European Food Safety Authority

EFSA Journal 2012;10(10):s1014

SPECIAL ISSUE

Preparing the way for accurate calculations of dietary exposure to chemicals

Stefan Fabiansson, Francesco Vernazza[1, 2]

European Food Safety Authority (EFSA), Parma, Italy

Received: 28 May 2012

ABSTRACT

Important tasks of the European Food Safety Authority include compiling central repositories for European data on the presence of beneficial or harmful chemical substances in food and feed, and data on food consumption, to facilitate European dietary exposure assessment as well as harmonising data collection activities. The past ten years have seen considerable progress in harmonising European data collection activities. Initial shortcomings in contaminant data descriptions, data submission procedures and coverage of European food consumption data, as well as the problem of matching foods analysed for chemical substances with foods as consumed, were addressed by EFSA in close cooperation with EU Member States. A standardised occurrence data structure and automated data submission methods were developed to improve results transfer and validation. Detailed food consumption information was collected covering, at least partially, all age groups. Currently, the data structure hosts almost 2.5 million records on contaminants, it receives every year around 15 million records on pesticide residue monitoring and includes over 6.3 million food consumption records. EFSA also published uniform terminology for identifying and characterising food, thus providing the essential link between analytical data and food consumption information. Consequently, exposure assessments within EFSA's Risk Assessment framework have greatly improved. EFSA can now provide more robust data to risk managers for setting maximum levels in foods or performing trend analyses to measure the impact of legislative activities, as demonstrated in the number of contributions to scientific opinions and stand-alone reports produced by the Dietary and Chemical Monitoring (DCM) Unit. Further ongoing improvements include a common methodology for food consumption surveys, better predictions of usual intake from short term consumption data, and a coordinated approach for assessing the presence and levels of chemical substances in food as actually consumed.

© European Food Safety Authority, 2012

KEY WORDS

Exposure assessment, chemical substances, food consumption, food description

[1] Correspondence: dcm@efsa.europa.eu

[2] Acknowledgement: The authors wish to thank the staff of the Dietary and Chemical Monitoring Unit for the collaboration in developing this document.

Suggested citation: Fabiansson S, Vernazza F; Special issue: Preparing the way for accurate calculations of dietary exposure to chemicals. EFSA Journal 2012;10(10):s1014. [8 pp.]. doi:10.2903/j.efsa.2012.s1014. Available online: www.efsa.europa.eu/efsajournal

© European Food Safety Authority, 2012

INTRODUCTION

One of the elements of a food safety risk assessment is the exposure assessment, i.e. the estimation of the likelihood that the consumer will be exposed to a substance and the quantification of the exposure. Exposure assessments combine data on concentrations of a chemical substance present in food with data on the quantity of those foods consumed. To be able to combine these different types of data it is necessary to consider standardisation of associated metadata, in particular harmonisation of the food description.

On its formation in 2002, the European Food Safety Authority (EFSA) received the task of centrally pooling data collected by European Union (EU) Member States on the presence of beneficial and harmful substances in food and feed as well as data from food consumption surveys with the particular aim of assessing dietary exposure. It was also tasked with harmonising data collection activities to improve technical compatibility. Data collection tasks in the EU had previously been handled ad hoc under the umbrella of scientific cooperation on questions relating to food (SCOOP)[3]. A SCOOP task involved coordination amongst Member States to provide pooled data from across the EU on food safety issues of concern to assist the European Commission (EC) in developing EU legislation for consumer protection.

For continuity reasons, EFSA initially built on the existing limited collaboration for access to the national data, while simultaneously exploring ways of gradually improving the system. In the period 2002-2006, the network of national organisations continued to be contacted for individual issues with ad hoc data requests and dietary exposure assessed by accessing food consumption information available in a limited number of collaborating countries.

During this initial phase, major shortcomings were identified in uniform descriptions of contaminant data, data submission procedures, coverage of the EU in relation to food consumption data and the problem of matching foods sampled for quantifying the presence of contaminants with food consumption data.

1. THE DIETARY AND CHEMICAL MONITORING UNIT

The Data Collection and Exposure Unit later renamed the Dietary and Chemical Monitoring (DCM) Unit, was created in 2007 within the Scientific Support and Assistance Directorate to provide staff resources to, among several other tasks, assist in collecting and evaluating contaminant and related data, compile European food consumption information, and develop harmonised procedures to facilitate calculation of dietary exposure.

The DCM Unit is now responsible for collecting and evaluating analytical data in a range of areas including but not limited to contaminants, pesticides and veterinary medicine residues, nutrients and food consumption. In this context, it actively cooperates with various EFSA scientific panels, participating to different Working Groups (WG) on specific hazards and contributing data analysis and exposure assessment. Guidance on inputs for simplified exposure calculations is also provided.

The outputs of these activities are presented in scientific or technical reports or form part of EFSA scientific opinions. Such outputs include a detailed presentation of the raw data collected, the methods used for validating the data and a summary presentation of the concentrations of the substance under review split into relevant food categories. For EFSA scientific opinions and, when needed, for scientific and technical reports, dietary exposure to the substances is also assessed and presented based on the most accurate food consumption information available to the DCM Unit.

Risk assessors will use the overall exposure results as inputs in risk characterisation and might require special analyses of sub-populations at risk. Risk managers might need support for setting maximum levels since this is often based on achievable levels while securing sufficient access to all food

[3] Available from http://ec.europa.eu/food/fs/scoop/index_en.html

commodities. Risk managers might also be interested in trend analysis to measure the impact of legislative activities. To focus their activities to the most important foods, the exposure assessment must present data at a sufficiently disaggregated food level relevant for the chemical substances reviewed.

In order to address the challenges, EFSA developed, in cooperation with EU Member States, a standardised data structure for occurrence data, including Total Diet Study designs, introduced a harmonised methodology for the reporting of food consumption data, and published uniform terminology for the identification and characterisation of food to provide an essential link between analytical data and food consumption information.

1.1. Data collection structure

Since EFSA receives an increasing volume of data on concentrations of chemical contaminants and residues from European national monitoring and surveillance programs, a standardised and structured approach is necessary.

Over the last few years, EFSA has significantly improved its data handling processes. In 2010, an automated database-to-database submission process was launched, called the data collection framework (DCF). The DCF is a web interface specifically set up for electronic data exchange based on the xml (eXtensible Markup Language) data transfer protocol. The system checks for the correct completion of mandatory fields and compliance to common business rules reported in the 'Guidance on Data Exchange' (EFSA, 2010a). Since the introduction of the DCF, EFSA has provided support to Member States for implementation of the protocol. Austria was the first country to successfully transfer data to EFSA using the fully automated procedure. Seventeen Member States now have the capacity to fully use the automated system of data transfer.

A prerequisite for the DCF to work was the simultaneous introduction of a standardised data format containing a generalised model to harmonise the collection of a wide range of measurements in the area of food and feed safety assessment. Thus, also in 2010, EFSA published the 'Guidance on Standard Sample Description (SSD) for Food and Feed' (EFSA, 2010b). This guidance specifies the data elements (items describing characteristics of samples or analytical results such as country of origin, product, analytical method, limit of detection, and result), the sample data structure and the format for analytical results for chemical contaminants and residues in food and feed included in monitoring and control programmes. It also lists controlled terminologies and simple validation rules to enhance data input quality.

The EFSA harmonised Data Collection Structure has received so far around 2.5 million records on contaminant occurrence. The analyses were performed on 422 single substances or substance groups and on roughly 1 800 different food or feed groups. Additionally, every year circa 15 million records are submitted in the framework of the pesticide residues monitoring.

At the data receiving end, EFSA has built a more complex validation system, including checking of the rules and interaction with the data submitter, in order to ensure that the data fulfil the standardisation requirements. Through the introduction of the above changes, precision of chemical occurrence data received from monitoring and surveillance activities have been considerably improved. Nevertheless, some shortcomings remain since data derived from the food control systems might be targeted to problem areas and the samples analysed may not be representative for the food as consumed.

1.2. Total Diet Study approach

The Total Diet Study (TDS) approach can be used to overcome such potential shortcomings. A TDS is a public health tool to determine population dietary exposure to chemical substances across the entire diet by analysing main foods prepared as consumed and pooled into representative food groups. Steps characterising a TDS include the selection of foods based on food consumption data to represent as

best as possible a typical diet, their preparation to food as consumed and the subsequent pooling of related foods before analysis.

Using pooled samples of individual food items implies that the analytical data generated represent averages of concentration data. Therefore, TDS results are best suited for calculating chronic exposure to chemical substances in food and may allow the analysis of trends, where the sample size is sufficiently representative. The TDS approach will provide background contamination levels in the general food supply suitable for estimating population dietary exposure, while monitoring and surveillance activities can capture more highly contaminated individual food items. Together, the two complementary approaches allow identification of the relative importance of individual sources of beneficial and harmful chemical substances through coverage of the whole diet.

To harmonise the TDS methodology and enhance the value of these programs at a pan-European level, EFSA developed, together with national and international participants, the guidance 'Towards a harmonised Total Diet Study approach: a guidance document' (EFSA et al., 2011). Using this document as the basis, a pilot project involving 19 EU Member States and supported by Directorate-General for Research and Innovation is currently underway[4].

1.3. Food consumption data

Activities towards a pan-European food consumption data collection were initiated in 2005, when a scientific opinion of the EFSA Scientific Committee suggested the establishment of a harmonised food consumption database in the EU (EFSA, 2005). The initiative was further supported in the conclusions of the EFSA Scientific Colloquium on 'European food consumption database', recommending that EFSA takes a leading role in the co-ordination and completion of associated tasks in meeting this initiative (EFSA, 2008a).

In close collaboration with the EU Member States, EFSA has so far established two food consumption databases. The EFSA Concise European Food Consumption Database, published in 2008, gathered data on food consumption for adults in Europe according to broad food categories only (EFSA, 2008). These data should ideally be used only for exposure screening. The EFSA Comprehensive European Food Consumption Database, assembled in 2010, is an improved source of information on food consumption across the EU at an individual consumer level (EFSA, 2011a). It provides information for an expanded range of EU countries at a detailed food category level for seven specific population age groups, including children. By June 2012, the EFSA Comprehensive European Food Consumption Database included more than 6.3 million consumption records on 1 504 food groups. These data have been reported by over 66 000 subjects in 32 food consumption surveys from 22 EU Member States.

Presently, methods for measuring food consumption vary among countries and surveys, thus not allowing pooling all the data to represent a European consumption pattern. Consequently, accurate exposure assessment is now performed at survey level and exposure at European level is estimated analysing the results in the different surveys. However, EFSA is leading a harmonisation effort to define a common methodology called the "EU Menu project". The objective is to provide standardised information on what people eat in all countries and regions across the EU in detailed categories and including all age groups. It will allow more efficient and accurate overall exposure assessment in Europe and support risk managers in their decision making on food safety. As a starting point, and in collaboration with Member States, EFSA developed the 'Guidance on the general principles for the collection of national food consumption data in the view of a pan-European dietary survey' (EFSA, 2009a). Two supportive methodological pilots, one focused on children and the other on adults, are already underway. The two first contracts were granted to France and Estonia during 2011 to support the first EU Menu data collections. The final pan-European food consumption database, expected to include millions of records referring to some ten thousand different foods, is expected to be fully completed in 2018.

[4] Available from http://cordis.europa.eu/projects/rcn/101656_en.html

1.4. Food description and classification

To provide a common link to the diverse occurrence and food consumption data used in exposure assessment, a system for the unique and universal identification and characterisation of food is essential. Typically, information on foods is held in a range of incompatible datasets reporting data on various aspects of the foods. Although there is a general agreement on the importance of standardised food nomenclature, many attempts to describe or classify food lack general applicability. The preparation of reliable data on food requires precise identification, but simple food names are often inadequate or ambiguous. A common name may be misleading when the same name is used for different foods in different regions or when it is used for foods having different scientific names. The situation is further confounded by homonyms, synonyms, identical brand names for different food products, and culinary or technological terms.

Over a two-year period, EFSA in collaboration with Member State representatives reviewed the state-of-the-art in describing and classifying foods. A system called 'FoodEx 1' was introduced as an interim measure in 2010 for the coding of the Comprehensive European Food Consumption Database (EFSA, 2011b). EFSA's 14th Scientific Colloquium called 'Unambiguous ambiguity – the challenge of describing food' (EFSA, 2010c) was organised to allow stakeholder input on a new food classification system for exposure assessment. After a phase of development, testing and refinements, EFSA published 'FoodEx 2' in 2011 (EFSA, 2011c) together with a report describing its use (EFSA, 2011d) and a browsing tool[5] to facilitate its use. The new system consists of a detailed food description system with a number of facets to define associated parameters like processing, packaging, fat or moisture content. The foods are linked in a parent-child relationship in a hierarchical classification system. Several hierarchical systems exist to serve different domains, but they all link to a common core food level that is the corner stone of the system.

'FoodEx 2' is being gradually introduced in pilot projects during 2012 and is expected to be fully operational for the 2014 data collections. Transcoding tools are available to help data originators to link current systems to 'FoodEx 2'.

1.5. Assessing exposure

Exposure assessment is defined as the qualitative and/or quantitative evaluation of the likely intake of biological, chemical or physical agents via food as well as exposure from other sources if relevant (WHO, 1997). Assessments can be made either for acute (e.g. EFSA, 2009b) or chronic exposure (e.g. EFSA, 2012), where acute exposure is estimated for a period of up to 24 hours, while chronic (long-term) exposure covers the average daily exposure over several years or an entire lifetime. A number of different methods exist to combine or integrate consumption estimates with chemical concentration data, ranging from quick worst-case estimations to refined methods aimed at assessing actual exposure.

The accuracy of any exposure assessment ultimately depends on the precision in the two calculation inputs: chemical concentration and food consumption. Introduction of the SSD format to capture important sampling details has enabled accurate validation of chemical concentration data. Introduction of statistically based sampling frames are being considered in collaboration with Member States for their monitoring programs and a coordinated approach of using data from TDS is actively promoted. With the availability of more refined and accurate food consumption information, summary statistics from the new databases are being introduced for evaluating additive exposure and to crosscheck and validate all standard portions and model diets used in EFSA's exposure calculations. The information available in the current food consumption database is complete enough to always allow consideration of the children population, and in particular toddlers, who often are at the high end of exposure estimates.

[5] Available from http://www.efsa.europa.eu/en/datex/datexfoodclass.htm

Estimates of usual intake - average intakes modelled over long periods - are needed for use in chronic exposure and risk assessments. Different statistical methodologies are currently available for the estimation of usual intake from short-term dietary data, none of them being a widely recognised standard. In an externally funded project such tools were evaluated on behalf of EFSA.

The use of probabilistic dietary exposure assessments on a more routine basis in case refinements are needed, exploration of cumulative exposure assessment for metabolically or structurally related chemical substances, and testing of statistical methodologies for the estimation of usual intake from short-term dietary data are under evaluation.

No direct assistance is provided to food/feed companies for their own assessments but guidance is provided in support to applications by companies. For example, a guidance document for submission for food additive evaluations has been recently published by the Panel on Food Additives and Nutrient Sources Added to Food (ANS) with the support of the DCM Unit. The guidance document also addresses exposure assessment and proposes a specific tool for it.

1.6. Data analysis and reporting

In parallel with the intensive activities in improving and harmonising data collections and exposure calculation methods, the DCM Unit has continued to provide data analyses and exposure assessments in support of a large number of scientific opinions published by different panels of EFSA. A range of scientific and technical reports have been produced as well, to provide a solid scientific basis for the European Commission's risk management activities.

In particular, the DCM Unit has in recent years evaluated extensive data submissions from EU Member States and other stakeholders and drafted the exposure chapters for four scientific opinions of the Panel on Contaminants in the Food Chain (CONTAM) on metals, covering arsenic, cadmium, lead and uranium. Occurrence and exposure chapters were also drafted for ten opinions on marine biotoxins (including okadaic acid group toxins, azaspiracids, yessotoxins, pectenotoxins, saxitoxins, domoic acid group toxins, cyclic imines, palytoxins, brevetoxins and ciguatoxins) and for seven mycotoxins and other plant toxicants (including zearalenone, T-2 and HT-2 toxins, alternaria toxins, phomopsins, opium alkaloids in poppy seeds and ergot alkaloids). For persistent organic pollutants, exposure estimates were provided for dioxins in sheep liver, mineral oil hydrocarbons and four opinions on different brominated flame retardants. The DCM Unit contributed occurrence and exposure analysis to opinions on nitrates and melamine, and process contaminants such as poly-aromatic hydrocarbons and ethyl carbamate. Overall, as part of CONTAM WGs the DCM Unit assisted in drafting more than 30 opinions covering diverse areas. The DCM Unit provided significant support to the Food Ingredients and Packaging (FIP) Unit (scientific opinions of the Panels on Food Additives and Nutrient Sources Added to Food (ANS) and Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)) for the evaluation of 13 smoke flavouring (including drafting an assessment framework), several other additives and melaware as food contact material. Contributions were provided to the Panel on Biological Hazards (BIOHAZ) for the scientific opinion on biogenic amines, to the Nutrition Unit for the review on beta-casomorphins in milk) and to the Feed Unit (in the development of different documents like the Guidance on data submission).

The DCM Unit also played a significant role in assessing emerging crisis issues including nicotine found in mushrooms, melamine in dairy products, the impact of ash from volcanic eruptions, the dioxin crisis when high levels were found in Irish pork, and advice on the leakage of 4-metyl-benzophenone from printing ink into breakfast cereals.

Finally, the DCM Unit has published separate scientific and technical reports covering topics as diverse as veterinary drug residues, perfluoroalkylated substances, aflatoxins in figs, furan, acrylamide, phytosterols, lead, cadmium, dioxins and polychlorinated biphenyls (PCBs). Other reports are planned or under development covering the more systematic collection of occurrence data from the EU Member States.

2. NETWORKING

Collaboration between EFSA and EU Member States in the data collection area is vital because the major resources will continue to be provided by national organisations. EFSA can only act as a catalyst to coordinate the building of central repositories for pan-European data. Two networks[6] with representatives from each EU Member State were formed in 2007 to facilitate the collaboration:

- The 'Expert Group on Food Consumption Data' coordinates harmonisation of the collection and collation of food consumption data from food dietary surveys of individuals and provides a platform for exchange of views between food consumption experts from the European countries.

- The 'Expert Group for Chemical Occurrence Data' coordinates harmonisation of the collection and collation of chemical substance data from monitoring and surveillance activities and provides a platform for exchange of views between chemical experts from the European countries.

To assist the collaboration efforts even further, attempts are already under way to build a data warehouse to generate a common data access platform available to all network participants.

CONCLUSIONS

The past ten years have seen considerable progress in the harmonisation of European data collection activities covering chemical substances in food and feed and the consumption of food, which has allowed the building of compatible pan-European databases to hold the information. As a result, the accurate and representative calculation and presentation of exposure has been much enhanced.

Further improvements already in the pipeline include a common methodology for food consumption surveys, better predictions of usual intake from short term consumption data, and a coordinated approach for assessing the presence and levels of chemical substances in food as actually consumed.

About the authors

Stefan Fabiansson, Head of the Dietary and Chemical Monitoring Unit from 2007 to 2012, now retired; **Francesco Vernazza**, Senior Scientific Officer, Deputy Head of the Dietary and Chemical Monitoring Unit.

[6] Available from http://www.efsa.europa.eu/en/datex/datexegs.htm

REFERENCES

EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Committee on a request from EFSA related to Exposure Assessments. The EFSA Journal (2005), 249, 1-26.

EFSA (European Food Safety Authority), 2008a. EFSA Scientific Colloquium Report: European Food Consumption Database - Current and medium to long-term strategies. EFSA, April 2005, Parma, Italy. Available from: http://www.efsa.europa.eu/en/supporting/doc/colloquiaconsumption.pdf.

EFSA (European Food Safety Authority), 2008b. Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment. Available from: http://www.efsa.europa.eu/en/datex/docs/datexfooddbguidance.pdf.

EFSA (European Food Safety Authority), 2009a. General principles for the collection of national food consumption data in the view of a pan-European dietary survey. EFSA Journal 2009;7(12):1435. [51 pp.].

EFSA (European Food Safety Authority), 2009b. Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Marine Biotoxins in Shellfish – Saxitoxin Group. The EFSA Journal (2009), 1019, 1-76.

EFSA (European Food Safety Authority), 2010a. Guidance document: Standard sample description for food and feed. EFSA Journal 2010;8(1):1457. [54 pp.].

EFSA (European Food Safety Authority), 2010b. Guidance on Data Exchange. EFSA Journal 2010;8(11):1895. [50 pp.].

EFSA (European Food Safety Authority), 2010c. EFSA Scientific Colloquium Report: Unambiguous ambiguity – the challenge of describing food. EFSA, June 2010, Parma, Italy. Available from: http://www.efsa.europa.eu/en/supporting/doc/colloquiafoodclassification.pdf

EFSA (European Food Safety Authority), 2011a. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097. [34 pp.].

EFSA (European Food Safety Authority), 2011b. Evaluation of FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. EFSA Journal 2011;9(3):1970. [27 pp.].

EFSA (European Food Safety Authority), 2011c. The food classification and description system FoodEx 2 (draft-revision 1). Supporting Publications 2011:215. [438 pp.]. Available from: http://www.efsa.europa.eu/en/supporting/doc/215e.pdf.

EFSA (European Food Safety Authority), 2011d. Report on the development of a food classification and description system for exposure assessment and guidance on its implementation and use. EFSA Journal 2011;9(12):2489. [84 pp.].

EFSA (European Food Safety Authority), Food and Agriculture Organization of the United Nations and World Health Organization, 2011. Towards a harmonised Total Diet Study approach: a guidance document. EFSA Journal 2011;9(11):2450. [66 pp.].

EFSA (European Food Safety Authority), 2012. Lead dietary exposure in the European population. EFSA Journal 2012;10(7):2831. [59 pp.].

WHO (World Health Organization), 1997. Food Consumption and Exposure Assessment of Chemicals. WHO/FSF/FOS/97 5. Geneva: FAO/WHO.