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European Food Safety Authority

Report on data collection

COVER NOTE

EFSA's Founding Regulation and other specific Community legislation, such as that related to zoonoses (Directive 2003/99/EC) and pesticide residues in food and feed (Regulation (EC) No 396/2005), mandate EFSA to coordinate the collection of data in relation to food and feed safety including nutrition, zoonotic organisms, chemical contaminants and residues, animal health and welfare, and plant health. This Regulation foresees that EFSA shall forward the results of its work in the field of data collection to the European Parliament, the Commission and the Member States.

Since its establishment in 2002, EFSA has built its data collection activities in cooperation with Member States, European institutions and other EU agencies. The outcomes of these activities have published in a series of reports, some annual and some *ad hoc*. The attached report provides an overview of these activities. It was sent to the European Parliament and made available to all stakeholders and interested parties.

It is noted that in a recent report the work done in the EU microbiological area by EFSA with the Member States for the European Commission has been recognised by US experts as a model to be considered in the USA (Building the Science Foundation of a Modern Food Safety System).

The review concerns data collection activities explicitly foreseen under Article 33 i.e. on food consumption, incidence and prevalence of biological risk, contaminants and residues in food and feed. The report covers the progress made on data collection networking with the Member States' competent organisations, the harmonisation and data reporting activities. It also makes proposals for further development.

The document is submitted to the Management Board for their information.

European Food Safety Authority

Technical Report of EFSA

EFSA Report on Data Collection: Future Directions[a]

European Food Safety Authority[b, c]

European Food Safety Authority (EFSA), Parma, Italy

EXECUTIVE SUMMARY

The European Food Safety Authority (EFSA) was established in 2002 by Regulation (EC) No 178/2002[d] of the European Parliament and of the Council as the European Union's independent risk assessment body for food and feed safety. It has a dual mandate: the provision of scientific advice and technical information to support the European Commission, the European Parliament and Member States in developing measures to protect consumers; and, in cooperation with Member States and the Commission, communicating on risks in the food and feed chain in a clear and coherent manner to a wide audience of interested parties including the general public. EFSA's evaluation of claims, substances and products is also a crucial part of the European system that enables access to the European market.

EFSA's Founding Regulation [d] and other specific Community legislation, such as that related to zoonoses (Directive 2003/99/EC[e]) and pesticide residues in food and feed (Regulation (EC) No 396/2005[f]), assign EFSA's data collection mandate in relation to food and feed safety including nutrition, zoonotic organisms, chemical contaminants and residues, animal health and welfare, and plant health. The Authority is also tasked with providing recommendations to the Member States and the Commission on how to improve the technical comparability of the data it receives and analyses. Furthermore, it stipulates that EFSA should work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries and international bodies, to exercise its mandate.

The process of risk assessment comprises four distinct but closely linked activities: hazard identification; hazard characterisation; exposure assessment; and risk characterisation. The third of these – exposure assessment – requires that the exposure of the consumer to a hazard must be ascertained. In relation to human diet, this requires information on the concentration of the hazardous substance in the food combined with data on the quantity of the food consumed. Hence, food consumption data are a prerequisite for risk assessment and the quality of the risk assessment is directly influenced by the accuracy, comprehensiveness and comparability of the available consumption data.

EFSA has an established data collection programme which issues a variety of reports, some of which are published annually, for example the Community Zoonoses Report (in collaboration with the European Centre for Disease Control and Prevention) or the Annual Report on Pesticide Residues in Food. Others are produced on

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[a] On request of EFSA, Question No EFSA-Q-2010-00167, issued on 28 February 2010.

[b] Correspondence: sco@efsa.europa.eu

[c] Acknowledgement: EFSA wishes to thank EFSA staff member Simona Androni for the drafting; DATEX, PRAPeR and ZOONOSES Units for their contributions.

[d] Regulation (EC) No 178/2002 of the European Parliament and 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. Official Journal L 31, 1.2.2002, p.1-24

an *ad hoc basis,* on microorganisms (mainly Salmonella and Campylobacter) and chemical contaminants. The latter have included polycyclic aromatic hydrocarbons, acrylamide, furan and dioxins. In 2009 alone, EFSA produced nine major reports which were communicated to stakeholders and interested parties. These reports enable both the characterisation and monitoring of risks; thus, they not only support risk assessments but are also useful in monitoring compliance and the impact of risk management measures.

EFSA also has an established food consumption data programme. In 2005, its Scientific Committee recommended the establishment of a harmonised EU food consumption database and a subsequent Scientific Colloquium[4] in Brussels recommended that EFSA take the lead role in the coordination of a pan-European dietary survey. The Colloquium also recommended that consideration be given as to how the food consumption data collected could support other aims of Member States such as data for nutritional and public health purposes.

With the support of Member States, EFSA established a "Concise European Food Consumption Database", operational since the end of February 2008, and it is the first database in Europe containing information from individual dietary surveys from 19 European countries. However, data from different countries are not pooled or compared because of the different methods used to collect the dietary information. Furthermore, the Concise Database only provides consumption data on a limited number of broad food categories, to be used for preliminary exposure assessments, as required. At the end of 2008, EFSA started a project to establish a "Comprehensive European Food Consumption Database" containing data from the most recent national dietary surveys in Member States at the level of consumption by the individual consumer. It is scheduled for completion in 2010. Both the Concise and the Comprehensive European Databases include dietary information for the adult population only. In 2008, EFSA launched a call for proposals focused on children. Within this project, which started at the end of 2008, food consumption data for 13 different Member States have recently been provided to EFSA at the finest level of detail. They were used to carry out exposure assessment studies in children (in particular young children, 1-3 years old) for food colours, selenium, chromium and lead.

The consumption data used by EFSA in its exposure assessments thus far are the most comprehensive and up-to-date currently available in the EU. However, as outlined above they include important methodological differences between the collaborating Member States making these data unsuitable for EU-wide analyses and country-to-country comparisons. From a practical risk assessment perspective, this can result in, for example, over-conservative exposure assessments with knock-on effects for risk management decisions. It is unsurprising therefore that the collection of accurate and harmonised food consumption data at European level is a primary objective for the European Community and has been recognised as a top priority by EFSA for collaboration with the Member States and other countries. Therefore, a project proposal has been developed for the establishment of an EU-wide standardised food consumption data collection system (EUMENU). The proposal has been widely welcomed by Member States and by the European institutions including the European Commission; members of EFSA's Advisory Forum representing the Member States' food safety assessment institutions signed a declaration of support for EUMENU at a recent meeting in Seville.

The added value of this data collection lies in the use of methodology that enables comparability of data and that provides information that is detailed enough for risk assessments that are representative of all countries and regions in the EU. In addition, the data will bring tangible benefits for the European nutrition community and public health policy makers. EUMENU is a progression of previous EU-funded initiatives and will incorporate international best practice such as the US National Health and Nutrition Examination Surveys (NHANES). The collection of food consumption data is planned to be carried out as a rolling programme from 2012 to 2017, with a preparatory phase in 2010-2011. That preparatory phase will include the collaborative development with Member States of technologies to transfer, collate, store and disseminate data and the establishment of a common and harmonised food classification system.

KEY WORDS: Harmonisation activities, data collection, dietary surveys, food consumption, Europe

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INTRODUCTION AND OBJECTIVES

There is a major emphasis in the European Union, as in other parts of the world, to ensure citizens' food is safe. Regulation (EC) No 178/2002[d] of the European Parliament and of the Council, through which the European Food Safety Authority (EFSA) was established, is the corner stone on which the European food safety system was built.

Pre-amble 49 of Regulation (EC) No 178/2002[d] states that: "The lack of an effective system of collection and analysis at Community level of data on the food supply chain is recognised as a major shortcoming. A system for the collection and analysis of relevant data in the fields covered by the European Food Safety Authority (EFSA) should therefore be set up, in the form of a network coordinated by the EFSA. A review of Community data collection networks already existing in the fields covered by the Authority is called for."

To achieve these goals, EFSA "shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries and international bodies." In 2006, the Management Board of EFSA endorsed the Strategy for Networking and Cooperation between EFSA and the Member States.[80] This Strategy sets out the framework for cooperation and networking between the EU Member States and EFSA to support the development of risk assessments in all fields within EFSA's remit. The Strategy recognises four priority areas for the establishment of a common approach of risk assessments and communication outputs throughout Europe:

- exchanging and collecting scientific data and information;
- sharing risk assessment practices;
- contributing to the harmonisation of methodologies for risk assessment; and
- promoting coherence in risk communications.

Regarding the exchanging and collecting scientific data and information, the strategy states that in order to achieve effective scientific cooperation, it is essential to establish efficient systems for the active exchange of information between Member States and EFSA. Therefore EFSA is to collect, collate and analyse relevant data from the Member States and store these in European databases also accessible for the National Authorities. These systems will facilitate the effective participation of Member States in EFSA's activities and also provide adequate information to EFSA in relation to activities undertaken in Member States.

According to Article 22 sub 4 of Regulation (EC) No 178/2002,[d] the purpose of the collection by EFSA of data within its mission is "to allow both the characterisation and the monitoring of risks which have a direct or indirect impact on food and feed safety". The data mentioned in article 22 are indeed needed to permit EFSA to carry out its risk assessments, the mainstay of EFSA's activities. The steps in such a risk assessment are shown in Figure 1.

To conduct a risk assessment, the hazard is described (Hazard Identification) and its health impact identified (Hazard Characterisation). In addition, exposure of the consumer to the hazard is ascertained. A critical element in the conduct of a risk assessment is therefore the exposure assessment i.e. the estimation of the likelihood that the consumer will be exposed to a substance and to quantify the extent of that exposure, when it occurs. To do so, exposure assessments combine data on concentrations of a chemical substance or a biological agent present in foods with data on the quantity consumed of those foods. Hence, it is important to know both the likelihood that a substance or biological agent would be present in a food and, if present, at which concentrations it can be found. The exposure methodology can be applied to harmful and beneficial effects of substances that are naturally present in food (including macro- and micronutrients), are added deliberately (food additives, food supplements) or not deliberately (contaminants and residues).

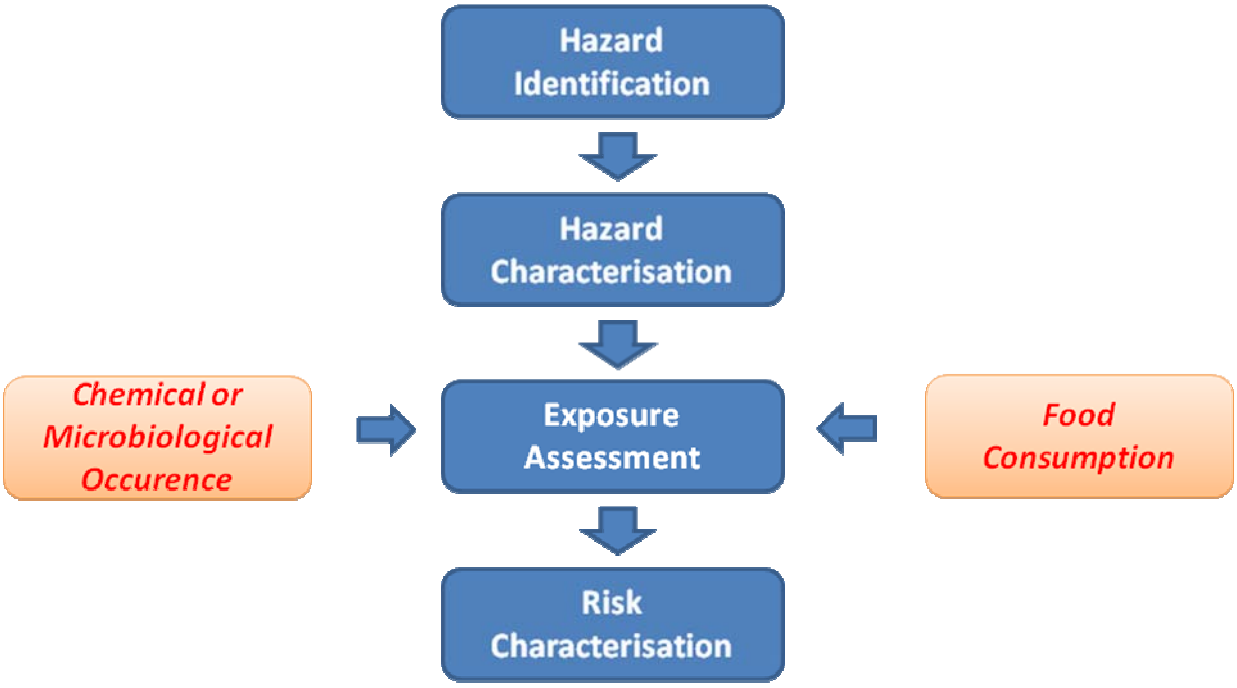

Figure 1: Steps in a Risk Assessment.

Finally, the health impact of the risks posed by ingesting the hazard at these exposure levels is evaluated and maximum levels that are permitted in various foods are proposed (Risk Characterisation).

The risk assessment performed in the MRL setting context is based on conservative worst case assumptions regarding the occurrence. To monitor compliance with established maximum residue levels representative occurrence (and food consumption) data are also needed. These actual occurrence data collected regularly following authorisation of a chemical allow for an exposure assessment to verify that the assumptions made in the MRL setting are indeed protective for the European population. As a concrete example, the results of the pesticide residue monitoring are used to close the feed-back loop on consumer exposure (see Figure 2).

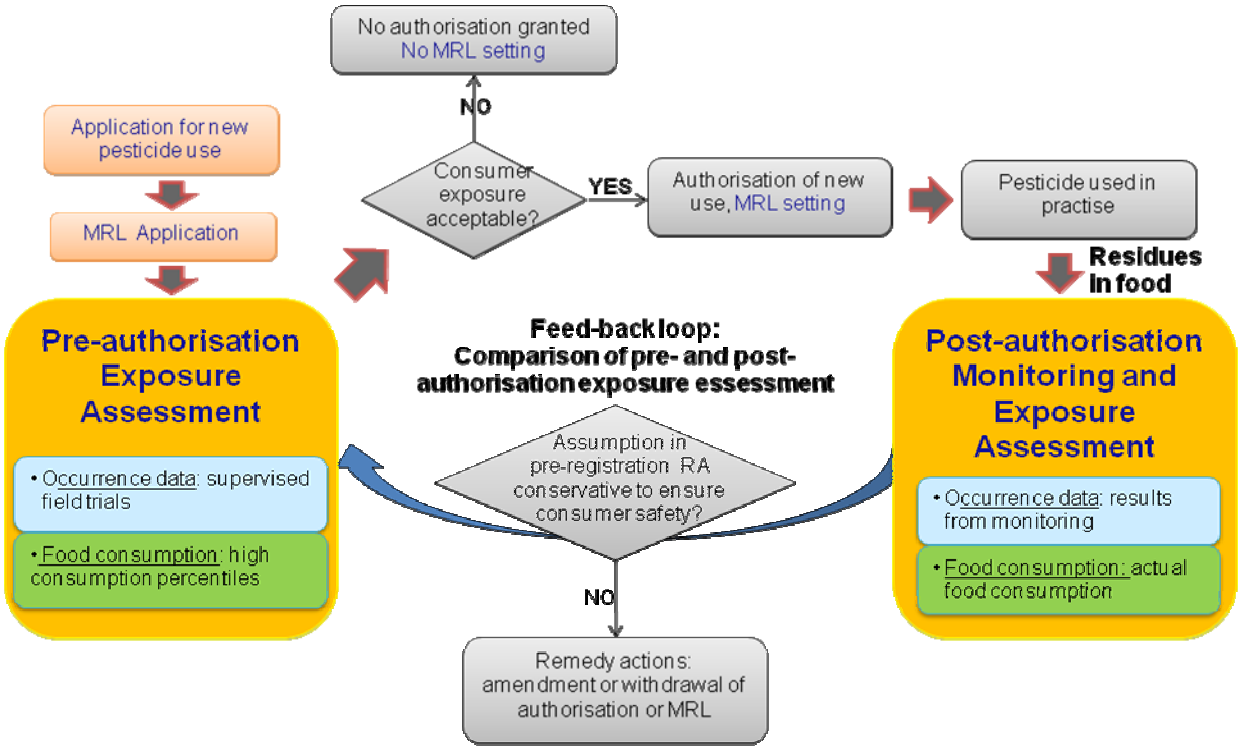

Figure 2: Link between pre-and post-authorisation exposure assessment.

To achieve these two major objectives, Article 33 of Regulation (EC) No 178/2002[d] stipulates that EFSA shall search for, collect, analyse and summarise particularly data on

- food consumption
- incidence and prevalence of biological risks,
- occurrence of contaminants and residues, and
- more in general, the exposure of individuals to risks related to the consumption of food.

Apart from Regulation 178/2002,[d] there is also specific Community legislation that assigns EFSA tasks related to data collection. Particularly,

- Directive 2003/99/EC[e] on zoonoses prescribes that EFSA has to examine the data submitted by the Member States on zoonoses, antimicrobial resistance and food-borne outbreaks and publish an annual Community Summary Report on the results.
- Regulation (EC) No 396/2005[f] provides that EFSA has to collect and analyse the results of the official controls on pesticide residues in food and feed.

The need for dietary data is included in Regulation (EC) 1338/2008[g] on Community statistics on public health and health and safety at work. The Regulation states that Member States shall supply to the Commission statistics on health status and health determinants (Article. 2) and specifies that the method used for the implementation of

[e] 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. Official Journal of the European Union L 325, 12.12.2003 p. 31-40.

[f] 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. Official Journal of the European Union L 70, 16.3.2005 p.1-16

[g] Regulation (EC) No 1338/2008 of the European Parliament and the Council of 16 December 2008on Community statistics on public health and health and safety at work. Official Journal L 354, 31.12.2008, p.70-81

data collection shall take into consideration national experience and expertise, and national specificities, capacities and existing data collection in the framework of the collaborative networks (Article 5.1). Article 5.2 indicates that the statistical methodologies and data collections to be developed for the compilation of statistics on public health shall take into consideration the need for coordination, whenever relevant, with the activities of international organisations in the field, with a view to ensuring international comparability of statistics and consistency of data collections as well as avoiding duplication of effort and of deliveries of data by the Member States. In this Regulation on Community statistics on public health and health and safety at work, the Collection of data on diet are specifically included in the Domain health status and health determinants (Annex 1). In particular as stated in Article 6 'whenever data are required in addition to those already collected and to those for which methodology already exist, or when insufficient quality of data is identified in the domains referred to Article 2, the Commission (EUROSTAT) shall institute pilot studies to be completed on a voluntary basis by the MSs...'.

The purpose of this document is to provide an overview of the progress made on networking on data collection with the Member States' competent organisations and the resulting data reporting and harmonisation activities conducted under Article 33 of the EFSA's Founding Regulation.

RESULTS

The results are presented by main area. They cover databases created and reports derived from it as well as both harmonisation activities. Table 1 provides a summary of the various data collection activities carried out for their use in risk assessment or for monitoring purposes in main areas within its remit. The latter reports are either topical or may be repeated annually.

The harmonisation activities initiated by EFSA that are cross-cutting, such as data storage, are presented in a separate section.

1.1. Zoonoses

1.1.1. Reports

1.1.1.1. Annual monitoring

EFSA publishes, in collaboration with the European Centre for Disease Prevention and Control (ECDC), annual Community Summary Reports based on the zoonoses, antimicrobial resistance and food-borne outbreaks, datasets reported by the Member States. Zoonoses are infections and diseases that are transmissible between animals and humans. The information on zoonoses, zoonotic agents and food-borne outbreaks are included in one Community Summary Report, and the data on antimicrobial resistance in another annual Summary Report. The information on the zoonoses cases in humans are received from ECDC already in an analysed format. Together, five Community Summary reports have been issued so far, and they cover the years 2004-2008.[5, 7, 16, 50, 52, 72, 83]

According the latest Community Summary Report, [83] in 2008 campylobacteriosis was again the most frequently reported zoonotic disease in human with 190,566 reported confirmed cases. Salmonellosis was the second most commonly recorded zoonosis accounting for 131,468 human cases, but the incidence of salmonellosis continues to decrease in the EU with a statistically significant trend. In foodstuffs, the highest proportion of *Campylobacter* positive samples was reported for fresh poultry meat where on average 30% of samples were found positive. *Campylobacter* was also commonly detected from live poultry, pigs and cattle. *Salmonella* was most often found in fresh poultry and pig meat, on average from 5.1% and 0.7% of the samples, respectively, whereas dairy products, vegetables and fruit were rarely found to contain the bacterium. The numbers of listeriosis cases in humans have been of concern in the EU, but *Listeria* bacteria were seldom detected above the legal safety limit from ready-to-eat foods. At EU level, the occurrence of bovine brucellosis remained largely unchanged in 2008, while that of bovine tuberculosis and sheep/goat brucellosis seemed to slightly decrease. Rabies was still found in domestic and wildlife animals in the Baltic and some Southern and Eastern European Member States, while the two reported zoonotic parasites, *Trichinella* and *Echinococcus,* were mainly detected in wildlife.

1.1.1.2. Topical reports

EFSA also analyses the results from the EU-wide baseline surveys on zoonotic agents in animal and food populations. These results have been published for *Salmonella* in holdings of laying hens, for flocks of broilers and turkeys and for slaughter pigs and for holdings of breeding pigs. [12, 17, 30, 31 33, 34] The observed EU *Salmonella* prevalence have been substantial in these animal populations, at levels of 30.8%, 23.7%, 30.7%, 10.3% and 30.9%, respectively, even though the Member State specific prevalence vary widely. Most recently on the report on the survey of methicillin resistant *Staphyloccus aureus* (MRSA) in holdings of breeding pigs revealed that 22.8% of the holdings were positive for MRSA in EU.[71] The baseline survey reports also include the analyses of factors potentially associated with the infection/contamination and the importance of the findings for human health.

Apart from the annual summary reports EFSA issues specific reports that include an in depth analyses of some interesting set of data received. This type of reports is currently being produced

- for trend analyses of data on antimicrobial resistance in food and animals from 2004-2007 [9, 37, 53] where resistance against antimicrobials was commonly found, and resistant for fluoroquinolones and third generation cephalosporins were of specific concern;
- for Salmonella serovar distribution as well as for *Salmonella* and *Campylobacter* source attribution analyses. [24, 38, 39, 54, 73] The most important sources of human salmonellosis cases were estimated to be eggs (32%) and poultry meat (15%) and for human campylobacteriosis cases broiler meat (10%).

1.1.1.3. Contribution to risk assessment activities

On the request of EFSA's BIOHAZ and AHAW Scientific Panels, extractions of specific datasets have been provided in preparation of Scientific Opinions. Datasets have been provided on

- opinions on *Salmonella* targets in breeding poultry flocks and flocks of laying hens [2] and
- Quantitative microbiological risk assessments (QMRAs) on *Salmonella* in pigs and *Campylobacter* in broiler meat;[75]
- For opinions on
  - Assessment of the risk of echinococcosis,[6]
  - Porcine brucellosis (*Brucella* suis).[41]

1.1.2. Harmonisation activities

The data collection system, laid down by the Directive 2003/99/EC,[e] obliges the Member States to submit their annual zoonoses report to the European Commission. However, this data flow is streamlined in a way the EFSA receives this data directly. The monitoring is based on the systems in place in Member States.

Part of the annual monitoring and reporting of zoonoses is already harmonised by Community legislation. This is the case for *Salmonella* (Regulations (EC) No 2160/2003,[h] 1003/2005,[i] 1168/2006,[j] 646/2007,[k] 584/2008[l]), as well as for zoonotic parasites within meat inspection (Regulation (EC) No 2075/2005[m]).

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[h] Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the control of salmonella and other specified food-borne zoonotic agents. Official Journal of the European Union L 325, 12.12.2003, p. 1-15.

[i] Commission Regulation No 1003/2005 of June 2005 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of Gallus gallus and amending Regulation (EC) No 2160/2003.Official Journal of the European Union L 170, 1.7.2005, p. 12-17

[j] Commission Regulation (EC) No1168/2006 of 31 July 2006 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) No 1003/2005. Official Journal of the European Union L 211, 1.8.2006, p. 4-8.

[k] Commission Regulation (EC) No 646/2007 of 12 June 2007 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in broilers and repealing Regulation (EC) No 1091/2005. Official Journal of the European Union L 151, 13.6.2007, p. 21-25

General guidance for the reporting of zoonoses is provided by EFSA's reporting manual.[49, 51] On top that EFSA has published harmonised monitoring and reporting specifications for antimicrobial resistance data for *Salmonella, Campylobacter,*[13, 21, 35] commensal *E.coli* and *Enterococci*[29, 35] isolates from food and animal populations in 2007 and 2008. The specification on *Salmonella*[8, 14, 15, 32] isolates from animals have also been laid down by Decision 2007/407/EC[n]. Also harmonised guidelines for reporting of food-borne outbreaks[18, 60, 74] were issued in 2007 by EFSA accompanied by a reporting manual. [59, 51]

Currently, EFSA is in the process of producing harmonised specifications for the monitoring and reporting of several zoonotic agents of importance. Some of these reports have already been published. These include

- EFSA, verotoxigenic *E.coli*, in animals and food,[65]
- *Yersinia enterocolitica* in slaughter pigs,[70]
- *Trichinella* in animals, [84]
- *Echinococcus* in animals,[85]
- *Cysticercus in animals,* [86]
- *Sarcocystis in animals,*[87]
- rabies and Q fever in animals,[59]
- as well as survey methodologies for *Salmonella*, *Campylobacter*, *Listeria monocytogenes*[55] and other food-borne pathogens in food.[o]

In addition, specific reports have been issued regarding the development of the analyses methods for the zoonoses data. In 2009, a report on the statistical and spatial analyses of the zoonoses data [53] was published and further reports on the trend analyses of zoonotic agents in animal and food populations are to be issued in 2010. These reports define the best available statistical methodology to be applied as well as give guidance on the sample sizes to be used and the pathogen/animal or food category where to follow trends over the years.

In case of EU-wide baseline surveys on zoonotic agents in animal and food populations, the monitoring and reporting is fully harmonised by Commission Decisions laying down the survey. However, EFSA has prepared, on the request of the Commission, technical specification for baseline survey protocols. The results of EU-wide baseline surveys have been published on Salmonella in broilers, turkeys and slaughter pigs in two parts: the A reports[30, 31] contain the prevalence estimates and the B reports[33, 34] cover the analyses of factors associated with the infection/contamination, for *Salmonella* in laying hens there is a preliminary report and a final one. The proposals for baseline survey protocols prepared by EFSA are also issued as separate reports on *Salmonella* and methicillin resistance *S. aureus* (MRSA) in breeding pigs,[14 19] *Salmonella* and *Campylobacter* in broiler meat[8, 32] and *Listeria monocytogenes*[55] in ready-to-eat food.

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[l] Commission Regulation (EC) No 584/2008 of 20 June 2008 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Community target for the reduction of the prevalence of Salmonella enteritidis and Salmonella typhimurium in turkeys. Official Journal of the European Union L 162, 21.6.2008, p. 3-8.

[m] Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for Trichinella in meat. Official Journal of the European Union L 338, 22.12.2005, p. 60-82.

[n] Commission Decision of 12 June 2007 on a harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs. Official Journal of the European Union L 153, 14.6.2007, p. 26-29.

[o] CFP/EFSA/ZOONOSES/2008/02 - Development of harmonised survey methods for food-borne pathogens in foodstuffs in the European Union

1.2. Chemical contaminants

1.2.1. Reports

1.2.1.1. Annual Monitoring

EFSA has recently been given the task of producing an annual report of veterinary medicinal product residues and other substances in food from animals and animal products. The report is part of an annual overview issued by the Commission on the current situation along with the proposed sampling plan for the following year.

The first annual report was issued by EFSA in November 2009 [61] based on Member State data submissions for 2008. The data evaluated in this report showed that the frequency of samples exceeding the respective Maximum Residue Limits was similar to previous years for most regulated veterinary medicinal residues.

EFSA technical reports [46, 47] on two process contaminants, acrylamide and furan, identified a scarcity of data in both areas. Acrylamide is a contaminant that may be formed in foods, particularly plant-based foods rich in carbohydrate during cooking, frying, baking or roasting, at temperatures of 120°C or higher. The critical effects of acrylamide are its neurotoxicity and carcinogenicity. The compound has been identified as genotoxic and carcinogenic in laboratory animals. Furan is an organic compound used in various chemical manufacturing industries which has been shown to be carcinogenic in animal studies. It can also form in foods during commercial or domestic heat treatment, including home cooking. It is known to occur in foods such as coffee, canned and jarred foods including baby food containing meat, and various vegetables. The Commission initiated Recommendations[p, q] to Member States to collect acrylamide and furan data and to report them annually to EFSA. The first two reports were issued by EFSA in 2009. The acrylamide [46] report also included data collected by the Joint Research Centre for a trend analysis of the situation after the publication of a toolbox including measures to reduce the formation of the substance. It was concluded that it was so far not possible to see a clearly discernable pattern of reduction in overall acrylamide levels as a result of the measures prescribed in the toolbox. The furan [47] report confirmed that coffee is the clearly dominating contributor to furan exposure in adults whereas jarred baby food is the major contributor for infants.

1.2.1.2. Topical reports

Most data requests for contaminants are initiated to address a risk assessment request from the Commission to EFSA. Occasionally, the Commission has requested the EFSA for a topical occurrence report for specified contaminants. EFSA, in close collaboration with the Commission, issues calls for contaminant data from Member States and other interested parties, as needed.

Polycyclic aromatic hydrocarbons (PAH) can be formed from a variety of combustion and pyrolysis processes and a number of them have been shown to be genotoxic carcinogens. Food can be contaminated from environmental sources, industrial food processing and from home food preparation. A topical report to the Commission has been issued covering polycyclic aromatic hydrocarbons[11] (PAH) to determine if benzo(a)pyrene is a suitable indicator substance for the presence of the most toxic PAH compounds. The report concluded that this was not the case. The Commission thus issued a risk assessment mandate to EFSA for a detailed review by the CONTAM.

As part of the Commission strategy[r] to reduce the presence of dioxins in food and feed, data collected by the Member States were sent to EFSA for statistical analysis. Dioxins are widely distributed contaminants formed as

[p] Commission Recommendation of 3 May 2007 on the monitoring of acrylamide levels in food. Official Journal of the European Union L 123, 12.5.2007, p. 33-40.

q Commission Recommendation of 28 March 2007 on the monitoring of the presence of furan in foodstuffs. Official Journal of the European Union L88, 29.3.2007, p. 56-57.

[r] Commission Recommendation of 11 October 2004 on the monitoring of background levels of dioxins and dioxin-like PCBs in foodstuffs. Official Journal of the European Union L 321, 11.10.2004, p. 45-52.

unwanted by-products in a number of anthropogenic activities, involving incomplete combustion processes, both industrial and natural and also occur as contaminants during various industrial processes. Due to their chemical properties they tend to accumulate in the fatty portion of foods. Different toxic effects have been reported including dermal toxicity, immunotoxicity, carcinogenicity, reproductive and developmental toxicity. A report was drafted in November 2009 covering the presence in food and feed of the 29 congeners of polychlorinated dibenzo-p-dioxins, dibenzofurans and dioxin-like polychlorinated biphenyls included in the dioxin and dioxin-like compound group.[76] A total of 8446 samples collected in the period 1999-2008 from 19 Member States, Norway and Iceland were analysed in detail. The highest mean levels of dioxins and dioxin-like PCBs in food and feed were observed in marine products, while the proportion of results exceeding maximum levels set by legislation was highest for porcine products and eel. These findings confirm what had been reported in the framework of a EU project in 2000 on the basis of occurrence data collected from ten Member States. [82]

1.2.1.3. Contribution to Risk Assessment activities

A number of data collections have been completed as part of the development of risk assessment opinions. Exposure has been calculated to make it possible for the Panels to assess potential public health risk posed by the presence of the substances. Substances covered over the last few years include

- aflatoxin,[44]
- ethyl carbamate,[10]
- heavy metals like
  - cadmium,[77]
  - lead,[22]
  - uranium[42] and
  - arsenic[45]
- nitrate in vegetables,[25]
- marine biotoxins,[36, 56, 57]
- melamine[27] and nicotine[43] in urgent requests and
- selenium and chromium as well as food colourings as part of calculating children exposure.[40]

1.2.2. Harmonisation Activities

An Expert Group for Contaminants, endorsed by the EFSA Advisory Forum, assists in harmonising data collection efforts across the Member States. Contact has also been established with several of the Community Reference Laboratories for important contaminant areas to discuss harmonisation of analytical methodology and sensitivity.

Most data on contaminants are collected through targeted sampling of suspect problem areas during implementation of Member State control programs. This will not provide a true reflection of the average contaminant situation. EFSA is preparing to launch a self-mandate to harmonise the collection of contaminant data through a total diet study (TDS) framework. The TDS approach involves selecting a typical basket of foods that are in common in the overall diet, randomly purchasing the nominated foods, processing them as for conventional food consumption, combining the foods into food composites or aggregates, homogenising them, and analysing them for an agreed range of chemicals. The analytical results are then combined with food consumption information for different population groups, and the dietary exposure to chemicals by different food groups is estimated. Together, the random and targeted sampling can provide better baseline information on which to base an exposure assessment.

The handling of results below the detection or quantification limits (left censored data), is critical for the accurate calculation of occurrence statistics. A Working Group for left censored data is due to report recommendations for the handling of such data in November 2009.[79] The outcome will facilitate harmonisation across Member States and laboratories of the details reported for a range of contaminants.

1.3. Plant protection products

1.3.1. Reports

1.3.1.1. Annual Monitoring

Regulation (EC) No 396/2005[f] on maximum residue levels of pesticides in or on food and feed of plant and animal origin foresees several data collection activities coordinated by EFSA. These data are used both in the risk assessment regulatory risk assessment in the framework of setting of maximum residue levels (MRLs) and for the actual consumer exposure assessment which is based on residue found samples available to European consumers. Member States have the obligation to control compliance of MRLs in food and feed by official controls and to submit the results of the control activities to the European Commission and to EFSA. Article 32 of Regulation 396/2005[f] requests EFSA to prepare an Annual Report on pesticide residues. The Report shall summarise the control activities of Member and provide statements of possible reasons why the MRLs were exceeded, together with any appropriate observations regarding risk management options. In addition, the submitted results should be used to perform an assessment of the consumer exposure. The data analysis consists in the assessment of MRL compliance rates and consumer exposure assessment. The Annual Report is submitted to the Commission (Art. 32(5) of Regulation 396/2005[f]).

In June 2009 EFSA published its first annual report on pesticide residues found in food which was on the market in 2007.[48] In total, more than 74,000 samples of nearly 350 different types of food were analysed for pesticide residues. 96% of the samples analysed were compliant with the legal MRLs; 4% of the samples exceeded them. The consumer exposure assessment identified some critical results, in particular with regard to acute consumer exposure. Based on these findings, EFSA derived recommendations to be considered for the future control activities.

1.3.2. Harmonisation Activities

Following its first annual report, EFSA identified deficiencies in the current format of reporting the results which impede to perform all the evaluations as described in the Regulation. Therefore EFSA started the initiative to develop a new data collection format providing all relevant information to EFSA. A pilot project was launched to test the suitability of the data model with real data. Six Member States (Germany, Ireland, Slovenia, Austria, Netherlands and Denmark) have submitted the results of the monitoring activities performed in 2008 using the new format. For this purpose pesticide residue results for ca. 27.000 samples (almost 6 million determinations) were submitted to EFSA. Taking into account the results of the pilot project, the data model was amended and is now recommended to the SCFCAH to be used by all Member States and the EEC countries for reporting the results of the pesticide residue control activities of 2009.

In 2006, when EFSA started the work on the implementation of Regulation 396/2005, [f] no agreed European model was available to perform consumer risk assessment for the whole European population. Several national models existed which were used by Member States. In order to be able to perform the activities assigned to EFSA in Article 24 of this Regulation (consumer risk assessment for more than 80,000 MRL proposals for more than 300 active substances), EFSA started developing a European model [20] implementing the internationally exposure assessment methodologies on the basis of the food consumption data available at Member State level. The exposure assessment performed with the EFSA PRIMo (Pesticide Residue Intake Model) should ensure that MRLs are set at levels which are safe for the European population, including in particular vulnerable subgroups of the population.

As a first step in developing the EFSA PRIMo, EFSA collected the available food consumption data which were used in the national risk assessment models. For this purpose a reporting schema was established to report the consumption for ca. 240 individual food commodities which reflects the food classification in Regulation 396/2005.[f] In total, food consumption data for different age groups and subgroups of the population with specific food consumption habits suitable to perform long-term and short-term consumer intake were collected from Member States. In addition, also food consumption data collected by GEMS/food (WHO) were integrated in the model.

The EFSA PRIMo revision 2 now comprises 27 diets (9 for children) from 13 Member States to be used for long-term exposure assessment and 19 diets for short-term exposure assessment from 11 Member States, among the short-term also 9 diets for children of different age groups. EFSA envisages launching a new revision of the EFSA PRIMo in the first quarter of 2010. In this new version the updated food consumption data provided by Member States will be included.

1.4. Food Consumption

1.4.1. Reports

In 2005, an opinion of the Scientific Committee[3] on exposure assessment suggested the establishment of a harmonised food consumption database in the EU. It further recommended that EFSA should contribute to the development of a European framework for the harmonisation of food related data collection in the EU and make these data publicly accessible.

To support the establishment of a common database on food consumption, EFSA organised the Scientific Colloquium "European food consumption database – current and medium to long-term strategies" (28-29 April 2005, Brussels, Belgium). The objective of this colloquium was to have an open scientific debate on the state of the art of harmonised approaches to food consumption data collection and the development of a database on food consumption at European and international level. A report is available on the EFSA website outlining suggested future initiatives.[4] The discussions among the participants led to the agreement that harmonisation of food consumption data was the ultimate requirement in addressing dietary exposure assessment at the European level. The Colloquium was in favour of a pan-European dietary survey and recommended that EFSA take a lead role in the co-ordination and completion of associated tasks in meeting this initiative. It was recommended however, that consideration be given to how food consumption data could support other aims of a Member State such as the collection of data for nutritional and public health purposes. The Colloquium also acknowledged the importance of co-operation and communication in the success of this initiative at national, EU and international levels.

In 2007, following the recommendations received at the Colloquium, EFSA created the "Expert group on food consumption data" (EGFCD), an EFSA network, with representatives from each EU Member State. The EGFCD coordinates an effort to harmonise the collection and collation of food consumption data and provides a platform for exchange of views between experts from the European countries.

As a first initiative, the EGFCD co-operated in the establishment of the "Concise European food consumption database" (Concise Database) as suggested in the above opinion of the Scientific Committee on exposure assessment. The Concise Database has been fully operational since the end of February 2008 and is the first database in Europe containing information from individual dietary surveys from 19 European countries. For each country, food consumption data are elaborated according to both broad categories and subcategories and in the total population and for consumers only. A Guidance Document for the use of the Concise European Food Consumption Database in Exposure Assessment was published on the 17th of March 2008.[28] Summary statistics are made available to the public on the EFSA web site. Data from different countries are never pooled or compared because of the different methods used to collect dietary information. The summary statistics include the total number of individuals and, for each food category and subcategory, numbers of consumers, the mean, the standard deviation, low and high percentiles. Summary results are also provided for total solid foods and total liquids in case consumption data are available for the relevant food categories and subcategories.

However, the Concise Database only intends to provide consumption data on a limited number of broad food categories, to be used for preliminary exposure assessments as required. More detailed information on food consumption in Europe is thus required to undertake full exposure assessments.

By the end of 2008, EFSA started a project aimed to establish the "Comprehensive European food consumption database" (Comprehensive Database)[s]. Within this project, competent organisations in EU Member States were requested to provide EFSA with data from the most recent national dietary survey in their country, including the adult population, at the level of consumption by the individual consumer. The consumption data were requested to be expressed at the most disaggregated level recorded at national level. Twenty Member States accepted to participate in this project and signed a collaboration agreement with EFSA for the provision and processing of such food consumption data. The Comprehensive database is planned to be completed by January 2010.

Both the Concise and the Comprehensive European Databases include dietary information for the adult population only. In 2008, EFSA launched a call for proposals focused on children: "Individual food consumption data and exposure assessment studies for children" (acronym EXPOCHI)[t]. Within this project, which started at the end of 2008, food consumption data for 13 different Member States were used to carry out exposure assessment studies in children (in particular young children, 1-3 years old) for food colours, selenium, chromium and lead. Moreover, food consumption data used for the exposure assessments has recently been provided to EFSA at the finest level of detail.[1]

1.4.2. Harmonisation Activities

Currently, no uniform methodology is applied across the European Community when performing dietary surveys and food consumption databases therefore vary from country to country in terms of format and content. In order to develop a common model that could be used by all Member States for the transmission of the data for the Comprehensive Database, all participating institutions were first requested to provide EFSA with a database schema describing their food consumption and related data tables.

In 2008, following a recommendation made at the second meeting of the EGFCD, EFSA created the Food Consumption and Exposure Working Group (FCE WG) aimed at drafting the Guideline of EFSA on "General principles for the collection of national food consumption data in the view of a Pan-European dietary survey". The main objective of the EFSA Guideline is to suggest methods and procedures for the collection of dietary information at national level in the framework of a pan-European data collection that can be used to perform risk assessment for all possible biological agents and chemical substances considered by EFSA's Scientific Panels. The Guideline has been discussed and endorsed by the EGFCD during an ad hoc meeting held in Parma on the 14th and 15th October 2009. [63]

The food consumption data gathered at EFSA in the Comprehensive European food consumption database and through the EXPOCHI project are the most up-to-date data currently available in the EU and will be very useful in the risk assessment work conducted by EFSA. However, they still include important methodological differences making these data unsuitable for country-to-country comparisons. The collection of accurate and harmonised food consumption data at European level is therefore a primary long term objective for EFSA and has been recognised as a top priority for collaboration with the EU Member States and other interested countries.

In July 2009, a call for proposal was launched for a "Pilot study in the view of a pan-European dietary survey – Infants and children".[u] The main objectives of the pilot study are to develop and test tools and procedures for the collection of individual food consumption data for children, infants and their breastfeeding mothers in the view of a pan-European survey and to analyse the collected data and evaluate the tools and procedures used to provide recommendations for potential improvements and/or revisions.

[s] M-2009-0260 - DPPA/EFSA/DATEX/2008/01-18 - DPPA/EFSA/DATEX/2009/01-02
[t] M-2009-0250 - CFP/EFSA/DATEX/2008/01 – in progress
[u] M-2009-0252 – CFP/EFSA/DATEX/2009/2 – in progress

1.5. Data management aspects

1.5.1. Data entry, transfer and validation

Since 2005, EFSA has created a web-reporting application which is used by the Member States in submitting their annual data on zoonoses, antimicrobial resistance and food-borne outbreaks. The tables, text forms and pick lists of the web application have standardised the reporting. Furthermore, EFSA has issued several reporting manuals to guide the reporting of zoonoses, zoonotic agents, antimicrobial resistance and food-borne outbreaks by the EU Member States. These reporting manuals are updated each year. While the data entry is mainly done manually, for food-borne outbreaks data XML submission can be also used. The use of XML will be gradually expanded to all reporting, starting with antimicrobial resistance data in 2010. The validation of the annual zoonoses datasets is made using SAS.

The zoonoses baseline survey data are received from the Commission in XML format and validated using SQL queries and Visual Basic routines. A number of agreed validation criteria are applied in each case. Based on the validation results, the Member States' reporting officers and coordinators are contacted for further clarification and possibilities for correcting and complementing the datasets.

Contaminant analytical results are today most often submitted by attaching an Excel spreadsheet to an email. The submitted data are uploaded into an Oracle database and data cleaning and validation are applied at EFSA using Excel macros. The data is subsequently uploaded into a SAS database and additional statistics applied for the final cleaning step.

A more efficient way is to harmonise the transfer of the information through an electronic data transmission standard. A Working Group is currently in place to specify this standard (hereafter referred to as Standard Sample Description[88]). The Standard Sample Description includes a harmonised standardised terminology (such as standardised lists of countries (i.e. ISO-3166), analytical methods, name of chemicals, etc…), a uniform database field structure and an XML schema to support the creation of standard XML files. Validation rules will be incorporated in the XML schema and feedbacks are to be provided to the data submitter should the file be non-compliant. Contaminant data following the Standard Sample Description will then be transmitted to EFSA with a software provided by EFSA called Data Collection Framework. Further validation (and cleaning) will be through a set of standardised procedures in SAS. A pilot project[66] to develop and test the Standard Sample Description for direct data transfer between databases in Member States is underway in five countries under the Article 36[v] funding umbrella.

For the first EFSA report (2007 data) on pesticide residues data, the process was as follows. Data were received in an aggregated format using excel workbooks. The data were checked by EFSA upon receipt and if needed Member States were asked to provide clarifications. The methodology applied was as follows 1) data were uploaded into an Access database and variables of the wrong data type or missing data were identified 2) commodities and chemical residues were coded to allow further aggregation and comparisons at EU level 3) subtotals and totals were checked for consistency using SAS and pdf summary reports were provided to the reporting organisations for verification.

For the next report (2008 data) a pilot project was implemented with six Member States (Germany, Ireland, Slovenia, Austria, Netherlands and Denmark. For the other Member States the methodology used in 2007 was applied). The project tested a standard data model for the submission of the laboratory results and their transmission in XML format via the EFSA data collection framework. The methodology provides three levels of validation: 1) the XML is valid according to the schema (i.e. whether all required variables have been returned and are of the correct type), 2) compliance with the controlled terminologies 3) additional business rules implemented in SAS. The first two steps check only the individual variables, the final steps check the relationships between variables i.e. if the sample is reported as non compliant that the residue level measured is above the EU MRL. All six member states were able to submit the data in XML format. It is proposed to expand this methodology to all

[v] M-2009-0251 CFP/EFSA/DATEX/2009/01 - Electronic Transmission of Chemical Occurrence Data – in progress

Member States for the 2009 dataset. For this the pesticide residues data will be transmitted according to the Standard Sample Description[88] used for contaminant occurrence data transmission.

Food consumption data for the Concise Database have generally been submitted through an Excel spreadsheet form attached to an Email. Two countries used an XLM schema developed by EFSA. The submitted data have been uploaded into an Oracle database. Data validation (and cleaning) were done in SAS.

As indicated previously, in order to develop a common model that could be used by all Member States for the transmission of the data for the Comprehensive Database, all participating institutions were first requested to provide EFSA with a database schema describing their food consumption and related data tables. Based on this information, EFSA developed a data model and defined a standardised terminology (e.g. food classification, age groups) that has been used for the data transmission of these food consumption data. All data were transferred to EFSA by means of the Data Collection Framework (DCF)[67] system developed by EFSA. The DCF system controls for the structure of the database and compliance with the controlled terminology. A further check is performed afterwards in SAS using ad hoc procedures.

1.5.2. Storage, analysis, and output

The annual zoonoses data from Member States and other reporting countries[w], received through the web reporting application, go directly into the EFSA Oracle database. The baseline survey data are currently stored in a Microsoft Access database. All validated datasets are also available on the SAS server for ad-hoc extractions and analysis.

A pilot project aimed to test a web based reporting system and a data warehouse for zoonoses has been carried out successfully in 2009.[89] The future web based reporting system and data warehouse will facilitate data validation, data access, data extraction and data visualization through tables, graphs, GIS maps and tools.

An Oracle database is under development to receive and store contaminant data submissions using the structure defined by the guidance on Sample Description.[69] It will protect the accuracy of the original data in that a permanent storage will be created for those files. This will strengthen security and prevent potential data loss due to manual file submissions.

The contaminant data collection will be accessible to approved users through a data warehouse system using a harmonised format. A project is currently underway to assess the needs of potential data users with Member States to determine the statistics that should be provided for data stored in the data warehouse.

The pesticide residue data are compiled into SAS datasets to allow the generation of tables and charts for the annual report. For the purpose of the exposure assessment, the data are compiled in the Excel-based risk assessment model. According to Article 31 of Reg. 396/2005,[f] Member States have to submit the relevant information on the control activities to the Commission and to EFSA. In order to simplify the procedures, it was agreed that the data are submitted only to EFSA and EFSA makes them accessible also to the Commission via the EFSA Extranet.

Individual food consumption data from the Concise Database and from the Comprehensive Database are stored by EFSA in an Oracle database. An Oracle database will also be used for the data gathered at EFSA through the EXPOCHI project.

1.5.3. Harmonisation across different data collection domains

For the purpose of conducting exposure assessments, it is necessary to be able to combine data on occurrence of micro-organisms and chemical contaminants or residues with food consumption data. Thus, it is necessary to also

[w] Norway and Switzerland

consider harmonisation across the different domains. All EFSA Units managing databases need to receive, store and share data in a harmonised standard form. This harmonisation has the pre-requirement of using standard terminologies to describe the information, so that the data can be collated easily. Standard terminologies (such as standardised lists of countries (i.e. ISO-3166), analytical methods, name of chemicals) can be complex lists or hierarchies. They need to be shared between all Member States. Member States may need to request new term and new terms must undergo a formal approval process and a strict version control. And they need tools for their development, implementation and maintenance. Therefore, a Web accessible system to create, use, maintain and share the terminologies between all the users (internal and external) to the EFSA data networks should be established. In this context, the use of ontology systems that are designed to define a computer classification system has been explored by EFSA. A pilot was performed to see if this solution is fit for use in the food domain.[68]

A particularly important area for harmonisation concerns the food classification. While not being an easy task, it is important to harmonise this area and the work that EFSA has started in this area is of key importance. The functionality of a "central repository for pan-European data" designed for exposure assessment relies to a large extent on the availability and implementation of a proper food classification and description system providing a common link to all the diverse datasets involved.
Many different systems to systematically define food items are available. Most of them are fit-for-purpose systems, focusing on e.g. food consumption (DAFNE, Eurocode2, EPIC) or food composition (BLS, EuroFIR, LanguaL) and some are highly specialised (on trade, on crops, on customs). So far no comprehensive system covering the needs of exposure assessment has been internationally adopted. The food classification and description system in use in the Member States vary from country to country and are characterised by different levels of detail (granularity). To assist EFSA in harmonising the categorisation of foods a Working Group for Food Classification was established in November 2009.

Furthermore, there is a need to harmonise technologies to transfer, collate, store and disseminate food and feed safety data.

There are many business intelligence technologies and innovations available to facilitate the storage of large datasets with web based access for reporting, analysis, mapping, dashboards, data integration and data mining.

For the purpose of its data storage EFSA is striving for a single repository structure (data warehouse) with standardised transfer and access for the different types of data it receives. IT requirements for such a data warehouse have been defined. The databases run on Oracle software.

An IT Working Group on Data Warehousing and Web Reporting[78] EFSA has explored the priorities for the deployment of (web) reporting technologies that would be most beneficial to Member State competent authorities and other EU stakeholders. Its focus was on identifying the most suitable reporting tools to allow the Member States to access the EFSA data warehouse, taking possible restrictions due to data confidentiality into account. Its focus was on web reporting solutions that allow intelligence and risk assessment analysis to be derived from EFSA food and feed monitoring datasets and food consumption datasets. To access the data EFSA has now acquired licenses of business intelligence and analysis software packages such as ArcGIS, MicroStrategy and SAS.

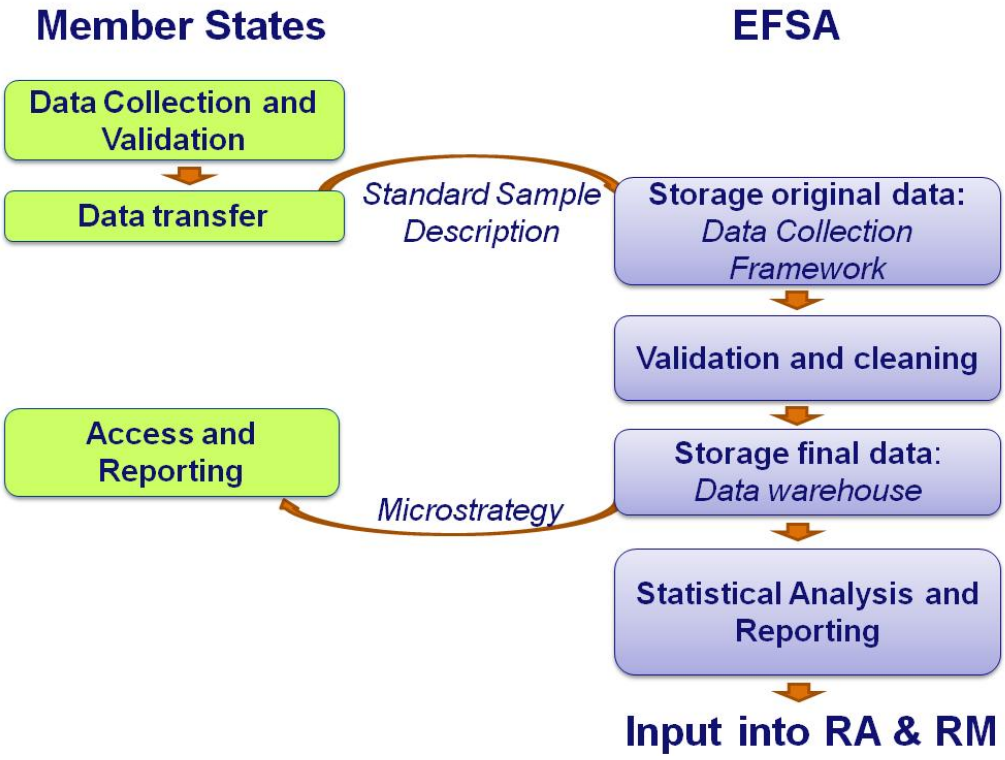

Figure 3: Harmonised process for data collection, validation, transfer and storage.

DISCUSSION

Decision-makers in the European Institutions, in Member States, in local government and in businesses need up-to-date food safety data and information to make informed decisions to protect citizens' health. The need to systematically collect, process and analyse standardised data for an effective monitoring of the state of health in the European Union, is highlighted e.g. in the second programme of Community action in the field of health (2008-2013).[x]

In accordance with the Founding Regulation [d] and with the Strategy on Cooperation,[81] networks with representatives from Member State institutions have been set up to coordinate the collection of the data on zoonoses, antimicrobial resistance and food-borne outbreaks, food consumption, chemical occurrence, and pesticide residues. Besides the Commission (including EUROSTAT), representatives from non-EU European countries and international organisations often participate as observers. This good cooperation in the networks has proven to be an essential element to achieve progress.

Following consultation of the Scientific Committee and the Advisory Forum, rules for the operation of EFSA networks have recently been drafted for consideration by the Management Board of EFSA. In close cooperation with the competent institutions, the Community Reference Laboratories, working groups have been established for the development of harmonized protocols for data collection on specific topics and to draft reports and review results.

[x] Decision No 1350/2007/EC of the European Parliament and of the Council of 23 October 2007 establishing a second programme of Community action in the field of health (2008-13). Official Journal of the European Union L 301, 20.11.2007, p.3-13.

The Founding Regulation [d] emphasises the need for technical comparability, which pertains both to the monitoring and data collection in the Member States and to their transfer, storage, and retrieval in EFSA. There is often useful data from Member States' monitoring and surveillance activities available. The usefulness of their inclusion in EFSA reports depends on whether the data can serve the purpose for which they are to be used. In that regard there is variability in the nature of the data provided. In several instances EFSA has been tasked by the European Commission to establish, in cooperation with the competent Member State institutions, a study protocol which is then implemented consistently across the EU. Data collection based on such pre-defined uniform methodology provide high-quality data and a solid basis for drawing conclusions. On the other hand, use of already existing data which have been collected for very different reasons often presents difficulties. For example, to accomplish their tasks as risk managers, officials in Member States are in need to carry out measurements on samples which were selected because of a suspicion of non-compliance. Being clearly targeted, these samples can often not be considered to be representative of the food that is on the market. For these same reasons it is not possible to compare results based on such samples between Member States or to conduct trend analyses over time. A large amount of data will not serve to correct for biased sampling resulting from a flawed study.

When there is a recurrent need to collect the same type of data the benefit from the harmonisation efforts is more compelling. Some of the EFSA data collection activities have already been conducted routinely for several years while others have only recently been initiated. In particular, in the zoonoses area programmes have been running for longer and have been able to progress technical comparability issues of data.

For the purpose of conducting exposure assessments, it is necessary to be able to combine data on occurrence of chemical or microbiological contaminants or residues with food consumption data. Thus, it is necessary to also consider harmonisation across the different domains. This is particularly relevant for the area of food classification. While not being an easy task, it is important to harmonise this area and the work that EFSA has started in this area is of key importance.

While technical harmonisation is progressing, the monitoring of its implementation through quality control and assurance is still under development. This is an area where further developments need to be and are being initiated.

As discussed above, the food consumption data are not only valuable from a nutrition point of view but they are also essential for risk assessments. The consumption data gathered at EFSA in the Comprehensive European food consumption database and through the EXPOCHI project contain the most up-to-date data on food consumption currently available in the EU and will be very useful in the risk assessment work conducted by EFSA. However, they still include important methodological differences making these data unsuitable for EU-wide analyses and country-to-country comparisons. The collection of accurate and harmonised food consumption data at European level is therefore a primary long term objective for EFSA and has been recognised as a top priority for collaboration with the EU Member States and other countries.[3] Therefore, a project proposal has been developed for the establishment of an EU-wide standardised food consumption data collection system (EUMENU). The added value of this data collection would be the use of methodology providing comparable and information that is detailed enough to be suitable for risk assessment purposes representing all countries and regions in the EU. It is the progression of previously EU-funded initiatives putting into practice this concerted European effort. The collection of food consumption data is planned to be carried out as a rolling program from 2012 to 2017, with a preparatory phase in 2010-2011.

The need for dietary data is included in Regulation (EC) 1338/2008[g] on Community statistics on public health and health and safety at work. The Regulation states that Member States shall supply to the Commission statistics on health status and health determinants (Article 2) and specifies that the method used for the implementation of data collection shall take into consideration national experience and expertise, and national specificities, capacities and existing data collection in the framework of the collaborative networks (Article 5.1). Article 5.2 indicates that the statistical methodologies and data collections to be developed for the compilation of statistics on public health shall take into consideration the need for coordination, whenever relevant, with the activities of international organisations in the field, with a view to ensuring international comparability of statistics and consistency of data collections as well as avoiding duplication of effort and of deliveries of data by the Member States. In this Regulation on Community statistics on public health and health and safety at work, the Collection of

data on diet are specifically included in the Domain health status and health determinants (Annex 1) In particular as stated in Article 6 'whenever data are required in addition to those already collected and to those for which methodology already exist, or when insufficient quality of data is identified in the domains referred to Article 2, the Commission (EUROSTAT) shall institute pilot studies to be completed on a voluntary basis by the MSs...'.

Since the data are owned by the Member States it is important that they have access to the data submitted by them. However, EFSA wishes to provide more than simple download access. EFSA aims to

- provide Member States with access to data which has been transformed for analysis; and
- provide charts, reports, statistical tools and geographical tools which allows intelligence to be drawn from the datasets at a European level or Member State level.

Finally, it should be noted that besides the data mentioned under Article 33, EFSA collects much more data and information to carry out its tasks. As an example, EFSA collects, as required in Article 41 of Regulation (EC) No 396/2005[f] on the setting of MRL for pesticide residues, toxicological reference values to be used in short-term and long-term consumer risk assessment of pesticide residues. Currently the database contains 1150 entries for Acceptable Daily Intake (ADI) values on 650 different active substances and metabolites. Almost 1000 Acute Reference Dose (ARfD) values are available for 530 different active substances. The data collection is made available to competent authorities in Member States via the EFSA extranet. Such data collections fall outside the scope of the present report but could be included in a future more comprehensive review.

CONCLUSIONS AND RECOMMENDATIONS

The collaboration with Member States and the Commission on technical comparability of occurrence data has allowed to make substantial progress in the implementation of harmonised methods to measure biological and chemical agents and food data, as well as on the schemes to record, electronically transfer, store and retrieve data, and report the results.

These data collected in a systematic way now provide reliable information for risk assessors and risk managers at EU level regarding the existence and the description of a food safety risk (e.g. which foods are most affected, which consumer groups are at highest risk). It is essential to collect such data in a systematic way such that much of it is readily available, also in case of crisis. This information is therefore very different from individual alerts that are exchanged through the Rapid Alert System for Food and Feed. The information from this platform can be a trigger for further inquiry.

Considering the progress made on networking on data collection with the Member States and the resulting data reporting and harmonisation activities conducted under Article 33 of the EFSA's Founding Regulation [d], the key priorities proposed by EFSA for further development are as follows:

- establish an EU-wide standardised food consumption data collection system (EUMENU);
- improve technical comparability for food and feed safety data across the different domains;
- establish a quality control and quality assurance system for food safety related data collection by EFSA;
- provide MSs with easy access to the data which they have transferred to EFSA; and
- further harmonise the methodology for conducting exposure assessment.

Table 1. Overview of data collection activities coordinated by EFSA.

Areas	Annual Monitoring	Topical reports	Risk Assessment
Zoonoses	• Trends and Sources of Zoonoses and Zoonotic Agents • Food-borne outbreaks in EU • Antimicrobial Resistance in Zoonotic Agents	• Reports on the analyses of the EU-wide baseline surveys on zoonotic agents in animals and food, such as *Salmonella* and MRSA in breeding pigs and *Salmonella* and *Campylobacter* in broiler meat • Source attribution of human *Salmonella* infections • Report on trends in antimicrobial resistance in food and animals	• Report on *Salmonella* in laying hens and breeding poultry flocks for scientific opinion • Report on *Salmonella* in slaughter and breeding pigs for a scientific opinion • Report on *Campylobacter* in broilers and broiler meat for scientific opinion • Report on *Brucella suis* for scientific opinion
Chemical Contaminants	• Veterinary drug residues • Acrylamide • furan	• Data collection and analysis for PAHs • Data collection and analysis for dioxins	• Exposure assessment on heavy metals, marine biotoxins, aflatoxins, flavourings and smoke flavourings, melamine and nicotine
Pesticides residues	• Pesticides Residues	• Toxicological reference values of active substances	• Residues exposure assessment
Food consumption		• Concise db • Individual data (children) • Comprehensive food consumption db	
Food composition		• Nutrient composition db of EU foods and test criteria	

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GLOSSARY / ABBREVIATIONS

ADI	Acceptable Daily Intake
AFSSA	Agence Française de Sécurité Sanitaire des Aliments
AHAW	Animal Health and Animal Welfare Panel
AMU	Assessment methodology unit
ARfD	Acute Reference Dose
CONTAM	Contaminants Unit
CFP	Call for proposal
EC	European Council
ECB	European Chemicals Bureau
EFCOSUM	European food consumption survey method
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
FAO	Food and Agriculture Organization
GEMS	Graphical Exposure Modelling System
GMO	Genetically Modified Organisms Panel
IGHRC	Interdepartmental Group on Health Risk from Chemicals
IPCS	International Programme on Chemical Safety
ISO	International Organisation for Standardisation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO meetings on pesticides residues
JRC	Directorate General Joint Research Centre
MRL	Maximun Residue Level
OECD	Organisation for Economic Co-operation and Development
PPR	Plant Protection Products Panel
PRIMo	Pesticide Residue Intake Model
SANCO	Directorate General for Health and Consumers
SAS	Statistical Analysis System
SC	Scientific Committee
SQL	Structured Query Language
TDS	Total Diet Study
WHO	World Health Organization
XML	eXtensible Markup Language