The importance of data collection for timely and accurate risk assessment

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Abstract. The European Food Safety Authority (EFSA) is responsible for food safety risk assessments at EU level. It provides independent scientific advice on risks associated with the food chain to support EU risk management decisions. Since its establishment, EFSA has amassed a wealth of data to underpin its risk assessments, such as food consumption data, monitoring data and experimental data. Increasing transparency of its risk assessments is a core objective of EFSA. EFSA aims to enhance the quality and transparency of its outputs by giving insofar as possible access to data and methods underpinning its scientific outputs. This paper provides an overview of the role of EFSA, its core data collections and their regulatory framework, as well as data quality and standardisation aspects. Finally, the paper elaborates on EFSA’s 2020 strategy in relation to data, and describes EFSA scientific data warehouse and Knowledge Junction in this regard.

1. European Food Safety Authority mandate
The European Food Safety Authority (EFSA) is responsible for EU food safety risk assessments to protect consumers. It provides independent scientific advice on questions relating to food and feed safety, animal health and welfare, plant health, nutrition, and associated environmental issues and emerging risks. In addition, EFSA communicates on its scientific assessments to all interested stakeholders, including risk managers, scientists and the public. The authority was established in 2002 in the aftermath of the BSE (Bovine Spongiform Encephalopathy) crisis in Europe, and constitutes an integral part of the EU food safety system to protect public health.

EFSA’s scientific advice informs EU risk managers (the European Commission, Parliament and EU Member States) who make regulatory decisions relating to food and feed safety (e.g. authorisation of a food ingredient or a new health claim, or the establishment or amendment of maximum legal limits for a food contaminant). The European Commission, Parliament and competent authorities in EU Member States are the only bodies entitled to ask scientific advice from EFSA. Once a request for scientific advice is accepted by EFSA, it becomes a mandate and is assigned to one or more Scientific Panels or EFSA’s overarching scientific committee depending on the scientific area to which the question pertains. EFSA’s scientific advice is provided in the form of scientific opinions or statements by one or more of its scientific panels or its scientific committee. These expert groups are composed of independent experts appointed through an open selection procedure. Experts mainly come from European universities, public research organisations, national authorities and food safety agencies. EFSA’s panels and its scientific committee also carry out scientific work on their own initiative, so called self-tasking, to examine emerging issues and new hazards or to update risk assessment
approaches for example. EFSA staff also produces scientific outputs such as peer reviews of the risk assessment of active substances in pesticides or dietary exposure to food-borne substances. Since its creation, EFSA’s experts and staff have produced assessments for more than 4,400 substances in over 1,650 scientific opinions, statements and conclusions. These assessments are published in the open access EFSA Journal. Openness and transparency are core values of EFSA and are embedded in all activities undertaken by the authority. Adherence to these values helps to ensure a high level of trust in EFSA’s work as well as accountability to society.

2. Food safety risk assessments
EFSA applies the overarching principles of the risk assessment paradigm in its food safety assessments: hazard identification and hazard characterisation (hazard assessment) determine safe levels of exposure of substances for human health, animal health or the environment. These safe levels are then combined with exposure estimates (exposure assessment) to determine the likelihood of risk associated with a given exposure (risk characterisation). Hazard assessments typically rely on toxicology data from animal studies. Dietary exposure assessments require data on the occurrence and levels of microbiological or chemical substances in food, as well as food consumption data.

EFSA’s scientific committee develops cross-cutting guidance documents to be implemented in the routine work of panels to further improve openness, transparency and robustness in the risk assessment process and to achieve a more harmonised approach to risk assessments across panels and in the wider risk assessment community [1]. Recent examples include guidance on use of the benchmark dose approach, use of the weight of approach in scientific assessments, assessment of biological relevance and uncertainty analysis.

In 2015 EFSA published principles and processes for dealing with data and evidence in risk assessments [2] which describe the process for performing fit for purpose risk assessments. A key component is that data used as evidence in scientific assessments are both relevant and reliable.

3. Data collection regulatory framework
EFSA’s founding regulation defines an overarching legal obligation on EFSA to collect, collate and summarise scientific and technical data to inform EU risk assessments and to work in close cooperation with all operators in the field of data collection to achieve this goal [3]. This framework is reinforced by sector specific EU legislation pertaining to chemical and biological hazards.

In the case of pesticide residues, Member States have a legal obligation to monitor pesticide residues in food commodities from national and EU co-ordinated sampling programmes and to submit monitoring results to EFSA and to the European Commission [4]. Some 18 million analytical records from European data providers are sent directly to EFSA annually.

In area of biological hazards, Member States have a legal obligation to monitor trends and sources of zoonoses, zoonotic agents and antimicrobial resistance and to transmit the results of monitoring programmes to the European Commission [5,6]. The European Commission entrusts the task of European data collation directly to EFSA.

To support EFSA’s risk assessments of intentionally added food ingredients such as food additives and flavourings, Member States are required to maintain systems to monitor the consumption and use of these intentionally added ingredients using a risk-based approach and to report their findings with appropriate frequency to the European Commission and to EFSA [7,8].

In the domain of chemical contaminants, Commission Regulation (EC) No. 1881/2006 [9] complemented by several pieces of contaminant specific legislation requests Member States to monitor contaminant occurrence in food and feed and to report findings to the Commission or EFSA. The European Commission entrusts EFSA with the task of collecting all contaminant data from Member State data providers on the occurrence of contaminants in foodstuffs on an annual basis.

In the field of veterinary medicinal product residues, Member States must submit to the Commission, on an annual basis, national monitoring plans together with the results of monitoring for the previous year [10]. The European Commission subsequently entrusted the task of data collection
(at sample level) to EFSA. EFSA is currently piloting a European data collection at sample based level.

For some of its risk assessments (e.g. in the regulated product area), EFSA relies on published information as well as on scientific studies sponsored and submitted by industry. Data requirements for regulated product areas are outlined in sector specific guidance documents issued by EFSA.

4. EFSA data collections
Since its foundation, EFSA and Member States have made significant progress in the area of data collection for risk assessment and monitoring. EFSA has become a central hub of European data on food consumption and monitoring data of food-borne hazards to support its scientific activities. The Evidence Management unit of EFSA is primarily responsible for collecting monitoring and food consumption data from EU Member States. Data are collected through various channels such as voluntary submissions from the food industry and academia in response to calls for data on EFSA’s website, direct submission of data from competent authorities in Member States to EFSA, as well as provision of funding to Member States via grants / procurements for data generation and collection.

EFSA receives support for its data collection activities from EFSA's advisory forum, the EFSA focal point network and EFSA scientific data networks composed of respective representatives from Member States. EFSA also engages with industry and other stakeholders through its stakeholder forum to collect food additive and contaminant data for its dietary exposure assessments.

EFSA’s Comprehensive European Food Consumption Database [11] contains individual dietary records from some 100,000 subjects (infants to elderly) from more than 510 million inhabitants in 23 Member States. This database is used for EFSA exposure assessments. One of the limitations of the database is that dietary surveys use different methodologies, e.g. 24h recall vs. 7 day food record. To address this, EFSA launched its EU Menu project which aims to provide more standardised and higher quality data on food consumption using FoodEx2 food classification and description [12] across the EU, following the EU Menu methodology [13]. EFSA provides guidance and financial support to participating countries to collect these food consumption data. To date, some 30 surveys covering different population groups (e.g. children, adults) are ongoing in the EU Menu project. EFSA aims to gradually update its comprehensive database with national surveys conducted according to the EU Menu project methodology.

EFSA’s databases on contaminant and pesticide residue occurrence are populated on an annual basis with some one million and 18 million analytical records, respectively. In order to standardise data on contaminants and pesticide residues transmitted to EFSA, EFSA developed the Standard Sample Description (SSD) data model [14]. Many public and private laboratories in Europe are now sending (electronically) laboratory results to EFSA using the SSD format. The inclusion of the SSD specification in pesticides legislation [15] has facilitated the adoption of this specification by laboratories. Veterinary medicinal product residue data are also reported in SSD format to EFSA. Using EFSA’s FoodEx2 food classification system, the monitoring results are combined with EFSA’s EU wide food consumption databases to estimate consumer exposure.

EFSA collects annually data on zoonoses, food-borne outbreaks, animal populations as well as data on antimicrobial resistance [16], and uses these data to generate annual EU summary reports together with ECDC (the European Centre for Disease Prevention and Control). EFSA has established a joint molecular typing database with ECDC, to share common data in a joint repository so that microbiological data from humans can be linked to similar data from the food chain. The goal is to enable early detection and investigation of cross border food-borne outbreaks and contribute to source attribution studies to better understand the epidemiology of food-borne pathogens [17].

Regarding data for hazard assessments, EFSA developed an open source chemical hazards database called OpenFoodTox. This database is available as a simple viewer through Microstrategy or as a downloadable database from EFSA’s Knowledge Junction. OpenFoodTox summarises the outcome of hazard characterisation for human health and, for some compounds, animal health and the environment (feed additives and pesticides). The data cover some 4400 substances including
information on substance characterisation and toxicological data (reference points, reference values and genotoxicity) linked to EFSA outputs [18]. EFSA also published a database on botanical species reported to contain naturally occurring substances of possible concern for human health when present in food. The database supports the safety assessment (hazard identification) of botanicals and botanical preparations intended for use in food.

4.1. Data quality

Data quality is defined as the fitness for purpose of the data for a specific risk assessment question. Many aspects of a data collection can affect data quality, e.g. the representativeness of a sample, the temporal relevance of a sample or the sensitivity of an analytical method used to detect a hazard in a sample. Timeliness and completeness are important aspects of data quality relevant to EFSA’s work, in particular given that many of its assessments pertaining to a specific time period are bound by legal deadlines. Good metadata allow end users to assess the fitness for purpose of a dataset for a particular assessment. EFSA’s standard for monitoring data transmission, the SSD, was developed to standardise and improve the quality of incoming data. The SSD contains some 80 different fields with metadata describing an analytical sample (e.g. year of sampling, analytical method, limit of detection, sampling strategy, etc.).

Poor data management handling can also introduce errors into datasets that can affect data quality. EFSA continually improves its data management processes and tools to detect any anomalies in the data received that may impact data quality. Data are mainly submitted through EFSA’s Data Collection Framework (DCF), a web interface to receive data from data providers. The DCF contains in-built business (validation) rules to perform automatic checks on incoming data. Automatic feedback is sent to data providers and files are rejected in case issues are identified. Additional quality checks are performed on the data following standard operating procedures to identify any anomalies in the data that may impact its quality.

Close cooperation with data providers is important to ensure data quality at source. EFSA regularly publishes guidelines for data providers on data reporting and invests in training on data reporting and transmission. Training on data collection and reporting is also extended to pre-accession countries in preparation for their future participation in the EU. In 2017, EFSA started to piloting a project with five Member States with a view to improving data quality at Member State level.

5. EFSA 2020 strategy: data

EFSA has accumulated a wealth of risk assessment data since its foundation. In parallel, the work of EFSA is increasingly subject to demands for more openness and transparency across its spectrum of stakeholders. EFSA’s 2020 strategy includes a strategic objective to ‘widen EFSA’s evidence base and optimise access to its data’. Under this objective, EFSA aims to enhance the quality and transparency of its outputs by giving insofar as possible access to data and evidence underpinning its scientific outputs [19, 20]. Many of EFSA’s data collections can now be accessed through its Knowledge Junction or its scientific data warehouse. EFSA’s Knowledge Junction is a community on the EU-funded Zenodo research-sharing open data platform. Uploaded items have a unique digital object identifier to make them citable. The contents can then be cited and re-used by the scientific community and other interested stakeholders. EFSA’s scientific data warehouse currently contains monitoring, food consumption and hazard data, and is publically accessible from EFSA’s website. Access rules define different levels of data access for different stakeholders [21]. In 2017, EFSA became a partner of GODAN (Global Open Data for Agriculture and Nutrition) which advocates open data and open access policies by default while respecting legitimate concerns such as relating to privacy, security and commercial sensitivity. EFSA also plans to migrate insofar as possible from unstructured to structured scientific data to increase efficiency, innovation and enable data re-use. Within this context a transformational project is currently ongoing on electronic submission of industry dossier data.
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References
[1] European Food Safety Authority 2009 Guidance of the scientific committee on transparency in the scientific aspects of risk assessments carried out by EFSA Part 2: general principles EFSA J. 1051 1
[2] European Food Safety Authority 2015. Scientific report on principles and process for dealing with data and evidence in scientific assessments EFSA J. 13 4121
[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety OJ L 31
[4] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC OJ L 70
[5] Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC OJ L 325
[6] Commission Implementing Decision 2013/652/EU of 12 November 2013 on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria OJ L 303
[7] Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives OJ L 354
[8] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC OJ L 354
[9] Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs OJ L 364
[10] Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC OJ L 125
[11] Merten C, Ferrari P, Bakker M, Boss A, Hearty A, Leclercq C, Lindtner O, Tlustos C, Verger P, Volatier JL and Arcella D 2011 Methodological characteristics of the national dietary surveys carried out in the European Union as included in the European Food Safety Authority (EFSA) comprehensive European food consumption database Food Addit Contam 28 975
[12] European Food Safety Authority 2015 The food classification and description system FoodEx2 (revision 2) EFSA supporting publications EN-804
[13] European Food Safety Authority 2014 Guidance on the EU menu methodology EFSA J. 12 3944
[14] European Food Safety Authority 2013 Standard sample description version 2.0 EFSA J. 11 3424
[15] Commission Implementing Regulation (EU) No 2016/662 of 1 April 2016 concerning a coordinated multiannual control programme of the Union for 2017, 2018 and 2019 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin OJ L 115
[16] Boelaert F, Amore G, Van der Stede Y and Hugas M 2016 EU wide monitoring of biological hazards along the food chain: achievements, challenges and EFSA vision for the future *Curr Opin Food Sci* **12** 52.

[17] Rizzi V, Da Silva Felicio T, Felix B, Gossner CM, Jacobs W, Johansson K, Kotila S, Michelon D, Monguidi M, Mooijman K, Morabito S, Pasinato L, Torgny Björkman J, Torpdahl M, Tozzoli R, Van Walle I 2017 The ECDC-EFSA molecular typing database for EU public health protection *Euroreference* **2** 4.

[18] Dorne JL, Richardson J, Kass G, Georgiadis N, Monguidi M, Pasinato L, Cappe S, Verhagen H and Robinson T 2017 Editorial: Open FoodTox: EFSA’S open source toxicological database on chemical hazards in food and feed *15* e15011.

[19] Gilsenan MB, Abbinante F, O’Dea E, Canals A and Tritscher A 2016 Open risk assessment: data. *EFSA J.* **14** s0509.

[20] Verloo D, Meyvis T and Smith A 2016 Open risk assessment: methods and expertise *EFSA J.* **14** s0505.

[21] European Food Safety Authority 2015 The EFSA data warehouse access rules. EFSA supporting publications EN-768.