

Collaboration

Scientific Cooperation with the European Food Safety Authority (EFSA)

Cristina Alonso Andicoberry, *Scientific Co-ordination Unit. Spanish Agency for Food Safety and Nutrition (AESAN)*

Abstract

Scientific Cooperation between the European Food Safety Authority (EFSA) and the Member States is a basic part of EFSA's foundational Regulation and a priority in its Strategy for Cooperation and Networking and its Strategic Working Plan 2009-2013. Close cooperation with Member States is essential to ensure that consumer's protection and health policies are firmly based on the best scientific evidence available. Its ultimate objective is to unify all the scientific excellence in Europe. Overall scientific cooperation occurs through the national competent authorities, scientific organizations and individual experts.

Key words

Scientific Cooperation, EFSA, Article 36 List, Expert Data Base, Information Exchange Platform.

Introduction

From among the different agencies of the European Union (EU), the European Food Safety Authority (EFSA) is one of the so-called community agencies. As such it is an European Public Law body with independent legal status that performs specific tasks of a technical, scientific or managerial nature and is financed with funds from the EU budget. Nevertheless, the community agencies act, within the framework of their competence, independently to the European institutions (European Commission, European Parliament and Member States).

The EFSA was created in 2002 under Regulation (EC) No 178/2002 (EU, 2002), following a series of food crises at the end of the nineties. Its main role is the scientific and technical assessment and reporting of existing and emerging risks, with respect to the food and feed safety, throughout the whole food chain. This means that its scope covers food, feed, plant health and protection and animal health and welfare.

The creation of EFSA was part of an extensive EU programme to improve food safety in Europe, to guarantee a high level of consumer protection and to restore and maintain the consumers' confidence in European food products.

Ultimately, the EFSA is the EU risk assessor and prepares scientific opinions and advice that provide a solid base to enable risk managers to draw up suitable policies and regulations and to support the European institutions (Commission, Parliament and Council) and the Member States in making relevant and effective decisions.

The EFSA works in close collaboration with the competent national authorities of the Member States in food and feed safety and maintains open communication with all other parties involved. Scientific cooperation between the Authority and the Member States is an essential part of the founding Regulation of the EFSA (EU, 2002) and, therefore, a priority in its Strategy for Cooperation

and Networking (EFSA, 2006) and its Strategic Plan 2009-2013 (EFSA, 2008b). For EFSA, close cooperation with Member States is vital for guaranteeing that consumer protection and health policies are firmly based on the best available scientific evidence (EFSA, 2011d). The latest objective of this cooperation is to benefit from the scientific excellence existing in the Member States.

At a national level, in accordance with article 4.7 of Law 11/2001 (BOE, 2001), by which the Spanish Agency for Food Safety and Nutrition (AESAN) was created, the AESAN is responsible for interlocution with the European Food Authority. This involves the double mission of distributing the information from the EFSA and of transmitting Spanish criteria and viewpoints on the different aspects related to food safety.

EFSA has five pillars of support in the scientific cooperation with the Member States: the Advisory Forum (AF), the Focal Points (FP), the EFSA Network of Experts, the Article 36 List and the Expert Database (EDB), (EFSA, 2011d). To sum up, scientific cooperation takes place through the competent national authorities (AF and FP), scientific organisations (EFSA Network and Article 36 List) and individual scientists and experts (EDB and members of scientific Panels, Working Groups and Scientific Committee).

In parallel with this, in their annual budget the EFSA has allowed for financial aids for certain scientific cooperation activities, and therefore the different strategies of cooperation could equally be classed as financed or unfinanced.

This paper describes the tools used by the European Food Safety Authority to guarantee scientific cooperation with Member States.

Scientific cooperation at national level

Scientific cooperation between the EFSA and the competent national authorities with respect to food, feed, plant health and protection and animal health and welfare is the key to guaranteeing that the Authority is able to provide risk managers with the best scientific opinions, as scientific priorities and the tools required to perform the work are established in collaboration with Member States.

In scientific cooperation at national level, the participants in the cooperation activities represent their Member State.

1. Advisory Forum

The Advisory Forum (AF) connects the Authority to the competent national authorities for food safety in the Member States, Iceland and Norway. In addition, representatives from Switzerland and the EU candidate States take part in the meetings as observers.

The AF has a strategic role, as its members advise the Executive Management of the EFSA on scientific matters, work plans and priorities and, moreover, help with the early identification of emerging risks.

The EFSA, with the assistance of the AF, may join forces with the Member States to identify the areas of interest in Europe for the assessment and notification of the risk. Similarly, the AF plays an essential role in correctly implementing the Strategy for Cooperation and Networking (EFSA, 2006), by providing a suitable framework for developing quality risk assessments based on solid scientific foundations and harmonised methodologies.

One of the main tasks of the AF is to create links between the national institutions, in each Member State, that work within the powers of the EFSA. The objective is to maximise participation and the exchange of scientific information, collaboration to avoid divergent opinions, the promotion of coherence in the communication of risks, the early identification of emerging risks and coordination to avoid duplicating work.

In Spain, the Chair of the AESAN is the national representative in the AF, as a full member. In addition, there are two alternates (Executive Director and the Assistant to the Executive Director).

ESCO Working Groups

The ESCO (EFSA Scientific Cooperation) Working Groups were set up on the basis of recommendations from the Authority's Board of Management (EFSA, 2006). These groups are created in accordance with the guidelines of the AF and of the Scientific Committee of the EFSA.

The groups focus on specific areas of food and feed safety, identified as being of interest to both Member States and the EFSA. To date, seven working groups have been set up for seven ESCO projects focussing on very varied subject matters: safety assessment of plant-based preparations, tackling emerging risks, creation of an expert database, folic acid, establishment of harmonised risk assessment strategies, isoflavones and food contact materials other than plastic materials.

The members of the working groups are national experts recommended by the competent authorities of the Member States via the AF. Members of scientific Panels, the Scientific Committee and scientific personal from the EFSA also take part. The joint projects are supervised by the Steering Group on Cooperation, SGC, formed from members of the EFSA Scientific Committee and of the AF.

The ESCO project reports are sent to the EFSA Executive Management, who decides whether or not further information is required from the scientific Panels or the Scientific Committee.

Given the existence of numerous work networks, the EFSA is currently considering the possibility of reducing the number of ESCO projects and reconsidering the mandate of the Steering Group on Cooperation.

2. Focal Points

The Focal Points Network was set up in 2007. Its main role is to help and support the AF in the creation and strengthening of national networks (that is, within each Member State) and raising the visibility of the EFSA.

It is a co-financed network of scientific cooperation. It is maintained through the annual signing of a cooperation agreement between the EFSA and the competent national authority acting as representative. In Spain, the AESAN acts as the EFSA Focal Point and as such it is responsible for distributing relevant information in the form of newsletters and for the organisation of various meetings.

To date, the EFSA has signed agreements with all the Member States, Iceland and Norway. Observers belonging to the network include Switzerland, a member since the start of the Focal Points, and the EU candidate countries since September 2009.

The functions of the Focal Points are varied and include the exchange of information with the EFSA and other Focal Points in areas of interest, the collection of risk assessment data in specific areas, the

maintenance of the Information Exchange Platform (IEP), publicity of and support to the EFSA in the inclusion of experts in the Database and the maintenance, extension, improvement and strengthening of the Article 36 List.

Ultimately, the objective of the Focal Point network is to improve and enhance the visibility of the EFSA within the Member States. Therefore, the Focal Points perform and organise activities in their respective countries, including the creation of specific web pages, the publication of calls, calls for data and other requirements from EFSA and the organisation of national events to which, among others, members of the EFSA or other Focal Points are invited.

In Spain, the Focal Point has its own space on the AESAN web page and, in addition it uses an electronic newsletter to send information to its recipients: The newsletter, nodoAESAN informa, in which all news relating to the EFSA is published, in addition to other news of interest to AESAN.

The Focal Points meet three times a year to exchange experiences, receive additional information from the EFSA and to further develop their networks.

3. EFSA Network of Experts

The creation and coordination of networks of national organisations (represented by experts) which operate within their field of action is one of EFSA's duties, as defined in article 23(g) of Regulation (EC) No 178/2002 (EU, 2002). Moreover, a wide range of sectorial legislation is available (for example, in the area of genetically modified organisms), establishing close collaboration between the Authority and Member States.

The standards for creating and using these networks are defined in an EFSA Board of Management Decision published in 2010 (EFSA, 2010b). According to this Decision, the networks shall be formed of representatives from scientific organisations in the Member States, usually one per country, appointed by the AF.

Currently there are a number of networks in operation:

- Expert Group on Chemical Occurrence
- Pesticide Steering Committee
- Networking Group on Pesticide Monitoring
- Task Force on Zoonoses Data Collection
- Expert Group on Food Consumption
- Scientific Network for Risk Assessment of GMOs
- Scientific Network for Risk Assessment in Plant Health
- Scientific Network for Risk Assessment in Animal Health and Welfare
- Scientific Network for Microbiological Risk Assessment
- Scientific Network on BSE/TSE
- Network on Emerging risks
- Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed

The activities of these networks are to be further clarified in the near future and documented every year; moreover, the AF is to be regularly notified of the results and activities of each network (EFSA, 2011d).

Financing support of the EFSA

As part of the financed and co-financed scientific cooperation, EFSA offers calls for grants and procurements.

The calls for grants (calls for proposals) are aimed at the organisations included in the Article 36 list. The Article 36 List has its legal basis in article 36 of Regulation (EC) No 178/2002 (EU, 2002), and more specifically, in section 2 which indicates that:

The Management Board, acting on a proposal from the Executive Director, shall draw up a list to be made public, of competent organisations designated by the Member States, which may assist the Authority, either individually or in networks, with its mission. The Authority may entrust to these organisations certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, collection of data and identification of emerging risks. Some of these tasks may be eligible for financial support.

At present, the List includes almost 400 organisations, of which, to date, 22 are Spanish (Table 1).

Table 1. Article 36 list. Spanish organizations

1	Agencia Catalana de Seguridad Alimentaria (ACSA)
2	Centro Nacional de Alimentación (CNA-AESAN)
3	Consejo Superior Investigaciones Científicas (CSIC)
4	Departamento de Nutrición y Bromatología. Facultad de Veterinaria. Universidad de Murcia
5	Departamento de Nutrición, Bromatología y Tecnología de los Alimentos. Facultad de Veterinaria Universidad Complutense de Madrid
6	Fundación Centro de Investigación en Sanidad Animal (CRESA)
7	Fundación Vasca para la Seguridad Agroalimentaria (ELIKA)
8	Grupo de Investigación en Seguridad Alimentaria y Microbiología de Alimentos (DHT03/GR155) Facultad de Veterinaria. Universidad de León
9	Grupo SALUVET. Departamento Patología Animal I (Sanidad Animal). Facultad de Veterinaria Universidad Complutense de Madrid
10	Instituto de Investigación y Tecnología Agroalimentarias (IRTA)
11	Instituto de Nutrición y Tecnología de Alimentos (INRYA)
12	Laboratorio Agroalimentario de Cabriels. Generalitat de Cataluña
13	Laboratorio Arbitral Agroalimentario de Madrid. Ministerio de Medio Ambiente y Medio Rural y Marino
14	Laboratorio Central de Veterinaria de Algete. Ministerio de Medio Ambiente y Medio Rural y Marino
15	Laboratorio de Biología Molecular, Nutrición y Biotecnología. Universidad de las Islas Baleares
16	Laboratorio de Micología Clínica. Facultad de Veterinaria. Universidad Complutense de Madrid
17	Laboratorio de Referencia de la Unión Europea de Biotoxinas Marinas (EURLMB-AESAN)
18	Laboratorio de Salud Pública de Lugo. Consellería de Sanidade. Xunta de Galicia
19	Laboratorio Regional de Salud Pública. Comunidad de Madrid
20	Servicio de Análisis de Fármacos. Facultad de Veterinaria. Universidad Autónoma de Barcelona
21	Universidad Complutense de Madrid
22	Universidad de Córdoba
23	Universidad de Santiago de Compostela

Source: (EFSA, 2011c).

Financing of the calls in article 36 is carried out through the so-called grants (with the signing of a convention). Only organisations included in the official list of article 36 may opt for financial aid. This is not the case with the procurements (agreed with the signing of a contract), for which the application is open to any organisation that meets the requirements established in the call. In addition, as can be seen in Table 2, the objectives and format of the two types of call are different.

	<i>Grants</i>	<i>Procurements</i>
Aim	To provide financial aid to carry out a task	To purchase a service
Data ownership	Beneficiary of the call	EFSA
Economic contribution from EFSA	90% of total cost estimate submitted by the beneficiary	Agreed price
Type of call	Call for proposal	Call for tender
Legal format	Agreement	Contract

In line with Regulation (EC) No 2230/2004 (EU, 2004), there are three areas of work in which the EFSA may request collaboration from organisations in the list:

- Data collection.
- Preparatory work for scientific opinions.
- Other scientific and technical assistance.

Every year EFSA publishes on their web page a forecast of the budgets allocated to each of these areas, with a proposal for the potential areas in which article 36 calls (calls for proposals) will be published.

The proportion of the annual budgets allocated to grants and procurements has been observed to be increasing. Nevertheless, the portion of the budget allocated to grants has hardly changed,

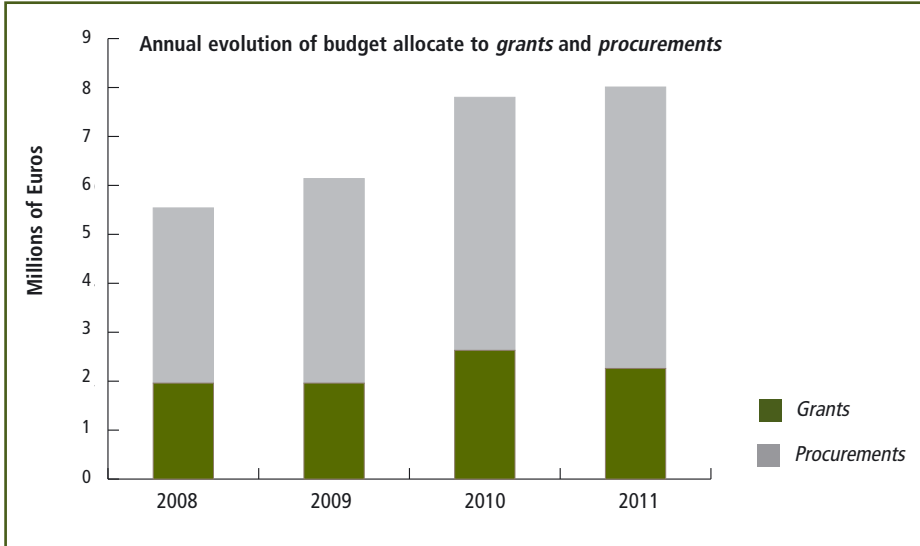


Figure 1. Annual evolution of the EFSA budget allocated to grants and procurements.

In addition, the number of annual calls for procurements is higher than that for grants (Figure 2).

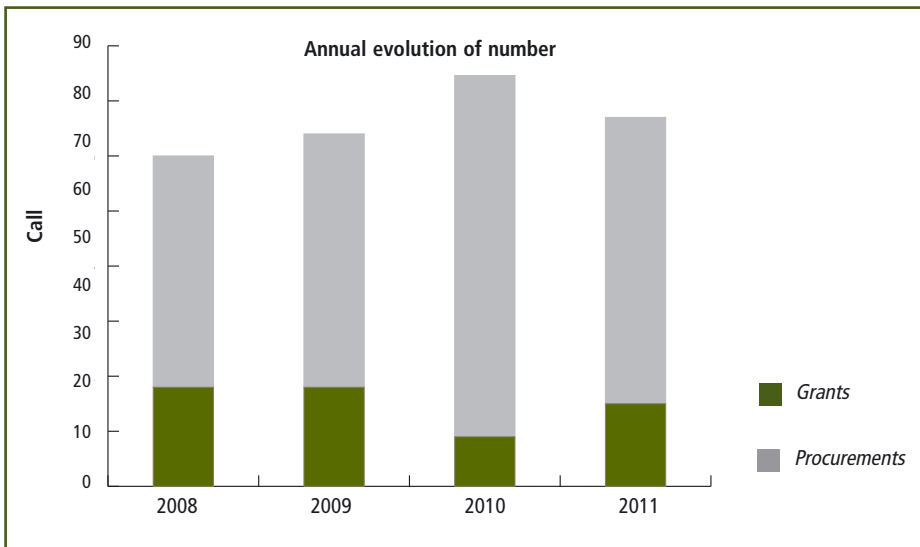


Figure 2. Annual evolution of the number of calls for proposals and tenders.

To increase the number and level of participation of Spanish organisations, the AESAN is working on the harmonisation and enlargement of the Spanish List. This harmonisation aims to reduce the number of small organisations or organisations without their own legal capacity to sign agreements with the EFSA in favour of larger organisations, legal entities in themselves with, therefore, greater possibilities of participation. In addition, the activities carried out by AESAN to improve Spanish participation in the article 36 calls include various informative workshops, with the participation of EFSA, and Spanish organisations with experience in this type of calls, and in the calls for procurements, and with the participation of representatives from other European organisations with broad experience in this area, such as ANSES. Representatives from the Spanish organisations in the article 36 List have taken part in these workshops, together with representatives from organisations which have shown an interest in being included in this list and members of the AESAN Scientific Committee.

Participation in either type of call (grants or procurements) may be individual (a single organisation) or in consortia formed from various organisations, from the same country or from different countries (Table 3).

Year	Grants or Procurements with Spanish participation	No of Spanish organisations
2007	1	2 (CReSA and the Complutense University of Madrid)
2008	1	1 (CReSA)
2009	2	1 (IRTA)
2010	0	0

Sources: (EFSA, 2008a, 2009a, 2010a, 2011b).

Scientific cooperation at individual level

1. Expert Database

The Expert Database (EBD) was set up in June 2008. Its main objective is to permit all those experts with proven experience working in the field of action of the EFSA, to form part of a database of external scientists able to assist the Authority and Member States in their activities.

Since its creation, the number of experts included in the EBD, has increased at a rate of approximately 100 applications per month. Applications are assessed and the EFSA decides whether or not to include the expert in the database. On the date of publication of the last report relating to the EBD (EFSA, 2011d), 2600 experts had been included in the database. Of these, 92% belong to different scientific organisations, 4% are self-employed, 3% are retired and 1% indicated that they were unemployed. Of the experts belonging to scientific organisations, 38% stated that they are employed by universities or other academic institutions, 32% work in government organisations (for example, national food safety agencies), 17% in other public institutions, 7% in private institutions, 3% in non-governmental organisations and the remaining 3% work in foundations or other types of institution (EFSA, 2011d). In October 2011, there were 150 Spanish experts registered in the EBD.

On the whole, all the areas of work of the EFSA are covered by the EDB. Certain fields, for example “new technologies” or “plant health” appear to be areas requiring some reinforcement in the number of experts registered, together with “GMO”, “toxicology” and “exposure assessment”.

The experts in the EBD belong to a wide range of countries. They are mostly from the European Union, although there is also a significant representation from countries such as the United States, Canada or Australia. Similarly, although to a lesser degree, the EU Candidate Countries (Turkey, Croatia and the Former Yugoslav Republic of Macedonia) are also represented.

Since its creation in 2008, the Focal Points have been responsible for much of the promotion of the EBD.

To register on the Database as an expert, an application must be submitted via the EFSA web page, providing information on the scientific experience of the applicant, publications and other aspects of interest (EFSA, 2011e).

2. Scientific Committee and EFSA Scientific Panels

Scientific Committee

The task of the Scientific Committee is to support the EFSA scientific panels on scientific matters of a horizontal nature, and to advise the Authority's Executive Management.

Similarly, it is responsible for the general coordination of the scientific opinions of the Panels and focuses its efforts on the development of harmonised risk assessment methodologies in those areas where EU-wide approaches are yet already undefined; for example, emerging risks, exposure assessment, tackling the exposure margin for substances that are both genotoxic and carcinogenic, or the scientific and procedural aspects that guarantee the transparency of the EFSA in risk assessments.

The Scientific Committee produces scientific opinions and offers advice to the risk managers. To do so, it operates independently and with transparency, carrying out its work in response to requests from the risk managers but also on its own initiative. All work is undertaken on the basis of certain terms of reference. The Scientific Committee frequently organises Working Groups involving external scientists, who may be drawn from the EBD.

To carry out their work, the Committee holds regular plenary sessions at which the work is discussed and scientific opinions adopted. Each opinion arises from a collective process of decision-making in which each member of the Committee holds an equal vote.

Currently the Committee is made up of 16 members, of which ten are chairs of the EFSA scientific Panels and the other six are independent scientists. Members of the Committee are selected by the Board of Directors of EFSA for a renewable period of three years. Appointments are based on the scientific excellence of the selected candidates after an open process of call for renewal. There is no Spanish representation on the existing Committee (2009-2012).

The EFSA Scientific Committee Unit offers administrative and scientific support to the Committee and may carry out other projects within the powers of the EFSA. The Unit may also produce scientific output on behalf of the Authority, for example in response to the urgent request for scientific advice.

With respect to cooperation with the national authorities of Member States, this is achieved through subcontracting. Examples of this include the recent contracts for collaboration in the work on

risk assessment terminology and the applicability of physical and chemical data, the Quantitative Structure-Activity Relationship (QSAR) and the extrapolation of the threshold in the Threshold of Toxicological Concern (TTC) assessment.

Scientific Panels

Unlike the Scientific Committee, whose task focuses on areas of a general scientific nature, the Panels have specialised scientific responsibilities. At present there are ten scientific panels in the EFSA:

- Animal Health and Welfare (AHAW).
- Biological Hazards (BIOHAZ).
- Contaminants (CONTAM).
- Plant Health (PLH).
- Additives and Products or Substances used in Animal Feed (FEEDAP).
- Dietetic Products, Nutrition and Allergies (NDA).
- Food additives and nutrient sources added to food (ANS).
- Food contact materials, flavourings, enzymes, and processing aids (CEF).
- Genetically Modified Organisms (GMO).
- Pesticides (PPR).

Each of these panels has the administrative support of the corresponding Unit with the same name.

The panels are made up of European experts of different nationalities with experience in the areas of interest. As with the Scientific Committee, members are elected by the EFSA Board of Directors for a renewable period of three years on the basis of the scientific excellence of candidates selected after an open process of call for renewal.

The Panels often request the help of external experts for the formation of Working Groups.

The Panels draw up opinions on risk assessment matters within their area, on evaluation reports on substances and products and they also prepare guidelines. As the regulatory base for each of these three main areas of work is different, cooperation with Member States is organised in a different way.

With respect to general risk assessments, when scientific cooperation is required, this is sought through subcontracting, especially through grants (i.e. calls in article 36; see Table 2). It is also carried out by sharing the mandates with the EFSA networks, organising conferences and workshops to discuss strategies for tackling the mandates or to discuss drafts of scientific opinions. EFSA also organises specific projects for collecting data to ensure that they have the best available data from the scientific organisations in the Member States and from other parties involved. In addition, they invite competent authorities from the Member States to share their risk assessment output on the Information Exchange Platform (IEP). Similarly, the competent national authorities may take part in public and targeted consultations on the drafts of opinions. Final opinions may be presented to the Standing Committee on the Food Chain and Animal Health (SCFCAH) for discussion, as required, thereby fostering mutual understanding between the Member States and the Authority. In addition, the specific networks offer a forum for the EFSA panels, the Units involved and the experts from the competent authorities. As a result of these talks, in some cases self-imposed mandates have been produced in the Panels on areas of mutual interest.

The evaluation of products, substances and claims that must be assessed or re-assessed in accordance with European legislation is an working area that has been increasing gradually in the recent years, creating a significant work load for the Authority, as in some cases, for example the assessments of nutrition and health claims (EU, 2006), the responsibility lies directly with the EFSA. In 2009, they made up 68% of the total number of scientific results of the Authority, requiring an ever-increasing quantity of resources (EFSA, 2011d). In addition to the legal provisions affecting this area within the founding Regulation of the EFSA, there is considerable specific sectorial legislation. Cooperation in this area is achieved in several ways. Firstly, through subcontracting; in this case, particularly through procurements (contracts). Secondly, the preparatory work is carried out by the competent authorities of the Member States, where this is established in sectorial legislation, together with the collection of data on specific substances. The data is collected provided there are no applicants involved (for example, in re-assessments). Thirdly, through the assessment of the comments received from the national authorities of the Member States on the applications and reports.

Other areas of scientific cooperation

1. Regular data collection programmes

In addition to the specific calls for data of a set length published by the EFSA and distributed by the Focal Points in each country, there are a number of ongoing programmes for the collection of data. The collection of reliable, representative data in quantity is essential for the performance of risk assessments.

The collection of data relating to foods and feed has its base and mandate in the founding Regulation of the EFSA (EU, 2002) and in the extensive specific community legislation, for example, Directive 2003/99/EC (EU, 2003) or Regulation (EC) No 396/2005 (EU, 2005). To coordinate data collection, networks with representatives from the Member State institutions have been created. To guarantee the validity of the data, appropriate methods for its analysis are essential. Therefore the EFSA is also responsible for the task of making recommendations to the Member States and to the European Commission to improve the technical compatibility of the data it receives. Technical compatibility is a point on which the founding Regulation of the EFSA (EU, 2002) places considerable importance and which affects both the collection of data and the transfer, storage and recovery of the data. Uniform and predefined methodologies are required in the data collection processes to guarantee that the data collected is good enough for subsequent use. The EFSA has created certain working groups to develop harmonised data collection protocols in specific areas.

On the basis of the data collection programmes, the EFSA publishes a series of documents, some of which are annual, such as the Community Zoonoses Report, prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC) or the Annual Report on Pesticide Residues in food. Other documents are prepared ad hoc, as the need arises, such as those written about particular microorganisms or certain contaminants. These types of report permit both the characterisation and the control of the risks. Therefore, they help in the preparation of risk assessments and also serve to monitor compliance to management measures of the same.

At present the main data collection activities focus on exposure through food to microbiological and chemical contaminants, pesticides and to veterinary medical products. In this respect, new

activities are emerging, mainly related to the control of regulated substances after their release in the market; for example, food additives or control data on environmental exposure to GMO.

To make quantitative risk assessments and exposure evaluations, the emerging data on chemical contaminants, residues or microbial agents must be combined with data on food consumption. This is why the harmonisation of working methodologies is complicated as it affects different areas of work.

Zoonoses, antimicrobial resistance and food-borne outbreaks

To prepare the annual report on zoonoses, antimicrobial resistance and food-borne outbreaks, in collaboration with the ECDC, the EFSA provides Member States with some general guidelines. In addition, it has published harmonised specifications for the control and publication of data on zoonotic agents in food and animal populations, food-borne outbreaks and verotoxigenic *Escherichia coli* and *Yersinia enterocolitica* in animal populations. Similarly, calls have been published for article 36 projects which provide new guidelines for the control and harmonised publication of data on zoonotic parasites, Q fever, rabies, etc.

In addition, the EFSA has also drawn up protocols and has analysed data from a series of preliminary questionnaires on zoonotic agents in animal and food populations, the results of which are used to establish European objectives for the reduction of the prevalence of *Salmonella* in various animal species. It is also used as a base if management measures are needed for other zoonotic agents.

With respect to Spain, the AESAN is the competent authority for coordination with the autonomous regions in regard to ensuring the correct monitoring of the zoonoses transmitted by foods destined for human consumption.

AESAN activity in this area aims to comply with that established in article 3 of Royal Decree 1940/2004 (Real Decreto, 2004) and article 9 of Directive 2003/99/EC, on the monitoring of zoonoses and zoonotic agents, and consists in coordinating the collection of information by the autonomous regions, analysing it, carrying out the relevant studies, and acting as the point of contact with the EFSA for the activities and projects developed for the control of zoonoses in food.

In addition, the research data on zoonotic agents in foods is collected annually from the autonomous regions and submitted to the European Commission using the data communication system created by the EFSA since 2005, in order to obtain uniform data which is comparable among all the Member States.

Pesticide residues

Pursuant to article 32 of Regulation (EC) No 396/2005 (EU, 2005), the EFSA is responsible for the preparation of the Annual Report on Pesticide Residues. This task involves the collection of the results of the pesticide control tests carried out by Member States and countries in the European Economic Area (EEA), the analysis of the data collected and an assessment of the true exposure of European consumers to pesticide residues.

Unlike the procedure for the risk assessment of Maximum Residue Levels (MRL), which uses the measured concentration of the residue in supervised field trials, the true assessment of the exposure uses "real" residues quantified in products on the European market.

Since 2010, the EFSA has been receiving the control data in a new Standard Sample Description (SSD) format, which permits disaggregated data and information to be sent, and to unify the structure of the data for all the Member States, thus obtaining quality information which is easily comparable at the level of individual determinations. In 2010, more than 60,000 samples of fruit, vegetables, cereals and other foods of animal or plant origin were tested for residues from approximately 600 pesticides. This led to more than 17 million determinations. The annual collection of data on pesticide residues will enable the creation of a database which may be used to analyse trends with respect to the appearance of waste and exposure of consumers.

In Spain, AESAN is the point of contact with the EFSA and with the Commission regarding the collection of data from the Programme for Pesticide Residue Monitoring and Control, and the organisation for coordination with the autonomous regions. Therefore in order to facilitate the incorporation of the new format established by EFSA, in 2010 AESAN developed a national database totally adapted to the SSD, which would permit the collection of information from all the units of the autonomous regions and transfer it to the EFSA quickly and efficiently.

In addition, since 2009, AESAN has taken part in the Pesticide Residue Control Network.

Harmonised food consumption database

The risk assessment procedure involves four different but closely linked activities: hazard identification, hazard characterization, exposure assessment and risk characterization. The exposure assessment requires the determination of the consumer's exposure to a certain risk. With respect to human food, information about the concentration of hazardous substances in food is required and this information is then combined with data on the quantity of food consumed. Therefore, the quality of the risk assessment is directly affected by the accuracy, detail and possibility of comparing the available consumption data.

In 2005, during a scientific colloquium (EFSA, 2005), the Scientific Committee for the EFSA recommended the creation of a harmonised consumption database at pan-European level. In collaboration with the Member States, the EFSA set up the Concise European Food Consumption Database, which has been operative since February 2008. This database contains information from individual food surveys in 19 European countries, although the data has not been combined because different methods were used to collect the information; moreover, this database only offers information about consumption grouped into large food categories. Therefore, at the end of 2008, the EFSA started a project aimed at establishing the Comprehensive European Food Consumption Database, using data from most recent national food surveys. In the same year, the EFSA also published a call for article 36 focussing on child consumption. The new Comprehensive Database contains food consumption data for adults and children from 20 and 15 Member States, respectively.

Given the importance of harmonisation in all areas and particularly in the classification of foods, the EFSA has embarked on a significant task in this challenging area. Firstly, in 2009 (EFSA, 2009b), a guide was published listing the general principles for the collection of consumption data in surveys. In 2011 (EFSA, 2011a), EFSA published a scientific report on FoodEx, the food classification system for use in the Comprehensive European Food Consumption Database.

This database is currently the most extensive and up-to-date of the databases available in the EU. However, it faces difficulties as the collaborating Member States and their scientific organisations use different methodologies, and consequently the data is unsuitable for use in an analysis at European level or for comparisons between countries. This is the reason that the collection of precise and harmonised data in Europe is considered to be a priority of cooperation between EFSA and the Member States, and with other countries, and a project has been developed to create a standardised food consumption data collection system in the EU: the EUMENU. At the same time, to incorporate new data in the database, the EFSA has opened a call for procurement: Update of EFSA Comprehensive European Food Consumption Database.

The role of AESAN in this area involves participation in the Food Consumption Data Expert Group, belonging to the group of networks supporting the EFSA units; specifically, with respect to the Dietary and chemical monitoring unit. In addition, AESAN is working on the inclusion of national food consumption data, obtained in the ENIDE survey (National Survey of Spanish Dietary Intake), in the Comprehensive European Food Consumption Database, which requires the classification of all the data in accordance with the FoodEx system.

2. Exchange of scientific information

Information Exchange Platform

The Information Exchange Platform (IEP) was created in 2008 to facilitate the exchange of information about activities of a scientific nature in the Member States. The Platform contains documents relating to risk assessments, work plans, crisis management manuals, quality manuals and country profiles.

In August 2011, the IEP contained 945 documents, of which almost 800 are risk assessment outputs. In Spain, AESAN handles the inclusion of data in the IEP and has uploaded all the reports by its Scientific Committee since the creation of the Platform.

In September 2008, a Working Group was created within the Focal Points network to improve and review the development of the IEP, responsible for making proposals for the development of the platform. Initially, only members of the Advisory Forum and the Focal Points had access to the IEP. In 2009, read-only access was extended to include all members of the scientific panels and individual contacts proposed by the AF. Therefore, the Focal Points have been responsible for the inclusion of the majority of the existing documents in the Platform.

National competent authorities work plans

The general objective of this initiative is to improve knowledge about the activities planned at national level and to avoid possible duplications of work. Originally, the documents were shared on the IEP; however, there is huge variety in the way in which different Member States and their competent national authorities prepare their work plans, making it difficult to summarise all the documents in order to make a harmonised assessment of them.

Therefore, the EFSA Scientific Cooperation Unit has drafted a harmonised and simple format in collaboration with the Focal Points, in the form of a table. This system permits the listing of the activities planned for risk assessment, and for data collection and research, and is the system chosen by AESAN to incorporate information about their work plans.

Thanks to both methods, information is now available on the IEP about the work plans and programmed activities in 18 countries.

Conferences and meetings with the competent national authorities

When necessary, the EFSA invites national experts appointed by the competent national authorities in each Member State to meetings at which they discuss and share scientific experiences, and sensitive or controversial subjects. This type of activity helps the EFSA in their work, by enabling the exchange of points of view and obtaining information from highly qualified experts.

One of the best-known examples of this type of meeting is that held to assess the safety of aspartame. Aspartame is an artificial sweetener authorised in some countries for several years, about which the EFSA prepared a scientific opinion in 2006 (EFSA, 2006). At the initiative of the EFSA, in liaison with the Advisory Forum, 18 experts from ten different risk assessment organisations were invited to three meetings held between November 2009 and January 2010.

Another example of joint events is the event held in Seville in February 2010, organised between the EFSA and the Spanish Agency for Food Safety and Nutrition (AESAN): Science Supporting Risk Surveillance of Imports; or that held in October 2008 and organised with the French Agency for Food Safety (now ANSES): Assessment of the health risks of food, animal and plant imports in the European Union.

Lastly, a joint event organised by the EFSA and the Dutch Food and Consumer Product Safety Authority (VWA) in 2008, led to a special issue of the *International Journal on Food Microbiology* (Vol.139, Suppl. 1, 2010), with several articles on Microbial Risk Assessment.

EFSA Scientific Colloquia

The scientific colloquia were set up in 2004 to create a forum for debate and scientific discussion among scientists from the EU and other countries. EFSA hosts at least one colloquium per year. The subject area varies according to the subjects of interest in the area of food and feed and the final objective is to deepen understanding of these topics.

Each colloquium has an organising committee that prepares briefing notes for the participants, including a set of discussion points. In addition, each event is organised into separate work groups, with plenary sessions at which the conclusions of each group are discussed. At these sessions the conclusions are agreed and, as appropriate, recommendations made to the EFSA and the relevant panels. Lastly, a final report is drawn up and published by the EFSA.

16 scientific colloquia have been held to date, the most recent of which was in June 2011.

Public consultations

Making public consultations about draft scientific opinions is part of the EFSA's commitment to transparency, scientific quality and efficiency. This fosters the EFSA's interaction with European citizens, consumers and all the parties involved, including competent national authorities. To encourage the participation of all the parties concerned, the EFSA publishes these consultations on their web page, as well as reporting them to the members of the AF and the Focal Points for their diffusion at national level.

Initially, although these public consultations may not be considered as strategies of scientific cooperation in themselves, they form part of this category as, in the majority of cases, the scientific organisations of the Member States are the organisations that most contribute with their observations.

Public consultations are made when the EFSA receives a new type of question, for example in areas in which the EFSA has not previously given an opinion. Emerging or complex scientific subjects are another example of situations in which the EFSA may make a public consultation.

Public consultations began in 2005 and 72 have been made since then. These include the guidelines concerning the safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements (2008); draft scientific opinions on Dietary Reference Values (previously called Population Reference Intakes) (2009) and on food-borne antimicrobial resistance as a biological hazard (2008) or the welfare aspects of genetic selection in broilers (2010).

Training requirements

The Strategy for Cooperation and Networking (EFSA, 2006) states that the EFSA must establish a programme of courses on risk assessment that involve experts from the Member States. This requirement was reiterated in the internal review of this document in 2008, following a request from the Member States to EFSA to increase training activities.

Therefore, the EFSA set up an initiative to determine the areas in which Member States considered training to be more necessary. The Scientific Cooperation Unit, together with the Focal Points, analysed the opportunities for training in food safety risk assessment offered by leading European and international institutions and by each Member State. On a national level, countries notified the EFSA Scientific Cooperation Unit, through their Focal Points, of a large number of training opportunities, in a broad variety of subjects.

On the whole, Member States mainly request training in general areas of risk assessment. Apart from the ECDC in Stockholm, few European or international organisations have a specific training programme in risk assessment. Nevertheless, ad hoc conferences and seminars are available. Similarly, the EFSA has organised exercises in collaboration with the competent national authorities and the European Commission to practice and test the effectiveness of collaboration in response to urgent requests. These exercises usually take the form of crisis simulation exercises.

Since 2006, the European Commission offers a training programme in food safety called Better training for safer food, which mainly focuses on risk and control management and is directed at personnel from the competent national authorities of Member States and candidate countries.

Another training programme also financed by the European Commission is the Toxicology Risk Assessment Training (TRISK), which offers training in toxicology risk assessment.

To conclude, although different organisations offer some variety of training activities, there would appear to be certain limitations in the provision of training in the general principles of food safety risk assessment. Consequently, the EFSA has recently organised a working group whose task is to develop a training module in general principles and methods of risk assessment. These modules will be introduced by EFSA personnel and external scientific experts.

It should be noted that the EFSA does not have the mandate to organise training courses for experts not being part of the Authority's staff and that the European Commission already has a programme in this area. In this context, the EFSA has strengthened collaboration with the Commission's service responsible for training programmes in food safety in order to increase the number of training opportunities.

References

- BOE (2001). Ley 11/2001 de 5 de julio, por la que se crea la Agencia Española de Seguridad Alimentaria y Nutrición. BOE 161 de 6 de julio de 2001, pp: 24250-24255.B
- EFSA (2005). European Food Safety Authority. EFSA 3rd Scientific Colloquium Report European Food Consumption Database-Current and medium to long-term strategies. Available at: <http://www.efsa.europa.eu/en/supporting/pub/110e.htm> [accessed: 6-10-11].
- EFSA (2006). European Food Safety Authority. Strategy for Cooperation and Networking between the EU Member States and EFSA. Available at: <http://www.efsa.europa.eu/en/keydocs/docs/msstrategy.pdf> [accessed: 6-10-11].
- EFSA (2008a). European Food Safety Authority. Annual List of Grant Agreements 2007. Available at: <http://www.efsa.europa.eu/en/art36grants/docs/art36grantsagreements2007.pdf> [accessed: 6-10-11].
- EFSA (2008b). European Food Safety Authority. Plan Estratégico de la Autoridad Europea de Seguridad Alimentaria para 2009-2013. Available at: <http://www.efsa.europa.eu/en/corporate/doc/stratplan09es.pdf> [accessed: 6-10-11].
- EFSA (2009a). European Food Safety Authority. Annual List of Grant Agreements 2008. Available at: <http://www.efsa.europa.eu/en/art36grants/docs/art36grantsagreements2008.pdf> [accessed: 6-10-11].
- EFSA (2009b). Guidance of EFSA. General Principles for the collection of national food consumption data in the view of a pan-European dietary survey. *EFSA Journal*. doi:10.2903/j.efsa.2009.1435.
- EFSA (2010a). European Food Safety Authority. Annual List of Grant Agreements 2009. Available at: <http://www.efsa.europa.eu/en/art36grants/docs/art36grantsagreements2009.pdf> [accessed: 6-10-11].
- EFSA (2010b). European Food Safety Authority. Decision concerning the establishment and operation of European Networks of scientific organizations operating in the fields within the Authority's mission. Available at: <http://www.efsa.europa.eu/en/keydocs/docs/networksoperation.pdf> [accessed: 6-10-11].
- EFSA (2011a). Evaluation of the FoodEx, the food classification system applied to the development of the EFSA Comprehensive European Food Consumption Database. *EFSA Journal*. doi:10.2903/j.efsa.2011.1970.
- EFSA (2011b). European Food Safety Authority. Annual List of Grant Agreements 2010. Available at: <http://www.efsa.europa.eu/en/art36grants/docs/art36grantsagreements2010.pdf> [accessed: 6-10-11].
- EFSA (2011c). European Food Safety Authority. List of competent organisations designated by the Member States which may assist the Authority with its mission. Decisión del Consejo de Dirección de EFSA. Adoptada el 16 de junio de 2011. Available at: <http://www.efsa.europa.eu/en/art36grants/docs/art36listg.pdf> [accessed: 6-10-11].
- EFSA (2011d). European Food Safety Authority. Technical report of EFSA on Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead. Available at: <http://www.efsa.europa.eu/en/supporting/doc/97e.pdf> [accessed: 6-10-11].
- EFSA (2011e). European Food Safety Authority. Available at: <http://www.efsa.europa.eu/en/networks/expertdb.htm> [accessed: 6-10-11].
- EU (2002). Corrigendum to 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 of February 2002, pp: 1-24.
- EU (2003). 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 of December 2003, pp: 31-40.

EU (2004). Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission. OJ L 379, 24 of December 2004, pp: 64-67.

EU (2005). Corrigendum to 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 of March 2005, pp: 1-16.

EU (2006). Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods. OJ L 404, 30 of December 2006, pp: 9-25.

Real Decreto 1940/2004, de 27 de septiembre, sobre la vigilancia de las zoonosis y los agentes zoonóticos. BOE 237 de 1 de octubre de 2004, pp: 32772-32777.