Fürst et al. (2019).

A webinar on the use of the RACE tool was organised by EFSA in April 2020 and it can be accessed via the web[5].

3.3. Feed Additives Consumer Exposure (FACE) calculator

FACE (Feed Additives Consumer Exposure calculator) is an online tool developed by EFSA to estimate acute and chronic dietary exposure to residues of feed additives and their metabolites that may be present in food of animal origin.

As in the case of food additives, applicants that intend to place a feed additive in the EU market need to submit an application to the European Commission (European Commission, 2003). EFSA is responsible for conducting a risk assessment prior to authorisation. The application dossier must contain information on the feed additive, its conditions for use, control methods, data demonstrating its efficacy and an assessment of the safety for consumers exposed to food derived from animals given feed containing the additive (European Commission, 2008a). FACE provides estimates of chronic and acute dietary exposure for different population groups (e.g. infants, toddlers, adults) and is based on the methodology recommended in the EFSA Guidance on the assessment of the safety of feed additives for the consumer (EFSA et al., 2017a). FACE uses individual food consumption data from the Comprehensive database, which were disaggregated into raw primary commodities (RPC) of animal origin (e.g. meat, eggs, milk), using EFSA's RPC model (EFSA, 2019).

FACE is freely available (using MicroStrategy) on EFSA's website. To use the tool, the user needs to register by sending a request to EFSA. When accessing the tool, the user sees a list of RPCs of animal origin (e.g. bird's fat tissue, liver, meat and offal, fish meat, honey, fat tissues, liver, meat and offal, milk and eggs). The user can enter the estimated residue levels of a feed additive for each relevant food commodity in mg/kg. Depending on the nature of the health-based guidance value, the tool calculates acute or chronic exposure at the individual level. For chronic exposure, relevant residue levels are combined with average daily consumption of the corresponding food commodities and the resulting exposures per food are summed to generate total chronic exposure at the individual level standardised by body weight. A distribution of individual dietary exposures is calculated for each survey and population group from which mean and high percentile exposure are derived. For acute exposure, relevant residue levels for a commodity are combined with total corresponding consumption within each single day. High percentile exposure based on consuming days are calculated for each commodity, dietary survey and age class separately. All exposure estimates are expressed in mg/kg body weight per day. FACE also provides information on the mean exposure contribution to total exposure of each food group and survey of each country.

3.4. Food Enzyme Intake Model (FEIM)

FEIM (Food Enzyme Intake Model) is an Excel tool for estimating chronic dietary exposure to food enzymes used in different food processes following the methodology of EFSA's CEF Panel (EFSA CEF Panel et al., 2016).

Applicants intending to place a food enzyme on the EU market need to submit an application to the European Commission in accordance with Regulation (EC) No 1331/2008 (European Commission, 2008b). EFSA is responsible for carrying out a safety assessment prior to authorisation. Administrative and scientific data requirements for food enzyme applications, which include a need to estimate dietary exposure, are outlined in Commission Regulation (EU) No 234/2011 (European Commission, 2011b) amended by Commission Implementing Regulation (EU) No 562/2012 (European Commission, 2012). With experience gained from the evaluation of initial enzyme application dossiers, EFSA's CEF Panel issued a statement describing an updated methodology using actual food consumption data to be used to estimate dietary exposure to food enzymes (EFSA CEF Panel et al., 2016).

FEIM estimates dietary exposure to food enzymes for different food processes. As food enzymes are typically added to raw material used in food manufacturing processes (e.g. starch dry matter) it is necessary to link levels used in raw material to the amount of food consumed when estimating dietary exposure. This is done through the use of technical factors for different food processes (e.g. baking, brewing) that EFSA collated in Annex B of Exposure assessment of food enzymes statement (EFSA CEF Panel et al., 2016). These technical factors, assigned to FoodEx food categories corresponding to specific food processes, allow the conversion between a food or food ingredient and the raw material to which a food enzyme is added as well as the estimation of the ingredient fraction of a food (e.g. proportion of bread containing flour).

To date, FEIM contains three process-specific calculators: FEIM-baking (EFSA Panel on Food Contact Materials, 2018a), FEIM-brewing (EFSA Panel on Food Contact Materials, 2018b) and FEIM cereal based processes (EFSA CEF Panel, 2019). The calculators contain in-built conversion factors (EFSA CEF Panel, 2019) to allow the estimation of chronic dietary exposure to food enzymes used in baking, brewing and cereal based processes, respectively.

FEIM is freely available on EFSA's Knowledge Junction. The user is requested to enter the use level of a food enzyme, e.g. the maximum recommended use level for a specific food manufacturing process in mg of TOS (Total Organic Solids)/kg of raw material. FEIM estimates chronic dietary exposure by combining the use level of a food enzyme with summary statistics of food consumption pertaining to FoodEx categories relevant to a specific process from the EFSA Comprehensive database. The identified FoodEx categories are assumed to contain the food enzyme-TOS at the corresponding recommended use level. Dietary exposure is calculated by multiplying the intake of the relevant food by the matching food enzyme TOS at individual level. Exposure results are presented in mg/kg body weight per day for the mean and 95 percentile intakes (mg TOS/kg body weight per day) per population group (e.g. infants, toddlers, adults) and survey. The tool also generates the percentage contribution to exposure of the different food groups.

It is foreseen that FEIM will be expanded with additional process-specific calculators as they are developed in due course. It is envisaged that in each release the most recent consumption data from the Comprehensive database will be used.

3.5. Pesticide Residue Intake Model (PRIMo)

PRIMo (Pesticide Residue Intake Model) is an Excel based model developed and maintained by EFSA to calculate deterministic acute and chronic dietary exposure to pesticide residues (Table 2).

Regulation (EC) No 396/2005 laid down a requirement to establish harmonised safety limits (Maximum Residue Levels (MRLs)) for pesticide residues in food and feed at EU level (European Commission, 2005) which prior to then were not fully harmonised between EU Member States. Within this context, EFSA was entrusted with the task of estimating potential exposure of European consumers to pesticide residues in some 260 food commodities using a list of proposed temporary MRLs (collated from existing national MRLs), and to assess potential risks to consumers arising from these proposed harmonised safety limits. The methodology used to deliver this task (EFSA, 2007) was subsequently developed as a tool, PRIMo (Reich, 2007).

PRIMo is accepted as the tool to underpin risk management decisions

[5] https://www.efsa.europa.eu/en/events/event/webinar-rapid-assessment-contaminant-exposure-race-tool.

at EU level[6] concerning MRL applications within the frame of Articles 6–10 of Regulation (EC) No 396/2005 (EFSA et al., 2020b) and within the context of an ongoing review programme of existing MRLs for active substances in the EU under Article 12 of Regulation (EC) No 396/2005 (EFSA et al., 2020c). PRIMo is also used for safety assessments of new active substances for use in plant protection products within the frame of Regulation (EU) No 1107/2009 (European Commission, 2009) and Commission Implementing Regulation (EU) 844/2012 (European Commission, 2012; EFSA, 2019a, 2020a). Although primarily developed to estimate prospective dietary exposure, PRIMo can also be used to estimate retrospective (post-market) dietary exposure to pesticide residues by inputting residue data from residue monitoring programmes in place of residue input data (e.g. estimations from residue field trials or MRLs) used in prospective dietary exposure assessments. EFSA estimates acute and chronic post-market exposure to pesticide residues in Europe using annual monitoring data submitted by European countries to EFSA (EFSA et al., 2020g).

PRIMo is freely available for use on EFSA's Knowledge Junction and is intended to be used by applicants (e.g. agro-food industry), Member State competent authorities and EFSA to estimate prospective dietary exposure. It consists of several Excel spreadsheets tailored for data entry, calculation and reporting of results. It is populated with food consumption statistics of food/crop commodities relevant to pesticide risk assessment for different population groups (e.g. children, adults) from dietary surveys in 14 European countries collected from Member States as well as the WHO Global Environment Monitoring System (GEMS/Food) cluster diets for the European population (EFSA et al., 2018a). For chronic exposure assessment, mean consumption in the total population was provided by Member States for each raw agricultural commodity, survey and subgroup of the population. For acute exposure assessment, high percentiles consumption in consumers only was provided for each raw agricultural commodity, survey and subgroup of the population. Data on unit weights of the edible parts of food commodities as well as variability factors (to take account of non-homogenous distribution of pesticide residues in foodstuffs) are also included. The food classification for setting of legal limits for pesticide residues described in Regulation (EU) No 752/2014 is incorporated (European Commission, 2014).

PRIMo has been updated to incorporate new food consumption data as well as new functionalities. In the latest major revision, in-built algorithms allow the user to estimate acute dietary exposure to pesticide residues based on the IESTI (International Estimate of Short Term Intake) approach, and chronic dietary exposure based on the TMDI (Theoretical Maximum Daily Intake), NEDI (National Estimated Dietary Intake) and IEDI (International Estimated Dietary Intake) approaches (EFSA et al., 2018a). For chronic exposure assessment, mean consumption in the total population is generated. For acute exposure assessment, high percentiles of intake among consumers only is generated.

Exposure estimates from the population group with the highest consumption of a food commodity/commodities are used to represent the most critical European consumer. These estimates are then compared with health-based guidance values (e.g. ARfD/ADI), also included in PRIMo, to assess risk.

The latest major revision of PRIMo (revision 3.0) was released in January 2018 incorporating, amongst other features, new/updated on food consumption statistics and unit weights of commodities, together with an accompanying user guide (EFSA et al., 2018a). A subsequent version, revision 3.1 (EFSA et al., 2019a; EFSA, 2019b) was released in March 2019 implementing corrections identified by end-users of revision 3.0. Thus, PRIMo revision 3.1 is the latest version of the tool currently available.

[6] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_mrl_guidelines_primo-imp.pdf.

4. FoodEx2 food classification and description system

Collecting, collating, analysing and summarising data on food consumption, chemical and biological hazards and nutrients occurrence are core tasks of EFSA as stated in Regulation (EC) No 178/2002 (European Commission, 2002). As EFSA collects data for use in different legislative and scientific domains, it requires extensive harmonisation to ensure interoperability of the data for use in exposure assessments. Therefore, a system for a unique identification of food items was needed to provide a common link to diverse information sources (EFSA, 2011a; EFSA, 2011b). As a result, EFSA developed the FoodEx2 food classification and description system (EFSA, 2015b).

FoodEx2 (Fig. 3) is a comprehensive food classification and description system aiming at covering the need to describe food and feed in data collections across different domains, e.g. food consumption, chemical contaminants, pesticides, veterinary medicinal product residues. It therefore forms the basis on which diverse datasets from different regulatory domains can be combined to estimate dietary exposure. It consists of around 5300 base terms (e.g. A0BYR for wafer) of many individual food and feed items aggregated into groups and broader categories in a hierarchical parent-child relationship (e.g. A000J Grains and grain-based products, A009T Fine bakery wares, A009V Biscuits, A00AE Biscuit with inclusions, filling or coating, A0BYR Wafers) structure. Depending on the level of detail needed these base terms are characterised as hierarchy terms (most aggregated level-blue pyramid), generic terms (white sphere), non-specific terms (yellow sphere), core terms (acceptable level of detail - red sphere) and extended terms (most detailed level – green sphere) (Fig. 3). Base terms can be further described with additional information using facets. Some facets are inherent to the base terms and therefore automatically linked when selecting it (e.g. A0BYR#F02.A06DN Wafers having biscuit as part-nature). The system is structured in multiple hierarchies, serving the data reporting and data analysis needs of different safety domains. A specific hierarchy (exposure hierarchy) is needed to assess dietary exposure by combining occurrence of chemicals and food consumption data. Other hierarchies have different structures reflecting legislative and other analysis or reporting requirements. The current version

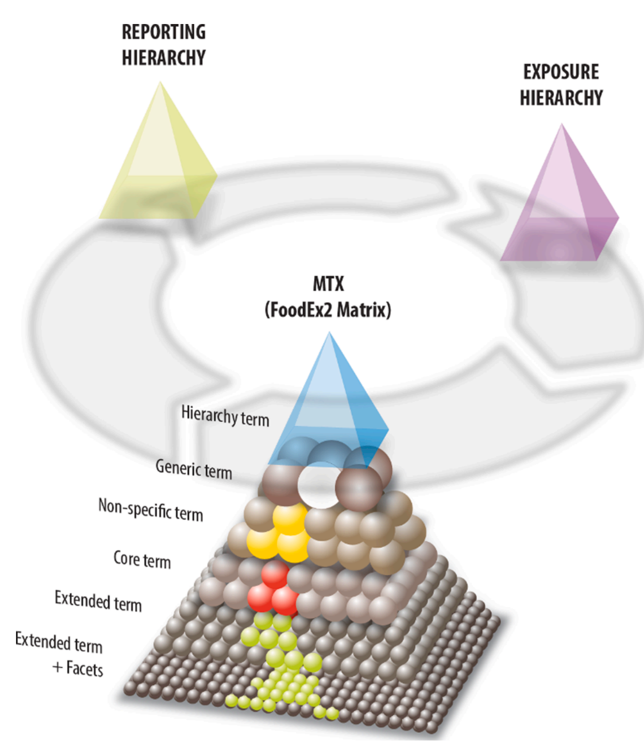

Fig. 3. The FoodEx2 classification system structure.

(August 2020) of FoodEx2 has eight hierarchies: seven domain-specific (Reporting, Exposure, Zoonoses, Feed, VetDrugRes,[7] Botanicals, FeedAddExpo[8]) and a general-purpose hierarchy available for users as a service (master hierarchy) hierarchy (MTX FoodEx2 Matrix) for the management of the terminology.

All chemical monitoring data (i.e. chemical contaminants, food additives, pesticides residues, veterinary medicinal product residues) are submitted to EFSA codified according to FoodEx2 (EFSA, 2020).

FoodEx2 is also used internationally. For example, it is used as a common food classification and description system in the FAO/WHO Global Individual Food consumption data Tool (FAO/WHO GIFT)[9] and the Global Dietary Database (GDD)[10] for the harmonization of dietary datasets worldwide for global diet monitoring (Karageorgou et al., 2019).

The FoodEx2 classification terminology can be accessed through a catalogue (called MTX (FoodEx2 Matrix)) hosted by the EFSA Catalogue browser (EFSA and Ioannidou, 2019a). This is a Java® based application, which allows the browsing, analysis and maintenance of the FoodEx2 catalogue (EFSA et al., 2020h) as well as other EFSA catalogues. This software is directly connected with the EFSA Data Collection Framework web platform through which data are submitted to EFSA and therefore data providers can download the latest version of the catalogue. FoodEx2 is open source. Its code can be downloaded from the GitHub platform[11] and the browser can be downloaded from the EFSA website.[12] The catalogue is freely available to the public using an Open API account.

In order to assist data providers in performing a quality check of the selected FoodEx2 codes before sending their datasets to EFSA, EFSA has also developed a FoodEx2 Interpreting and Checking Tool (ICT) (EFSA and Ioannidou, 2019b). This latest version is a Microsoft Excel® spreadsheet available as an add-on to the EFSA Catalogue browser and its main function is to decode and verify the quality of the FoodEx2 codes generated using the EFSA Catalogue browser.

5. Discussion

This paper provides an overview of a unique suite of dietary exposure assessment tools developed and maintained by EFSA to estimate dietary exposure to food-borne chemical hazards. All tools are open access (freely available) for use by EFSA experts, applicants of regulatory product dossiers, regulators, researchers or any interested party to estimate deterministic dietary exposure to food-borne hazards in the food sectors to which they are tailored (i.e. pesticide residues, feed additives, food additives, contaminants and food enzymes).

Open access exposure tools are particularly useful for applicants of dossiers in regulatory product domains to estimate anticipated intakes of food-borne chemical hazards as part of risk assessments, because food consumption data (at the level of individuals) are not easily accessible in many countries. In addition, estimates of dietary exposure can be generated without the need for statistical software programs or a high degree of data literacy.

The rollout of several of these tools is among a series of activities implemented to fulfil one of the goals of EFSA's 2020 strategy – widen EFSA's evidence base and maximize access to its data (EFSA, 2016). Related activities outside the scope of this paper include the release of an open access hazard assessment database (OpenFoodTox) that provides summary toxicological information (e.g. health-based guidance values, critical effects) on over 5,000 chemical substances used in EFSA risk assessments since its foundation (Dorne, 2021). With the exception of PRIMo, all tools generate estimates of dietary exposure using data from the most comprehensive and detailed pan-European food consumption database available (Comprehensive database) (Ioannidou et al., 2020). The addition of new dietary surveys to the Comprehensive database within the frame of EFSA's EU Menu project (EFSA, 2014; Ioannidou et al., 2020) ensures that the database and the exposure tools remain temporally relevant.

As the development of PRIMo pre-dates the Comprehensive database, its underlying food consumption data (summary statistics for different surveys and population groups) are not consistent with the food consumption database underlying FAIM, FACE, FEIM and RACE (Comprehensive database). Furthermore, the Comprehensive database contains intakes of food as consumed whereas summary statistics in PRIMo refer to raw agricultural commodities (RACs) converted by individual countries from foods consumed. In order to provide more detailed and comprehensive exposure assessments in the area of pesticide residues, EFSA developed a model to convert food consumed in the Comprehensive database into RPCs e.g. wheat, tomatoes (EFSA, 2019b). The next developments aim to apply the model to use data at RPC level from the Comprehensive database in the next release of PRIMo which is envisaged to be web based. When completed, all dietary exposure assessment tools will generate estimates of dietary exposure from a common data source (Comprehensive database) creating a sound basis for better harmonisation of EFSA's dietary exposure assessments throughout the different regulatory domains within EFSA's remit.

When managing large volumes of data, such as the Comprehensive database, the use of standard terminologies (information identifiers) is necessary. Standard terminologies for food are particularly important for food chemical exposure in order to link databases of chemical concentration with food consumption databases in a meaningful way. The FoodEx2 food classification and description system used to code foods in the Comprehensive database was designed to accommodate food classification in several regulatory domains within EFSA's remit (EFSA, 2015b). The flexibility of FoodEx2 allows users to cluster foods into groups (categories) that are pertinent to exposure assessments in the different regulatory domains for which the tools were developed. This flexibility facilitates the possible development of dietary exposure tools in new regulatory domains in the future. Although initially developed as a European food classification and description system, FoodEx has been adopted by the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) in an attempt to harmonise dietary food consumption databases in the FAO/WHO global repository for harmonised food consumption surveys (Karageorgou et al., 2019; Leclercq et al., 2019). Beyond Europe, FoodEx2 has served as a building block to design national food classification and description systems to facilitate global comparisons of food risk assessments (Chiu et al., 2018). Although user-friendly software programs have been developed to help users select and generate FoodEx2 codes (EFSA and Ioannidou, 2019b; EFSA et al., 2019c) during data collection or data curation, the process of coding databases using FoodEx2 is essentially performed manually at present. EFSA and others (Eftimov et al., 2017) are exploring use of machine learning techniques such as natural language processing to classify and describe foods according to FoodEx2 in a semi-automatic way.

Estimates of dietary exposure from the tools described in this paper assume that a food ingredient or chemical hazard is present in all foods within food categories included in the exposure assessment. In the case of food additives this is a conservative assumption (Gilsenan et al., 2002). Food ingredient databases and databases such as Mintel's global new products database (GNPD) provide information on the use of food additives based on information declared on food labels (Gilsenan et al., 2002; Diouf et al., 2014; Tennant and Bruyninckx, 2018). Brand loyalty is an important consideration when estimating dietary exposure to food additives. Although EFSA uses different assumptions to model brand

[7] Hierarchy originally developed to serve the Veterinary Medicinal Product Residues data collection.

[8] hierarchy developed to serve the FACE model.

[9] http://www.fao.org/gift-individual-food-consumption/en/.

[10] https://globaldietarydatabase.org/.

[11] https://github.com/openefsa/catalogue-browser.

[12] https://www.efsa.europa.eu/en/data/data-standardisation.

loyalty in refined food additive exposure assessments (EFSA et al., 2017b) these assumptions are not incorporated in FAIM.

Some food-borne hazards may be regulated by different regulatory frameworks. For example, the coccidiostat monensin sodium is used as a feed additive in poultry and as a veterinary medicine in bovine and therefore may be present in food of animal origin as a result of different routes of exposure. FACE provides refined estimates of dietary exposure to feed additives from food of animal origin using individual level data from the Comprehensive database. This approach is more refined compared to the methodology (e.g. model diet for adults) used by the EFSA FEEDAP Panel in the past (EFSA FEEDAP Panel, 2012) and which is currently used by the European Medicines Agency (EMA) to estimate dietary exposure to residues from animals treated with veterinary medicines. Given that different exposure models used in different regulatory frameworks could produce different risk assessment outcomes for the same substance, the European Commission recently asked EFSA and EMA to evaluate different exposure models for dual use substances.

All tools generate deterministic estimates of dietary exposure to single chemicals which, with the exception of pesticide residues and feed additives, is what sector specific EU legislation alludes to. In practice, consumers may be exposed to multiple chemicals from dietary and non-dietary sources prompting the need to consider combined exposure to multiple chemicals in risk assessments. EFSA's Scientific Committee has developed a harmonised framework to evaluate combined exposure to multiple chemicals (chemical mixtures) in food and feed which complements the current EU regulatory requirements for assessing single substances (EFSA Scientific Committee et al., 2019).

In the pesticides sector, where several active substances are typically used in or on food and feed, cumulative and synergistic effects of pesticides should be considered for dietary risk assessments. EFSA has implemented methodologies to carry out cumulative risk assessment of pesticide residues in food and, to date, has carried out two pilot cumulative risk assessments of pesticide residues, one considering chronic effects on the thyroid system and another looking at acute effects on the nervous system (EFSA et al., 2020e; EFSA et al., 2020f). As part of this endeavour, EFSA partnered with RIVM (National Institute of Public Health and the Environment) in the Netherlands to develop the MCRA (Monte Carlo Risk Assessment) web-based tool (version 8.3) which was used to perform cumulative exposure assessments on the nervous system and the thyroid (van Klaveren et al., 2019a; van Klaveren et al., 2019b) using a probabilistic approach. It is envisaged that the MCRA tool will continue to be used to support EFSA's work programme on combined exposure to multiple chemicals with eventual evolution to become open source.

Maximising access to EFSA's scientific data has been a key feature of EFSA's 2020 strategy. Making exposure data more open and accessible, in this context through the development of open access dietary exposure tools with in-built European food consumption data, has been a key achievement in this context. As the agency prepares for its next strategic cycle (Cappè et al., 2019), it will build on these achievements to date.

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.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.envint.2020.106357.

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