

# The EFSA Data Warehouse access rules

## European Food Safety Authority

### Abstract

The European Food Safety Authority (EFSA) is in the process of developing a Data Warehouse (DWH) that will allow the publication, analysis and distribution, in different formats and at different levels of granularity, of data collected by EFSA. These data include, among others, information on zoonoses, antimicrobial resistance, foodborne outbreaks, pesticide residues, chemical contaminants, food consumption and chemical hazards. In the EFSA DWH, data will be accessible through specific web reporting tools by means of tables, reports, graphs, maps and dashboards. In accordance with the proposed DWH access rules, EFSA staff members and nominated European Commission staff members have access to all data that are relevant to their duties at the lowest level of aggregation. Members of the EFSA Scientific Committee and Scientific Panels and their Working Groups have a similar access to data that are relevant to the specific mandate they are working with, but only until the mandate is completed. The data providers always have full access to their data. All stakeholders, including the general public, will have access to the data through pre-defined queries at the level of aggregation decided by EFSA, in agreement with the data providers and/or the data owners and the European Commission. However, some data collections, such as the Chemical Hazard Database and ad hoc data collections may apply more specific data access rules. It is recommended that these DWH access rules are applied to the DWH project to be carried out in 2015 and 2016, after which the rules may be revised if necessary.

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**Key words:** data collection, EFSA Data Warehouse, web reporting tools, access to data

**Requestor:** EFSA

**Question number:** EFSA-Q-2012-00637

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**Acknowledgements:** EFSA wishes to thank the members of the Internal Task Force for the support provided to this output: Fabrizio Abbinante, Ana Afonso, Marco Binaglia, Daniela Brocca, Stefano Cappe, Giancarlo Costa, Jean-Lou Dorne, Mari Eskola, Andrea Gervelmeyer, Diane Lefebvre, Marco Leoni, Pia Makela, Winy Messens, Ilias Papatryfon, Citlali Pintado, Claus Reunis, Pablo Romero Barrios and Giuseppe Antonio Triacchini.

**Suggested citation:** European Food Safety Authority, 2015. The EFSA Data Warehouse access rules. EFSA supporting publication 2015:EN-768. 18 pp.

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## 1. Introduction

This technical report provides general rules on access to data in the European Food Safety Authority's (EFSA) Data Warehouse (EFSA DWH). These rules define the persons and EFSA stakeholders who will have access to the data published by EFSA in its DWH, the type and format of the data they will have access to and specific restrictions that may apply in some fields of data collection.

In the EFSA DWH, the data will be accessible through web reporting tools via tables, reports, graphs, maps and dashboards. Some of the tables, reports, graphs, maps and dashboards will be static, i.e. they cannot be changed by the user, while others may be more interactive, allowing the user to see the information retrieved in different ways.

In this report the DWH access rules are first analysed at a general level and then described at a more specific level for each data collection domain.

In this report, data refer to values representing a set of qualitative or quantitative properties of items relevant in a specific domain. These properties are known and defined before the data are generated and they describe a certain level of abstraction in a domain from which information and then knowledge are derived in principle through automated summarising or methods of analysis. The data are often represented in tables, graphs or images. The results from analysis of a food sample, assessed by a competent authority, and aggregated prevalence data on zoonoses are examples of data, as these values can be further analysed and summarised through automated data analysis procedures.

This technical report takes into account the European Commission recommendation on access to and preservation of scientific information<sup>1</sup> and the digital agenda for Europe, a Europe 2020 initiative<sup>2</sup>: this European framework recommends that publicly funded research should be widely disseminated through open access publication of scientific data.

This technical report is without prejudice to rules deriving from the European Union (EU) Treaty and EU legislation. In particular, it does not address the specific legal framework in the area of openness and transparency applicable to EFSA, which currently is followed up separately. This includes the application of Regulation (EC) No 1049/2001<sup>3</sup> regarding public access to documents and Regulation (EC) No 1367/2006<sup>4</sup> on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies.

The rules proposed for access to the EFSA DWH are without prejudice to cases in which data are shared in a specific context such as a scientific opinion involving different EU scientific agencies or management of a crisis requiring sharing of data between Member States, the European Commission and EFSA.

## 2. Background and Terms of Reference as provided by EFSA

### 2.1. Background

The Risk Assessment and Scientific Assistance Directorate (RASA) in collaboration with the IT System Unit is in the process of developing an EFSA Data Warehouse (EFSA DWH) that will allow the publication, analysis and distribution, in different formats and at different level of granularity, of data collected by EFSA.

Several databases are currently maintained by EFSA which contain information which EFSA uses in its scientific outputs (e.g. opinions and reports) and more databases are expected in the coming

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<sup>1</sup> European Commission Recommendation COM(2012)401 of 17.7.2012 on access to and preservation of scientific information.

<sup>2</sup> Available online: <http://ec.europa.eu/digital-agenda/>

<sup>3</sup> Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and European Commission documents. OJ L 145, 31.5.2001, p. 43–48, applicable to EFSA.

<sup>4</sup> Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies. OJ L 264, 25.9.2006, p. 13–19.

years (e.g. the EU Menu database). The data collected, either on an annual basis (e.g. Zoonoses, Pesticides and Contaminants) or sporadically (e.g. data collections supporting urgent requests from the European Commission), will be exported, transformed and loaded<sup>5</sup> in the EFSA DWH in order to facilitate data analysis, data extraction as well as harmonisation and comparisons among the different data collected by EFSA.

EFSA's DWH will allow the publication and distribution of data in different formats (e.g. reports, maps, graphs, dashboards).

The DWH needs to be supported by a clear policy on access to the system, e.g. who can access the data, at which level of granularity and which restrictions (if any) should be applied. Finally, as data will be distributed *via* data extractions through the EFSA DWH, a clear policy on the right of publishing data distributed by EFSA, for example in scientific articles or other documents, is also needed.

In the area of contaminants in food and feed, the Standing Committee for Plants, Animals, Food and Feed and related Expert Committees approved on 19 May 2010 a paper defining the rules on use, disclosure and re-use by EFSA, Member States and European Commission of occurrence data in the area of contaminants in food and feed collected in the frame of the activities of the Standing Committee for Plants, Animals, Food and Feed<sup>6</sup>. Those rules should be taken into account in the definition of the EFSA's DWH Access Policy for data on contaminants in food and feed.

Other EU Agencies, such as the European Medicine Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), have already developed policies on access to collected data. EMA has recently adopted a "EudraVigilance Access policy for medicines for human use"<sup>7</sup> that addresses the access to data through a DWH and ECDC has recently adopted its annual revision of the "ECDC Data Access Policy"<sup>8</sup> that addresses the access to "raw" data as submitted to the Agency by the data providers (usually Member States), where data is usually not summarised, modified or manipulated by the Agency.

## 2.2. Terms of Reference

The BIOMO Unit (as of 1 January 2014, the DATA unit) is asked to set up an internal Task Force composed of representatives from BIOMO, DCM, PRAS, SAS, BIOHAZ, CONTAM and LRA units to develop a DWH Access Policy for EFSA. Additional EFSA's units have been involved during the work of the Task Force i.e. AHAW, GMO and PLH. This Task Force should:

- define the groups of stakeholders that will have access to the EFSA's DWH;
- for each type of stakeholder and for each type of collected data, define the rules on the access, use, distribution and publication of data using EFSA's DWH.
- In doing so the Task Force should:
  - review the approach taken by other EU Agencies;
  - investigate the presence of existing rules or agreements between EFSA and Data Providers (e.g. memorandum of understanding, contracts and service level agreements);
- after having consulted the concerned data collection networks of EFSA and other relevant stakeholders, produce a technical report on EFSA's DWH Access Policy on access, use, distribution and publication of data using EFSA's DWH.

This technical report will contribute to a more general EFSA Data Access Policy that will be produced at a later stage under another mandate.

<sup>5</sup> The process of exporting, transforming (i.e. modifying, correcting, normalising) and loading data in a DWH is generally referenced to as "E.T.L. process".

<sup>6</sup> SANCO—D1(2011)D/293964—Annex to Report (agenda Item 3)—Occurrence data collection in the area of contaminants in food and feed Collected in the frame of the activities of the Standing Committee on the Food Chain and Animal Health and related Expert Committees: *Rules on use, disclosure and re-use of these data*.

<sup>7</sup> Available online: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Other/2011/07/WC500108538.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/07/WC500108538.pdf)

<sup>8</sup> Available online: <http://ecdc.europa.eu/en/activities/surveillance/tessy/documents/tessy-policy-data-submission-access-and-use-of-data-within-tessy-2011%20revision.pdf>

### 3. The EFSA Data Warehouse scope

#### 3.1. Data collections at EFSA

Collection of data is one of the missions assigned to EFSA by its founding regulation, Regulation (EC) No 178/2002<sup>9</sup>. According to Article 33 of this regulation, EFSA shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve, in particular, the collection of data relating to:

- food consumption and the exposure of consumers to risks related to the consumption of food;
- the incidence and prevalence of biological risk;
- contaminants in food and feed;
- residues.

In addition, within the framework of some sectorial EU legislation, EFSA has been assigned specific tasks on data collection:

- Directive 2003/99/EC<sup>10</sup>, whereby EFSA has been assigned the task by the European Commission of examining data submitted annually by the EU Member States on zoonoses, zoonotic agents, animal population, foodborne outbreaks and antimicrobial resistance. Based on these data, EFSA prepares, each year, EU Summary Reports in close collaboration with the ECDC.
- Regulation (EC) No 396/2005<sup>11</sup> requires EFSA to collate and analyse the results of national controls on pesticide residues in food and feed. EFSA also draws up an annual report on pesticide residues. In addition to the general provisions on national monitoring programmes, the details of the EU-coordinated monitoring programmes for each monitoring year are established in a European Commission regulation that is published every year<sup>12</sup>.

EFSA's data collection activities are described in detail in the EFSA report 'Data Collection: Future Directions', which was published in 2010 and is available on EFSA's website (EFSA, 2010a).

Currently, EFSA's data collection activities are divided into two main categories:

- annual collection of EU data required by EU legislation;
- ad hoc data collections based on specific needs.

#### 3.2. Ownership and trusteeship of data

It is relevant to note that, for most of the data collections, the ownership of the data lies with the data provider (which is often a Member State's competent authority or in some cases regional authorities<sup>13</sup>) or with the third party mandating the data provider, thus not with EFSA.

The situation may be different with regard to "ad hoc" data collections resulting from public procurement contracts or grant agreements of EFSA, whereby ownership of the data by EFSA is governed by the provisions of the relevant contract. However, exceptions at contract level are also frequent. For instance, the bilateral collaboration agreements EFSA has concluded with EU Member

<sup>9</sup> 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, 1.2.2002, p. 1–24, as last amended.

<sup>10</sup> 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, 12.12.2003, p. 31–40, as last amended.

<sup>11</sup> 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, 16.3.2005, p. 1–16, as last amended.

<sup>12</sup> The list of the EU pesticide residue control programmes regulations can be found at: [http://ec.europa.eu/food/plant/pesticides/max\\_residue\\_levels/eu\\_multi-annual\\_control\\_programme\\_en.htm](http://ec.europa.eu/food/plant/pesticides/max_residue_levels/eu_multi-annual_control_programme_en.htm)

<sup>13</sup> This is the case in, for example, Germany, where the owners of the data are the Federal States (Länder) and not the Federal Republic of Germany, and also in Spain.

States' organisations for the collection of data related to the EFSA Comprehensive European Food Consumption Database (EFSA, 2011) confirm the data providers' ownership of the raw data and define specific user rights for EFSA in relation to the data. In the context of Article 36<sup>14</sup> on grants of EFSA, the ownership of data in principle lies with the grant holder<sup>15</sup>.

As an inherent part of the DWH project, EFSA shall be vested with trusteeship for all the activities related to the data management with regard to the access rules provided in the present rules, in the first place in order to fulfil its mandate on scientific risk assessment pursuant to EFSA's founding regulation, Regulation (EC) No 178/2002, and sectorial EU food safety legislation. In particular, EFSA is accountable for administering in the DWH the data collections it maintains pursuant to its founding regulation and EU sectorial food and feed legislation. This accountability is based on the principles of loyalty, due care and diligence and proceeds in the best interests of the data providers and/or data owners, keeping them informed. For managing the data collections, trusteeship entails the storage and retention of the scientific data at the lowest level of granularity in the DWH and their further analysis, validation, clearing and correcting in agreement with the data providers, as outlined in the validation reports that are sent to the data providers. Some sectorial EU legislation, such as that on monitoring of zoonoses and pesticide residues, includes an obligation to publish summarised data. Such aggregated data, currently presented in annual EU summary published reports, will be publicly available through the DWH.

With regard to aggregated data rendered public in accordance with the current EFSA DWH rules, it is the responsibility of the users accessing available datasets to respect any applicable proprietary rule, including copyright, as is already the case for data available on EFSA's website<sup>16</sup>. Appropriate legal notices explaining user responsibilities will be integrated in the DWH system, and EFSA will remain at all times in charge of handling any queries in this regard.

### 3.3. The EFSA Data Warehouse and web reporting tools

Data collected on an annual or ad hoc basis via the Data Collection Framework (DCF) or the Zoonoses Web Reporting Application will be exported, transformed and loaded (ETL) into the EFSA DWH in order to facilitate data analysis and data extraction as well as harmonisation and comparisons among the different data collected by EFSA.

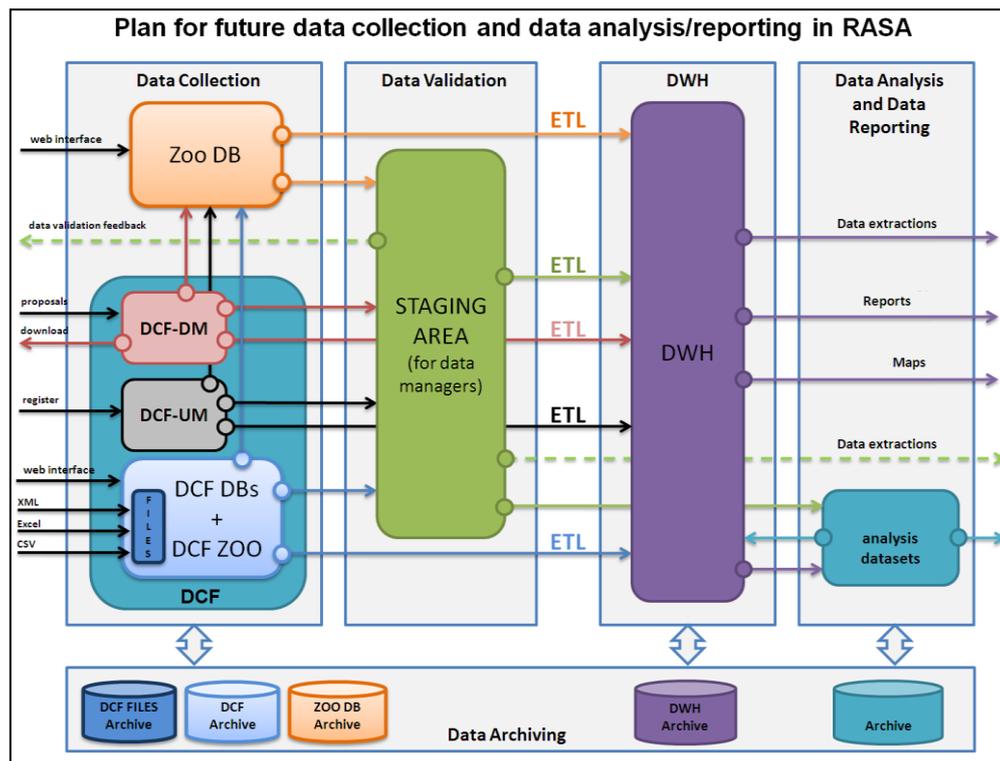
Figure 1 shows the flow of data collected by EFSA: starting from its data collection layer, and through the DWH layer, data are extracted and presented in the data analysis and data reporting layer to external and internal stakeholders by means of tables, reports, graphs, maps and dashboards. The figure represents all data collection and data analysis systems currently under development in EFSA, which include the following main information technology (IT) modules:

- the EFSA DCF, including its User Management Module (DCF-UM) and its Dictionaries Management Module (DCF-DM);
- the Zoonoses Database and its Web Interface (Zoo DB);
- the EFSA DWH and its ETL procedures;
- EFSA's business intelligence tools and geographical information systems.

<sup>14</sup> Article 36 of EFSA's Founding Regulation (EC) No 178/2002 promoting the European networking of organisations operating in the fields within the Authority's mission. Available online: <http://www.efsa.europa.eu/en/networks/art36.htm>

<sup>15</sup> In the present document, the term "*data providers and/or data owners*" is meant to cover all possible situations, including cases in which the Member States are either both data providers and data owners or only data owners.

<sup>16</sup> Available online: <http://www.efsa.europa.eu/en/legalnotice.htm>



**Figure 1:** Planned “data collection and data analysis systems” currently under development in EFSA

At the moment, data collected by EFSA cover the following fields:

- zoonoses, microbiological contaminants, animal population, antimicrobial resistance and foodborne outbreaks;
- chemical contaminants;
- pesticide residues;
- food consumption;
- chemical Hazard Database; and
- ad hoc data collections derived from:
  - procurements and Article 36<sup>17</sup> Grant calls;
  - ad hoc data collections to address specific mandates.

Some of the data collected and validated by EFSA in collaboration with the data providers will be moved into the EFSA DWH through a staging area, where, if needed, data cleaning, data normalisation and data harmonisation will be implemented.

A pilot DWH project is to be carried out in 2015 in the area of food consumption and chemical occurrence. After the pilot stage, the DWH will cover all the data domains listed above. In the case of ad hoc data collections, a decision whether or not to include them in the DWH will be made on a case-by-case basis taking into account contractual considerations.

<sup>17</sup> See footnote 19

### 3.4. Availability of the data in the Data Warehouse

The data stored in the EFSA DWH will be made available to different EFSA stakeholders defined in section 4 by means of simple data extraction and advanced reporting tools (e.g. business intelligence tools) and advanced geographical information systems.

In accordance with specific needs linked to different data collections, data stored in the EFSA DWH will be in one or several of the following formats:

- 1) a copy of the collected data (i.e. the entire set or a subset of the data);
- 2) a copy of the collected data integrated with additional information calculated and/or derived by EFSA;
- 3) an aggregated version of the collected data;
- 4) an aggregated version of the collected data with additional information calculated and/or derived by EFSA.

Independently from their formats, data moved and present in the DWH will be available and accessible to EFSA's stakeholders, as defined in section 4.

In most cases, when data are submitted to EFSA, they do not become automatically available in the DWH. Different data collections have set up different data validation processes that are carried out after data submission and which should include sending the data providers a validation report on the submitted data. For this reason, each data collection defines a specific time-point at which data become available in the DWH. This moment has to be clearly stated in the data collection documentation and the relevant stakeholders need to be informed. Data can be queried in the DWH only from this moment onwards.

## 4. The EFSA Data Warehouse stakeholder groups

A number of EFSA's stakeholders either need access to the data available in the EFSA DWH or are interested in having such access. These stakeholders include:

- 1) the European Commission (EC), particularly the relevant services in the Directorate General for Health and Food Safety (DG SANTE) that deal with food and feed safety, nutrition linked to food legislation, and animal and plant health;
- 2) the ECDC, the EMA, the European Chemicals Agency (ECHA) and other EU agencies;
- 3) members of EFSA's Scientific Committee and Scientific Panels and their Working Groups;
- 4) the providers of the data collected by EFSA, defined as:
  - a) the competent authorities that are assigned in the relevant EU legislation on data collection to provide the data,
  - b) EFSA's contractors and grant beneficiaries in the case of contracts and grants on data collection, or
  - c) any other organisation providing data to EFSA, e.g. food industry, institutes, academia;
- 5) Member States' and other countries'<sup>18</sup> national competent authorities for food and feed safety and for animal and plant health;
- 6) members of EFSA's Advisory Forum;
- 7) scientists and risk assessors in research organisations and universities;
- 8) international organisations such as the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization of the United Nations (FAO);
- 9) competent authorities and institutes in countries outside the EU;

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<sup>18</sup> Two European Free Trade Association countries (Iceland and Norway) with which EFSA has agreements and pre-accession countries.

- 10) non-governmental organisations in the field of food and feed safety, animal health and welfare and plant health;
- 11) food and feed industry and trade organisations and other legal entities;
- 12) members of the general public.

In addition, EFSA scientific staff members need access to the data related to their work.

Depending on the level of access, some of the abovementioned stakeholders will need to be registered in EFSA's IT system, while others will have an access to the DWH through EFSA's public website without the need for login and password details.

## 5. General rules for accessing data via the EFSA Data Warehouse

The general rules for accessing data stored in the EFSA DWH apply to the access provided automatically and proactively by EFSA to the relevant stakeholders through the DWH.

These present rules do not apply to the access to the data granted upon specific requests sent to EFSA and are without prejudice to Regulation (EC) No 1049/2001 on public access to documents.

As a general principle, the lowest level of aggregation of data for each variable (i.e. granularity) is defined by EFSA in agreement with the data providers, and/or, the data owners and the European Commission. Access to data will be provided through pre-defined queries prepared by EFSA.

The general rules for access to data stored in the EFSA DWH are defined as follows:

- 1) EFSA staff members and nominated staff members in the relevant units of DG SANTE in the European Commission have access to:
  - all data stored in the DWH needed for carrying out their duties, at the lowest level of aggregation included in the DWH.
- 2) Members of EFSA's Scientific Committee and Scientific Panels and their Working Groups have access<sup>19</sup> to:
  - all data of scientific importance stored in the DWH that are relevant to the specific mandate addressed to the Committee, Panel or Working Group at the lowest level of aggregation included in the DWH.

This access applies only for the time needed to complete the specific mandate.
- 3) Data providers<sup>20</sup> have access to:
  - the data provided by their own organisation at the lowest level of aggregation included in the DWH.

After the publication of EFSA's scientific or technical outputs reporting the data, the data providers have in addition the general access defined in Rule 4, below.
- 4) All stakeholders defined in section 4 - the EFSA DWH stakeholder groups, including the general public<sup>21</sup> - after the publication of EFSA's scientific or technical outputs reporting the data have access to:

<sup>19</sup> Access to EFSA's Scientific Committee and the Scientific Panels and their Working Groups will be initially managed manually by EFSA. This because a central "users management system in EFSA" has to be implemented and integrated in the DWH in order to allow the precise control of access for members of EFSA's Scientific Committee and the Scientific Panels and their Working Groups.

<sup>20</sup> Currently all data transmitted to EFSA are recorded at *data provider* level only. In the future, *data owners* could also be granted automatic access to their data from the Data Warehouse. The implementation of this requirement implies changes to the way data in which are submitted to EFSA. Firstly, all interested "data owner organisations", including their users, have to be registered with EFSA and this "data owners database" has to be maintained over time. Secondly, when transmitting the data, *data providers* will have to indicate for each data row who is the *data owner*. This will result in additional work for the *data providers*. The *data owners* will be able to access only the data for which they have been indicated as *data owner*. The access for *data owners* will exclude all historical data, up to the moment the *data owner identification* is reported to EFSA. In the meantime, provision of data to the data owners will be handled by EFSA manually and only when the owned data can be clearly identified.

<sup>21</sup> Any person using EFSA's website.

- the data presented in EFSA’s scientific or technical outputs, through pre-defined queries prepared by EFSA and at the level of aggregation decided by EFSA in agreement with the data providers, and/or the data owners and the European Commission<sup>22</sup>.

When appropriate, a disclaimer is added in the pre-defined queries warning about the possible misinterpretation of the data.

## 6. Specific rules for accessing data via the EFSA Data Warehouse

The general rules defined in section 5 are adopted or modified to serve the needs of each specific data collection, as specified in the following paragraphs.

Specific data access rules that are to be applied to specific data collection fields are detailed in the sub-points below and prevail, if different, over the general rules outlined in section 5 in accordance with the principle of prevalence of *lex specialis*<sup>23</sup>.

The rules reported in the following paragraphs have been agreed after consulting the European Commission (DG SANTE), the EFSA Networks concerned (Zoonoses, Pesticides, Food Consumption, Chemical Occurrence) and the concerned Standing Committee for Plants, Animals, Food and Feed sections (Biological Safety of the Food Chain, Toxicological Safety of the Food Chain, Phytopharmaceuticals Pesticides Residues).

### 6.1. Zoonoses Data Collection

#### 6.1.1. Background

Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents obliges the EU Member States to monitor and report annually EU-level data on zoonoses and zoonotic agents in animals, food and feed, on foodborne outbreaks and on antimicrobial resistance in zoonotic bacteria from animals and food. EFSA and the European Commission have agreed that the results of the monitoring of zoonoses and zoonotic agents will be submitted only to EFSA and that the results collected by EFSA would be accessible to the European Commission services. EFSA runs a web-based reporting application and DCF data submission systems for this data collection. The national reports submitted to EFSA shall be made publicly available. These national reports are published each year on EFSA’s website and all the data reported are also summarised and published as an annex (level 3 tables) to the EU Summary Reports.

The Directive also assigns to EFSA the task of analysing the data submitted by the Member States and publishing an EU Summary Report on the results. Currently EFSA publishes, in collaboration with ECDC, two EU Summary Reports each year, one on zoonoses and foodborne outbreaks and one on antimicrobial resistance.

EFSA is also requested by the European Commission to analyse EU-wide baseline surveys on zoonotic agents in food or animals. So far, the results from seven baseline surveys have been analysed and the results have been published in EFSA scientific reports.

#### 6.1.2. Proposal

For the data from the annual reporting of zoonoses, zoonotic agents, animal populations, foodborne outbreaks and antimicrobial resistance, the general rules specified in section 5 are applicable. The level of aggregation referred to in Rule 4 corresponds to that of the EU Annual Zoonoses Summary Reports.

These general rules also apply to the data from the EU-wide baseline surveys.

The Standing Committee for Plants, Animals, Food and Feed’s Biological Safety of the Food Chain section has been consulted on the proposal.

The proposed rules are summarised in Appendix 1.

<sup>22</sup> In the case of Rule 4, protection of commercially sensitive data and personal data is always guaranteed, as specified in section 8.

<sup>23</sup> *Lex specialis derogat (legi) generali.*

## 6.2. Pesticides Data Collection

### 6.2.1. Background

Pesticide monitoring data are collected by EFSA on an annual basis, as requested in Regulation (EC) No 396/2005. Data are collated and reported to EFSA by the Member States and two European Free Trade Association (EFTA) countries (Iceland and Norway). On the basis of these results, EFSA draws up the Annual Report on Pesticide Residues.

According to the above regulation, the reporting countries shall submit the results of the pesticide monitoring programmes to EFSA, the European Commission and the other Member States. EFSA and the European Commission have agreed that the results of the national pesticide control activities will be submitted only to EFSA and that the data collected by EFSA will be accessible to the European Commission services at any time.

So far, the data provided by a single Member State and stored in the EFSA DCF have not been available to other Member States, as an agreement on the data use, sharing and disclosure policy specific for the pesticide residue area has not yet been discussed and agreed among EFSA, the European Commission and the Member States.

### 6.2.2. Proposal

It is proposed that the general rules specified in section 5 are applicable to pesticide data. The level of aggregation referred to in Rule 4 corresponds to that of the Annual Summary Report on Pesticide Residues.

The Standing Committee for Plants, Animals, Food and Feed's Pesticides Residues section has been consulted on the proposal.

The proposed rules are summarised in Appendix 1.

## 6.3. Chemical Contaminants Data Collections

### 6.3.1. Background

Until 2010, in the area of contaminants in food and feed, EFSA received ad hoc mandates from the European Commission to perform data collection and risk assessments on specific substances depending on the European Commission's needs. In 2010, after the successful definition of the standard sample description (EFSA, 2010b), the EFSA standard for receipt of occurrence data, the European Commission issued a mandate to collect on a continuous basis all available data on the occurrence of chemical contaminants in food and feed (M-2010-0374). In particular, the European Commission summarises the scope of the continuous data collection by referring to previous mandates and indicating additional substances. For this reason, as of reporting year 2011, contaminant data are collected in a continuous manner through yearly transmission of the required substances.

The general rules regarding the use, disclosure and re-use of contaminant occurrence data from Member State competent authorities, including the provision of Member State contaminants data through EFSA to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and other relevant inter-governmental bodies, were discussed and agreed by the Standing Committee for Plants, Animals, Food and Feed on 19 May 2010<sup>24</sup>, and are still applicable.

The following proposed DWH access rules apply to contaminant data proactively published by EFSA in the DWH from all data providers.

### 6.3.2. Proposal

For contaminant data, either coming from *ad hoc* calls or the annual data collection, it is proposed to apply the general rules specified in section 5. The level of aggregation referred to in Rule 4 corresponds to that of the published EFSA outputs.

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<sup>24</sup> Formerly Standing Committee on the Food Chain and Animal Health.

The Standing Committee for Plants, Animals, Food and Feed's Toxicological Safety section has been consulted on the proposal.

The proposed rules are summarised in Appendix 1.

## **6.4. Food Consumption Databases**

### **6.4.1. Background**

Since 2008, the EFSA Comprehensive European Food Consumption Database (EFSA, 2011) (hereafter Comprehensive Database) has been built from existing national information on food consumption at a detailed level. Competent organisations from each Member State provide EFSA with data from the most recent national dietary survey in their country for different age classes (from infants to adults aged 75 years or older), at the level of individual consumption. It currently includes food consumption data for a total of 32 different dietary surveys carried out in 22 Member States. It is envisaged that data from new surveys will be added at the beginning of 2015.

An agreement between EFSA and the national data providers defines the conditions of use of these data. EFSA has the right to use the raw, individual food consumption data for carrying out risk assessments and other scientific analyses within the activities related to EFSA's mandate, and authorisation from the data provider must be requested for any other use of the data. Consequently, individual food consumption data are stored by EFSA. Only summary statistics from the Comprehensive Database are made available to the public on EFSA's website.

### **6.4.2. Proposal**

To comply with the access limitations stated in the procurement contracts for the food consumption data and reported in the paragraph above, it is suggested that the following access rules be adopted for this type of data: access to the most detailed level of information is allowed only to EFSA staff members and to data providers. The European Commission will have access to summary data. In all other cases, access should be provided only to statistics performed at a level of detail equal to or more aggregated than the summary food consumption statistics currently available on EFSA's website (EFSA, 2011). Further consultation with data providers may be performed by EFSA in due course to verify the possibility of amending the proposed rules in order to align them with the access rules proposed in section 5.

The proposed rules are summarised in Appendix 1.

## **6.5. Chemical Hazards Database**

### **6.5.1. Background**

The Chemical Hazards Database contains information and data that are already available in the public domain on EFSA's website within EFSA opinions. Such information has been previously validated and adopted by EFSA Panels and should therefore be made available to all stakeholders through the EFSA DWH.

### **6.5.2. Proposal**

It is therefore proposed to extend the general rules specified in section 5 and make available to all stakeholders the information available in the Chemical Hazards Database through the EFSA DWH with no limitations or restrictions.

The proposed rules are summarised in Appendix 1.

## 6.6. Ad hoc data collections derived from procurement, grants or specific mandates

### 6.6.1. Background

Ad hoc data collections are performed to answer specific mandates within the remit of EFSA's mission in accordance with Article 33 of Regulation (EC) No 178/2002. Specific legislative provisions for the mandatory provision of data exist when the question concerns an urgent matter of public health or an emerging risk (Article 34 of Regulation (EC) No 178/2002).

Ad hoc data collection activities may be performed by EFSA or by other organisations on its behalf when requested as part of contracts or grants awarded by EFSA.

In most situations, the conditions of data calls are agreed on terms that are specific to each call, and there are no general rules on use, disclosure and re-use of data. The terms of data calls often specify the objectives of the calls and the intended use of data. Access to data from other data providers may be granted when it is specified in the terms, but this provision is not always included.

### 6.6.2. Proposal

It is proposed that inclusion of data derived from ad hoc data collections in the DWH will be decided on a case-by-case basis, taking into account EFSA's openness and transparency policies. Nevertheless, unless otherwise agreed between EFSA and the relevant data provider, Rule 1 of the general rules will apply, i.e. EFSA and the European Commission should access all data stored in the DWH needed for carrying out their duties, at the lowest level of aggregation included in the DWH.

## 7. General rules for future data collections migrated into the EFSA Data Warehouse

For future data collections, e.g. Molecular Typing or Veterinary Drug Residues, to be implemented by EFSA and migrated into the EFSA DWH, the generic rules proposed in this guideline should be used as a basis for discussion and, if possible, applied.

In the case of specific needs, more open or restricted rules could be applied in agreement with the concerned stakeholders, especially the data providers and/or the data owners and the European Commission. It is recommended that the access rules are agreed and specified during the initial phase of setting up the data collection, e.g. the call for data, procurement or grant.

## 8. Protection of commercially sensitive data and personal data in the case of public access

The EFSA DWH may contain commercially sensitive raw data or data protected by intellectual property rights<sup>25</sup>. Under all circumstances EFSA bears the responsibility for ensuring that these datasets are not publicly disclosed in the context of the EFSA DWH and that they are aggregated in full respect of existing commercial interests and/or intellectual property rights.

Exceptionally, at its lowest level of granularity, the EFSA DWH may contain data from which individuals may be directly or indirectly identifiable in the sense of Article 2(a) of Regulation (EC) No 45/2001<sup>26</sup> on personal data protection applicable to EFSA. Prior to rendering datasets public, EFSA shall aggregate and filter them in order to ensure that they are properly anonymised<sup>27</sup> in compliance with the aforementioned regulation. EFSA bears, under all circumstances, full responsibility for complying with personal data protection rules with regard to the datasets contained in the EFSA DWH.

<sup>25</sup> As an example, chemical contaminant data originating from private enterprises and food consumption data collection.

<sup>26</sup> Regulation (EC) No 45/2001 of the European Parliament and the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data. OJ L 8, 12.1.2001, p. 1–22.

<sup>27</sup> Any parts of data collections qualified as personal data in the sense of Article 2(a) Regulation (EC) No 45/2001 will be agreed in consultation with data providers and/or data owners. Once established, these shall consistently be cleared in all data collections before they become publicly available in the DWH.

## 9. Use and distribution of data retrieved from the EFSA Data Warehouse

Data retrieved from the EFSA DWH in accordance with the general rules provided in this report, or, if different, in accordance with the specific rules applicable to the concerned data collection area, can be accessed and distributed as follows:

1. EFSA staff members and nominated staff members in the relevant units of DG SANTE in the European Commission can use, share and distribute among themselves and with Member States for risk management purposes within the frame of the Standing Committee for Plants, Animals, Food and Feed data retrieved from DWH at the lowest level of aggregation included in the DWH, unless otherwise agreed between EFSA and the data providers.
2. Members of the EFSA Scientific Committee and Scientific Panels and their Working Groups and members of EFSA Working Groups can use the data retrieved from DWH that are relevant to the specific mandate addressed to the Panel or Working Group at the lowest level of aggregation only to address the specific mandate in question and only for the time needed to complete the specific mandate. They are not allowed to use and distribute the data for any purpose other than the one set in the mandate. The data can be shared and distributed only among the members of the Committee, Panel or Working Group.
3. Before the publication of EFSA's scientific or technical outputs, data providers can use, share and distribute data retrieved from the EFSA DWH that have originated from their own organisation<sup>28</sup>.
4. All stakeholders defined in paragraph 2, including the general public, can use and distribute data to which they have access in the EFSA DWH at the level of aggregation included in the DWH. If distributed further or included in a publication, they shall always make reference to the origin of the data, in this case to the EFSA DWH.

## Recommendations

As regards the implementation of the DWH access rules outlined in this report:

- It is recommended that the presented access rules are applied to the EFSA DWH project that is to be carried out in 2015 and 2016<sup>29</sup>, after which the rules may be revised in the light of the experience collected and in agreement with the data providers and/or the data owners and the European Commission.
- It is recommended that for future ad hoc data collections, in which the data is intended to be moved into the EFSA DWH, the access rules are agreed and specified during the initial phase of the data collection set up, e.g. call for data, procurement or grant.

## References

- EFSA (European Food Safety Authority), 2010a. EFSA Report on Data Collection: Future Directions. EFSA Journal 2010; 8(5):1533, 35 pp. doi:10.2903/j.efsa.2010.1533.
- EFSA (European Food Safety Authority), 2010b. Standard sample description for food and feed. EFSA Journal 2010;8(1):1457, 54 pp. doi:10.2903/j.efsa.2010.1457.
- EFSA (European Food Safety Authority), 2011. Use of the EFSA Comprehensive European Food Consumption Database in Exposure Assessment. EFSA Journal 2011;9(3):2097, 34 pp. doi:10.2903/j.efsa.2011.2097.

<sup>28</sup> This also applies to the national reporting officers and the members of the Network for Zoonoses Monitoring Data with regard to reporting on zoonoses, foodborne outbreaks and antimicrobial resistance in accordance with Directive 2003/99/EC and as regards the data submitted by their country.

<sup>29</sup> At the beginning of 2015, EFSA plans to run a pilot, along with some volunteer Member States, in the area of Food Consumption and Chemical Occurrence. As of July 2015, EFSA plans to extend the use of the DWH to the Zoonoses Data Collection, the Pesticides Residues Data Collection and, in 2016, to the Chemical Hazard Database.

## Abbreviations

DCF	Data Collection Framework
DG SANTE	Directorate General for Health and Food Safety
DWH	Data Warehouse
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMA	European Medicines Agency
ETL	extract, transform and load process
FAO	Food and Agriculture Organization of the United Nations
JECFA	Joint FAO/WHO Expert Committee on Food Additives
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
WHO	World Health Organization

## Appendix A – Summary of proposed access rules

### Zoonoses Data Collection

	<b>Stakeholder Group 1</b> <b>EFSA + EC</b>	<b>Stakeholder Group 2</b> <b>EFSA Scientific Committee/Panels/WGs</b>	<b>Stakeholder Group 3</b> <b>Data provider</b>	<b>Stakeholder Group 4</b> <b>All</b>
Zoonoses Data Collection (including AMR) – before the publication of the Zoonoses Annual Reports	Full access	Raw data access limited by the Scientific Committee/Panel/WG mandate in agreement with EC (DG SANTE) <sup>30</sup>	Raw data access to provided data	No access
Zoonoses Data Collection (including AMR) – after the publication of the Zoonoses Annual Reports	Full access	Raw data access limited by the Scientific Committee/Panel/WG mandate in agreement with EC (DG SANTE) <sup>28</sup>  + Access to the level of aggregation defined in the Zoonoses Annual Report	Raw data access to provided data  + Access to data at the level of aggregation defined in the Zoonoses Annual Report	Access to data at the level of aggregation defined in the Zoonoses Annual Report

### Pesticide Data Collection

	<b>Stakeholder Group 1</b> <b>EFSA + EC</b>	<b>Stakeholder Group 2</b> <b>EFSA Scientific Committee/Panels/WGs</b>	<b>Stakeholder Group 3</b> <b>Data provider</b>	<b>Stakeholder Group 4</b> <b>All</b>
Pesticides Data Collection – before the publication of the Annual Report on Pesticides residues	Full access	Raw data access limited by the Scientific Committee/Panel/WG mandate in agreement with EC (DG SANTE) <sup>28</sup>	Raw data access to provided data	No access
Pesticides Data Collection – after the publication of the Annual Report on Pesticides residues	Full access	Raw data access limited by the Scientific Committee/Panel/WG mandate in agreement with EC (DG SANTE) <sup>28</sup>  + Access to the level of aggregation defined in the Annual Report on Pesticide Residues	Raw data access to provided data  + Access to data at the level of aggregation defined in the Annual Report on Pesticide Residues	Access to data at the level of aggregation defined in the Annual Report on Pesticide Residues

<sup>30</sup> Access to EFSA's Scientific Committee and Scientific Panels and their WGs will be initially managed manually by EFSA. This because a central "users management system in EFSA" has to be implemented and integrated in the DWH in order to allow a precise control of access for members of EFSA's Scientific Committee and Scientific Panels and their WGs.

## Chemical Contaminants Data Collections

	<b>Stakeholder Group 1</b>	<b>Stakeholder Group 2</b>	<b>Stakeholder Group 3</b>	<b>Stakeholder Group 4</b>
	<b>EFSA + EC</b>	<b>EFSA Scientific Committee/Panels/WGs</b>	<b>Data provider</b>	<b>All</b>
Chemical Contaminants Data Collections – before the publication of the EFSA output(s)	Full access	Raw data access limited by the Scientific Committee/Panel/WG mandate <sup>28</sup>	Raw access to provided data	No access
Chemical Contaminants Data Collections – after the publication of the EFSA output(s)	Full access	Not applicable(*)	Raw access to provided data	
		(*) <i>Mandate is closed and EFSA output published</i>	+ Access to data at the level of aggregation as defined in the published EFSA output(s)	Access to data at the level of aggregation as defined in the published EFSA output(s)

## Food Consumption Database

	<b>Stakeholder Group 1</b>	<b>Stakeholder Group 2</b>	<b>Stakeholder Group 3</b>	<b>Stakeholder Group 4</b>
	<b>EFSA + EC</b>	<b>EFSA Scientific Committee/Panels/WGs</b>	<b>Data provider</b>	<b>All</b>
Food Consumption Database	Full access for EFSA		Raw access to provided data	
	Access to summary data for EC	Access limited to the level of aggregation defined in the EFSA Comprehensive European Food Consumption Database in Exposure Assessment	+ Access limited to the level of aggregation defined in the EFSA Comprehensive European Food Consumption Database in Exposure Assessment	Access limited to the level of aggregation defined in the EFSA Comprehensive European Food Consumption Database in Exposure Assessment

## Chemical Hazards Database

	<b>Stakeholder Group 1</b>	<b>Stakeholder Group 2</b>	<b>Stakeholder Group 3</b>	<b>Stakeholder Group 4</b>
	<b>EFSA + EC</b>	<b>EFSA Scientific Committee/Panels/WGs</b>	<b>Data provider</b>	<b>All</b>
Chemical Hazard Database	Full access	Full access	Not applicable <sup>(a)</sup>	Full access

(a): There is no data provider.