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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 created a unique hub of European data on food consumption and occurrence of food-borne chemical and biological hazards with support from Member State data providers. These data are used to underpin many of EFSA's risk assessments. Increasing transparency in risk assessments is a core objective of EFSA and access to the data used is pivotal in this regard. This paper presents an overview of the core data collections of food-borne chemical and microbiological hazards within EFSA's remit as well as their underpinning regulatory framework. Progress towards standardisation of data from several food safety domains using the Standard Sample Description (SSD), the EFSA standard for receipt of analytical occurrence data on food-borne hazards, is described. The establishment of an EFSA data warehouse is described, which aims to provide several stakeholders with web access to European data at different levels of aggregation. Finally, opportunities and challenges of moving towards more open data are discussed.

Keywords. Data – Contaminants – Food consumption – Zoonoses – Legislation – Data Warehouse – Standard Sample Description (SSD).

Traitement des données : Observatoires/bases de données/stockage des données/cadre juridique. Collecte des données à l'EFSA

Résumé. *L'Autorité européenne de sécurité des aliments (EFSA) est responsable de l'évaluation des risques liés à la sécurité des aliments au niveau de l'UE. Elle formule des avis scientifiques indépendants sur les risques associés à la chaîne alimentaire de façon à étayer les décisions de l'UE en matière de gestion des risques. Depuis sa création, l'EFSA a mis en place un pôle unique de données européennes portant sur la consommation alimentaire et la présence de dangers biologiques et chimiques d'origine alimentaire, avec le soutien des données fournies par les États membres. Ces données sous-tendent un grand nombre de travaux d'évaluation des risques de l'EFSA. Le renforcement de la transparence dans l'évaluation des risques est un objectif central de l'EFSA et, à cet égard, l'accès aux données exploitées est essentiel. Cet article propose un aperçu des principales collectes de données réalisées sur les dangers microbiologiques et chimiques d'origine alimentaire relevant de la compétence de l'EFSA, ainsi que les cadres réglementaires qui les régissent. Une présentation est également donnée des progrès réalisés en vue de normaliser les données émanant de plusieurs domaines de sécurité des aliments différents grâce à l'utilisation de la « description type des échantillons » (SSD), la norme de l'EFSA pour la réception de données analytiques sur les dangers d'origine alimentaire ; une description de la manière dont sont gérées les données est aussi proposée. L'article décrit en outre la mise en place d'un entrepôt de données de l'EFSA, qui vise à fournir à plusieurs parties prenantes un accès via le site web aux données européennes à différents niveaux d'agrégation. L'article évoque enfin les opportunités et les défis liés à une évolution des pratiques vers des données ouvertes.*

Mots-clés. *Données – Contaminants – Consommation alimentaire – Zoonoses – Législation – Entrepôt de données – Description type des échantillons (SSD).*

I – Introduction

The European Food Safety Authority (EFSA), established in 2002, is responsible for food safety risk assessments at EU level. Its remit covers food and feed safety, animal health and welfare, plant health and nutrition. Within the remit of food and feed safety, EFSA provides scientific advice on the safety of regulated ingredients (pre- and post-market) and of contaminants unintentionally present in the food chain. EFSA's advice is mainly in the form of Scientific Opinions agreed by an independent panel of experts who are appointed through an open selection procedure. Other EFSA outputs include guidance, statements, reasoned opinions as well as scientific and technical reports (Pintado, 2014). EFSA's risk assessments are used to inform risk management decisions by EU risk managers (European Commission, Member States and European Parliament). Such decisions may entail, for example, authorisation of an ingredient for use in food or feed, the establishment or amendment of maximum legal limits or the establishment of codes of practice.

Food safety risk assessments comprise four steps: hazard identification, hazard characterisation, exposure assessment and risk characterisation. Hazard identification and hazard characterisation typically entail a review of the pertinent toxicology literature. Hazard identification entails identification of known or potential adverse health effects (e.g. carcinogenicity) that may be caused by exposure to a particular agent, whereas hazard characterisation entails a qualitative and/or quantitative evaluation of the nature of the adverse effects at different levels of exposure (e.g. using dose response studies). The third step, exposure assessment, requires data on the amount of food consumed as well as the levels and fate of the hazard in food. The last step, risk characterisation, combines data from hazard characterisation and exposure assessment to estimate a likelihood of risk associated with a given exposure. EFSA works in close collaboration with EU Member State data providers to collect data for its risk assessments, in particular for dietary exposure assessments. EFSA has collated a wealth of food consumption data as well as data on occurrence of chemical and biological hazards in food data from European data providers to support its risk assessment activities. The majority of occurrence data sent to EFSA comes from laboratories involved in national monitoring programmes and are submitted to EFSA by national competent authorities in EU Member Sates. Other data providers include the food industry (mainly via associations), universities, consumer associations and, in some cases (e.g. perchlorate), the European Commission (DG SANCO). EFSA has established several data collection networks, composed of representatives of national competent authority data providers, to support its data collection activities. In addition, when there is a scarcity of data for a particular risk assessment opinion, EFSA issues ad hoc calls for data collection through grants and/or procurements within the framework of scientific co-operation with Member States.

II – Regulatory framework

As the EU's food safety risk assessment body, EFSA's founding regulation, Regulation (EC) No. 178/2002, as amended, lays down an overarching legal obligation on EFSA to collect, collate and summarise relevant scientific and technical data to inform EU risk assessments and to work in close co-operation with all operators in the field of data collection to achieve this aim (article 33). This overarching legal framework is reinforced by sector specific EU legislation pertaining to different 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 (Regulation (EC) No. 396/2005, as amended). In practice, some 14 million analytical records from Member State data providers are sent directly to EFSA annually. EFSA is responsible for preparing an annual European summary report on pesticide residues (EFSA, 2013a) based on these data.

In area of biological hazards, Member States have a legal obligation to monitor trends and sources of zoonoses, zoonotic agents and antimicrobial resistance (AMR) and to transmit the results of monitoring programmes to the European Commission, which should be subsequently forwarded to EFSA (Directive 2003/99/EC). In 2004, the European Commission entrusted EFSA with the task of setting up an electronic reporting system and a database concerning monitoring of zoonoses (EFSA mandate No. 2004-0178[1]). Thus, in practice, data are sent directly from Member State data providers to EFSA. In 2013, detailed rules were laid down concerning harmonised monitoring and reporting of antimicrobial resistance by Member States within the framework of Directive 2003/99/EC (Commission Implementing Decision 2013/652/EU). EFSA is responsible for the compilation and publication of an annual summary report on trends and sources of zoonoses, zoonotic agents and AMR in the EU (EFSA, 2014 a, b). Under the general legal framework of EFSA's data collection activities (article 33 of EFSA's founding regulation), on request from the Commission (EFSA mandate No. 2013-0082[1]), EFSA is in the preparatory phase of establishing a European data collection on molecular typing (DNA fingerprinting) in food and feed isolates of food-borne infections to complement a database on humans (TESSy MSS) managed by the European Centre for Disease Prevention and Control (ECDC). It is envisaged that this database will facilitate epidemiological investigations of food-borne outbreaks and the identification of emerging health threats.

In the field of food additives and flavourings, sector specific legislation lays down a requirement for Member States 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 (Regulation (EC) No. 1333/2008, as amended; Regulation (EC) No. 1334/2008, as amended). A common methodology for the collection of data by Member States on the consumption and use of food additives and flavourings is not yet in place. In the case of food additives in particular, Regulation (EC) No. 257/2010 lays down a requirement for the safety of all food additives permitted for use before January 2009 to be re-evaluated by EFSA. To fulfil this obligation, EFSA collates data on food additive occurrence and usage from several stakeholders (e.g. Member State competent authorities, industry associations and consumer associations) through specific calls for data, and has evaluated the safety of some 50 food additives to date within the framework of the EU food additive re-evaluation programme.

In the area of contaminants, Commission Regulation (EC) No. 1881/2006, as amended, lays down maximum levels for several contaminants (e.g. industrial and environmental) in foodstuffs. This regulation also lays down a requirement for Member States to monitor and report findings on several contaminants such as nitrates in vegetables, aflatoxins, dioxins, dioxin-like polychlorinated biphenyls (PCBs), non-dioxin-like PCBs, ochratoxin A and fusarium toxins, to the Commission. One amendment to this regulation, (Commission Regulation (EC) No. 629/2008), lays down a requirement for Member States to report findings directly to EFSA on acrylamide and furan, respectively. In 2010, the European Commission entrusted EFSA with the task of collecting data from Member State data providers on the occurrence of contaminants in foodstuffs on a continuous basis (EFSA mandate No. 2010-0374[1] thus transferring the task of data collection on contaminants from the Commission to EFSA. Since then, EFSA has established a continuous annual call for data on contaminants in food and feed. More recently, specific Commission Recommendations have been published on acrylamide (Commission Recommendation 2010/307/EU), ergot alkaloids (Commission Recommendation 2012/154/EU), ethyl carbamate (Commission Recommendation 2010/133/EU), perfluoroalkylated substances (Commission Recommendation 2010/161/EC) and cadmium (Commission Recommendation 2014/193/EU) all of which request Member States to monitor and report occurrence data

[1]EFSA Register of Questions: http://bordeaux-as2:8080/raw-war/login [Enter mandate number from this page].

directly to EFSA. In 2013, EFSA collated some one million analytical records on contaminants in food and feed to support its risk assessment activities in the field of contaminants.

In the area of veterinary drug residues, Council Directive 96/23/EC requires Member States to adopt and implement a national residue monitoring plan for specific groups of residues. The directive lays down sampling levels and frequency as well as the group of substances to be monitored for each category of live animals or animal products. Member States must submit to the Commission, on an annual basis, national monitoring plans together with the results of monitoring for the previous year. Monitoring data are reported in aggregated format (i.e. not sample based results). In 2009, the European Commission asked EFSA for assistance in preparing an annual technical report on the results of residue monitoring in food of animal origin from Member States (EFSA mandate No. 2009-0257[1)]. In practice, the Commission provides EFSA access to the veterinary residues database managed by the Commission to analyse the results and subsequently prepare an annual technical report. Thereafter, the Commission sends to the European Parliament and the Council an annual communication on the results and actions taken at regional, national or EU level. EFSA has recently received a request from the European Commission to set up an annual European data collection on veterinary drug residues at sample based level. Given EFSA's previous experience of setting up data collections at European level, EFSA plans to run a pilot data collection as a first step. Until such time as a robust European data collection at sample based level is tested and in place, Member States will continue to send data on veterinary drug residues to the Commission.

Under the general regulatory framework of EFSA's data collection activities (article 33 of Regulation (EC) No. 178/2002, as amended), EFSA established the Comprehensive Food Consumption Database, which is a compilation of food consumption surveys at individual level from respective data providers in Member States (EFSA, 2011b; Merten *et al.*, 2011). It comprises 3.6 million food consumption records from 32 dietary surveys carried out in 22 Member States, covering infants to elderly. The database is currently the best available database of food consumption data at European level and is the primary source of food consumption data used in EFSA exposure assessments. EFSA is engaged in a collaborative project with Member States (2011-2020) to collect more harmonised food consumption data at EU level using a more standardised dietary survey methodology (EU Menu project).

III – Data management

Since its establishment, EFSA has received an increased volume of data from several data sources covering several food safety domains (i.e. pesticides, contaminants, zoonoses) rendering their manual processing unfeasible. In order to manage the high volume of data received, EFSA developed the Standard Sample Description (SSD), in collaboration with Member States, which is the EFSA standard for transmission of analytical occurrence data to EFSA. The SSD data model contains approximately 80 standardised data elements (fields) that describe the characteristics of an analytical sample and result (e.g. laboratory sample code, analytical method, limit of detection of the analytical method, country of origin etc.), of which approximately 20 are mandatory. In addition, it contains in-built controlled terminologies (e.g. standard lists of analytical methods, names of chemicals etc.) and business (validation) rules (e.g. whether data pertaining to data elements have been submitted in the required format) to guarantee a minimum level of data quality. The IT protocol to transmit data to EFSA using the SSD standard data model is described in a complementary guidance document, Guidance on Data Exchange (EFSA, 2010). Data providers transmit data through the EFSA Data Collection Framework (DCF) web-based interface providing also functionalities of automatic validation of the incoming messages. The system checks for the correct completion of mandatory fields and compliance with business rules, after which data providers receive automatic feedback. Different file formats can be used to transmit data via the DCF (i.e. Microsoft Excel®, Comma Separated Values (CSV) and Extensible Markup Language (XML)). XML is the preferred file

format to be used for the capability of providing natively an initial file validation through its XML schemas. After transmission, data are stored in an Oracle database. A further data cleaning step is carried out using standardised procedures in SAS®. During data analysis, additional data checks are performed as well as clarification requests to data providers in the case of anomalous results. Initially developed with a focus on pesticide residues and contaminant occurrence data in food and feed, the SSD has been extended (EFSA, 2013b) to encompass food additives, food contact materials, as well as sample based biological monitoring data within the framework of the zoonoses directive (Directive 2003/99/EC) and several European countries are currently testing its practical implementation as part of a pilot study (EFSA mandate No. M-2013-0254[1)]. The added value for Member State data providers is that occurrence data from several food safety domains can be reported to EFSA in a standardised format. EFSA provides financial and technical support to official reporting organisations in Member States to implement the SSD in their data management systems. Consequently, the SSD is becoming the accepted European standard for describing and reporting monitoring results for food-borne hazards. An additional benefit at national level is that Member States are accumulating a large volume of data from their national control and monitoring activities in a harmonised format. These data can also be used to support risk assessment activities at national level. In the case of pesticides, Member States have a legal obligation to report residue monitoring data from samples tested in 2013, 2014 and 2015 from the EU coordinated multiannual control programmes in SSD format to EFSA (Commission Implementing Regulation (EU) No. 788/2012).

IV – Data accessibility

Within the scientific community there is a strong shift towards the principles of 'open data' as a mechanism to improve the transparency and reproducibility of scientific research (UK Royal Society, 2012). The movement towards open data has also entered the radar of European public institutions with a general acknowledgement of the added value of re-use of public sector data to boost research and innovation (Commission Open Data Strategy for Europe, 2011) and to increase transparency in risk assessments. Although EFSA has unique access to a European hub of food consumption and food-borne hazard occurrence data, in most cases, Member State data providers maintain ownership of their data and therefore EFSA does not have an automatic right to share raw data with third parties. In the area of contaminant occurrence data in particular, rules regarding use, disclosure and re-use have been agreed with Member States at the former European Commission Standing Committee on the Food Chain and Animal Health (SCFCAH)[2], section on toxicology in the food chain (SCFCAH, 2010). These rules also encompass transmission of contaminant occurrence data for use in the joint Food and Agriculture Organisation of the United Nations (FAO)/World Health Organisation (WHO) Expert Committee on Food Additives (JECFA) risk assessments (EFSA, 2014c). In practice, requests from third parties to access or re-use raw data from EFSA's data hub data require contact with relevant data providers on a case-by-case basis to seek their agreement. In the long term, this approach is neither efficient nor aligned with EFSA's goal and stakeholders' need for more openness and transparency in EFSA's risk assessments (EFSA, 2009).

EFSA is currently developing a data warehouse which aims to provide Member State data providers, as well as EU citizens, web-based access to EU risk assessment data at different levels of aggregation using simple query and download functionality (Fig. 1).

The data warehouse needs to be supported by a policy on access to the database, e.g. who can access the data, at which level of granularity and which restrictions (if any) should be applied. Therefore, in parallel to technical developments, EFSA is engaging with the European

[2]The name of this committee has changed to Standing Committee on Plants, Animals, Food and Feed (PAFF)

Commission and Member States through respective sections of the Standing Committee on Plants, Animals, Food and Feed to seek agreement on proposed data warehouse access rules applicable to different stakeholders.

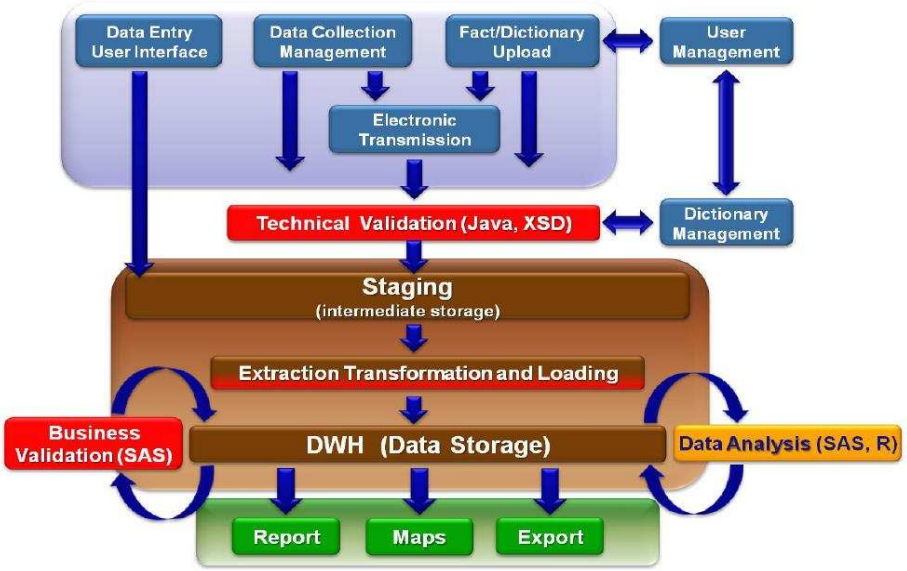

Fig. 1. Graphical depiction of the data workflow within the EFSA data warehouse (EFSA, 2011a).

Building on the EFSA data warehouse initiative, EFSA envisages continued liaison with Member State data providers and the Commission to explore and agree legitimate boundaries for more openness of risk assessment data. A greater focus on working with sister EU agencies and other international organisations to promote sharing/access to data for risk assessment purposes is also envisaged. EFSA is already collaborating with ECDC to develop joint standards for molecular typing and arthropod vector distribution, and has established a collaboration with the WHO concerning sharing of contaminant occurrence and food consumption data for use JECFA risk assessments.

Following a decade in which EFSA focused heaving on data collection, EFSA's priority in the data arena for the coming years is to further enhance data standardisation and to work with Member States to improve data accessibility of EU risk assessment data for EFSA's stakeholders.

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Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives. OJ L80, 26/03/2010, pp. 19–27.

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Commission Recommendation 2010/133/EU of 2 March 2010 on the prevention and reduction of ethyl carbamate contamination in stone fruit spirits and stone fruit marc spirits and on the monitoring of ethyl carbamate levels in these beverages. OJ L52, 03/03/2010. pp. 53-57.

Commission Recommendation 2010/161/EU of 17 March 2010 on the monitoring of perfluoroalkylated substances in food. OJ L68, 18/03/2010. pp. 22-23.

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Commission Recommendation 2014/193/EU of 4 April 2014 on the reduction of presence of cadmium in foodstuffs. OJ L104, 08/04/2014. pp. 80-81.

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