European Food Safety Authority

SCIENTIFIC COOPERATION UNIT

TECHNICAL REPORT OF EFSA[1]

on

Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead

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1 SUMMARY

Scientific cooperation between the European Food Safety Authority (**EFSA**) and European Union (**EU)** Member States is an integral part of EFSA's Founding Regulation (EC) No 178/2002[3] and thus is a key priority of EFSA, as set out in its Strategic Plan 2009-2013[4][5]. The December 2006 EFSA Strategy for Cooperation and Networking[6] identified four priority areas for scientific cooperation between EFSA and Member States. Two years later, an Interim Review[7] of the Strategy aimed at further strengthening the cooperation. Strong cooperation with Member States remains crucial for EFSA to ensure that consumer protection and health policy are supported by the most robust scientific evidence available. It takes place through national competent authorities, scientific organisations, and individual experts.

This Report summarises scientific cooperation activities of EFSA's Scientific Committee (**SC**), its Panels and Units in the area of food and feed safety, animal health and welfare, plant health and plant protection, while also looking at the challenges that are waiting for EFSA in the coming years. It covers data collection, research and scientific evaluation activities which underpin EFSA's work.

The Advisory Forum, Focal Points, and dedicated networks are key vehicles for data and information exchange, consultation, and work sharing between EFSA and Members States. The importance of networks, both for supporting the risk assessment process and for data collection programmes, will further increase. These networks facilitate scientific cooperation through the coordination of activities, the exchange of information (e.g. on recent risk assessment activities or on data collection), the development and implementation of joint projects (e.g. scientific events and workshops), and the exchange of expertise and best practice in the fields within EFSA's mission. Under Article 36 of EFSA's Founding Regulation, the Authority can award grants to organisations that have been officially nominated by Permanent Representations of Member States to assist EFSA in its tasks - a successful way to bundle expertise and resources at national and EU level. In addition, the Authority commissions scientific projects under procurement. Effective pooling of excellence is also supported through EFSA's steadily growing Expert Database, which is accessible to EFSA and to competent authorities in Member States to search and identify the most appropriate experts available. The following specific cases provide examples of efficient scientific cooperation:

(a) In the area of contaminants in the food chain, Member States cooperate with EFSA by submitting occurrence data for various contaminants in food and/or feed (e.g. heavy metals, persistent organic pollutants, and marine biotoxins). Dietary habits can vary considerably between Member States. Hence, it is important to assess exposure in the Member States. A good example is a series of risk assessments related to marine biotoxins carried out by the Panel on Contaminants in the Food Chain (**CONTAM**). To this purpose the unit dealing with Data Collection and Exposure (**DATEX**) compiled data submitted by competent authorities in Member States on both toxin occurrence and shellfish portions consumed in single meals. These data enabled the CONTAM Panel to identify an appropriate estimate of a large portion size consumed in Europe to be used in the risk assessments, and thus helped protecting consumers with a high consumption of shellfish against acute effects of marine biotoxins.

(b) Since 2005, EFSA also ensures a close collaboration with competent authorities in Member States in the framework of applications in the area of genetically modified organisms (**GMO**) for cultivation (submitted under Regulation (EC) No 1829/2003). In this context, EFSA collaborates with competent

[3] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

[4] EFSA's Strategic Plan 2009-2013 can be found in all EU languages at http://www.efsa.europa.eu/en/keydocs/strategicplan.htm

[5] The Work Plan 2010 is available at http://www.efsa.europa.eu/en/workplan/docs/wp10.pdf

[6] http://www.efsa.europa.eu/en/keydocs/docs/msstrategy.pdf

[7] http://www.efsa.europa.eu/en/keydocs/docs/msstrategyreview.pdf.

authorities of Member States that have volunteered to take charge of the initial Environmental Risk assessment (**ERA**) of GMO applications for cultivation. In 2010 the dialogue with competent authorities in Member States has further been strengthened through the creation of a network, where scientific experts from competent authorities and EFSA work together.

(c) With regard to biological hazards (covered by the **BIOHAZ** Panel), cooperation with Member States takes place through the networks on spongiform encephalopathies (**BSE-TSE**) and the Microbiological Risk Assessment (**MRA**). These networks have identified emerging issues and triggered several self-tasking mandates.

(d) EFSA's Zoonoses Data Collection Unit (**ZOONOSES**) collects, analyses, and reports data on zoonoses, antimicrobial resistance, microbiological contaminants, and food-borne outbreaks. It further extracts specific datasets to support the preparation of scientific opinions. Datasets have been provided e.g. on

- opinions on *Salmonella* targets in breeding poultry flocks and flocks of laying hens;
- Quantitative Microbiological Risk Assessments (**QMRA**s) on *Salmonella* in pigs and *Campylobacter* in broiler meat; and
- opinions on the assessment of the risk of echinococcosis and porcine brucellosis (*Brucella* suis).

These reports are key tools for risk managers to monitor progress in the achievement of the targets.

(e) In the area of pesticides, EFSA is responsible for the EU peer review of active substances used in plant protection products. This task is carried out in line with procedures and deadlines set out in the European legislation; it involves applicants, competent authorities and the European Commission. The Regulation on Maximum Residue Levels (**MRL**s) of Pesticides[8] foresees several data collection activities to be coordinated by EFSA. This work is coordinated by the Pesticide Risk Assessment Peer Review (**PRAPeR**) Unit, whilst the Plant Protection Products and their Residues (**PPR**) Panel is responsible for the establishment of Risk Assessment Guidance of these compounds.

Besides effective scientific cooperation, communications and dialogue on risk assessment is equally important. The promotion of coherence in risk communications was therefore identified as one of the four priority areas for strengthening the cooperation and networking between the Member States and EFSA. Cooperation and coherence in communications, implemented through the Advisory Forum Communications Working Group (**AFCWG**), has been strengthened through: continued pre-notification of public announcements on EFSA's scientific work; proactive exchanges on key issues such as GMOs, food colours, and nanotechnology; and the exchange of information on "emerging issues" in individual Member States, focusing on the implications for communications.

EFSA will further build on the progress made in recent years and further engage with partners and stakeholders at national and European levels. Looking ahead to 2011 and beyond, EFSA will continue to see its workload increase, particularly in the area of authorisations. Therefore increasing efficiency is key, while boosting risk assessment capacity in Europe[9] is equally important.

This document is addressed to organisations in Member States to reflect on which areas of cooperation in food safety they wish to prioritise. Focal Points are asked to assist the Advisory Forum in starting this discussion within Member States. Bilateral discussions between EFSA and competent authorities in Member States will follow. In addition, EFSA will work together with the European Commission to anticipate the tasks allocated to EFSA in the coming years.

[8] 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/EECText with EEA relevance, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:EN:PDF.

[9] "Moving ahead from cooperation between EFSA and Member States to boosting the capacity of risk assessment in Europe" discussed at the EFSA Management Board meeting of 18 June 2009, available at http://www.efsa.europa.eu/en/090618/docs/mb090618-ax7.pdf.

2 INTRODUCTION

The role of EFSA is to assess and communicate on risks associated with the food chain. EFSA's Scientific Committee and Panels are responsible for EFSA's risk assessment work and provide independent scientific advice in the area of food and feed safety. In addition, EFSA provides scientific and technical support to risk managers such as the European Commission and Member States' authorities through several data collection programmes, which enable monitoring and the characterisation of risks. In carrying out its work, EFSA relies on data, information, and expertise from Member States' authorities and other national scientific institutions. Scientific cooperation between EFSA and Member States is also an integral part of EFSA's Founding Regulation (EC) No 178/2002[10] and a key priority of EFSA as set out in its Strategic Plan 2009-2013[11] and in its Work Plan 2010[12].

The Strategy for Cooperation and Networking and its Review, adopted by EFSA's Management Board in December 2006, already identified four priority areas: (1) exchanging and collecting scientific data and information, (2) sharing risk assessment practices, (3) contributing to the harmonisation of methodologies for risk assessment, and (4) promoting coherence in risk communications. It also sets the basis for the establishment of Focal Points in Member States. An Interim Review of the Strategy was carried out in December 2008 stating that scientific cooperation between Member States and EFSA overall proved to develop well in these areas and should be continued. Nevertheless, it was emphasised that activities in some areas, namely harmonisation of risk assessment, data collection and training, should be further strengthened.

EFSA and the Member States benefit from the various initiatives e.g. in the following areas:

- ability to cope with an increasing workload, while improving quality and efficiency;
- less duplication of work and efforts;
- higher consistency and better quality of data; and
- harmonisation of risk assessment requirements and convergence in the interpretation of scientific information.

The objective of this Report is to summarise the main scientific cooperation tools, activities and achievements in the area of food and feed safety, animal health and welfare, plant health and plant protection, while also looking at the challenges in the coming years. The Report does not cover projects with other EU agencies or activities within the scope of the pre-accession programme. Nor does the Report include other ongoing cooperation activities between EFSA and international organisations working in the same field as EFSA, such as United Nations (**UN)** organisations (e.g. World Health Organisation (**WHO**), the US Food and Drug Administration (**FDA**), Health Canada, and New Zealand Food Safety Authority and Food Standards Australia New Zealand. Nevertheless their contributions are equally acknowledged as they complement the scientific work of EFSA in risk assessment and nutrition.

For the purpose of this document a Member State is understood to be a country that is a Member of the European Union, and now also Iceland and Norway. Based on the Strategy for Cooperation and Networking, EFSA's scientific cooperation with Member States is supported by a number of collaboration mechanisms established between EFSA and Member States. At Member State level this is taking place through the Advisory Forum, Focal Points, and networks, at organisational level by multilateral or bilateral cooperation with organisations designated by their Member State to support EFSA in its tasks, as well as by individual experts.

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[10] 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, available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF

[11] EFSA's Strategic Plan 2009-2013 can be found in all EU languages at http://www.efsa.europa.eu/en/keydocs/strategicplan.htm

[12] The Work Plan 2010 is available at http://www.efsa.europa.eu/en/workplan/docs/wp10.pdf

3 MEDIUM-TERM ACTIVITIES PLAN

The overview of the medium-term planning (Appendix 1) summarises the activities for each scientific unit of EFSA, referring to the respective legislation, as appropriate. The table also gives information about the cooperation mechanisms applied such as grants and procurement schemes; networks; workshops and seminars; and public consultations. To complete the picture, it also indicates in which areas data and information collection is planned to underpin the risk assessment work.

4 PILLARS OF SCIENTIFIC COOPERATION WITH MEMBER STATES

4.1 Advisory Forum

4.1.1 Taking stock

EFSA's Advisory Forum connects EFSA with national food safety authorities of Member States. It has a strategic role as its members advise the Executive Director of EFSA on scientific matters, its work programme and priorities, and address emerging risk issues as early as possible. With the support of the Advisory Forum, EFSA and the Member States can join forces in addressing European risk assessment and risk communications issues. The Advisory Forum plays a crucial role for the successful implementation of the Strategy for Cooperation and Networking and provides the framework for cooperation and networking in order to support the development of risk assessments of the highest quality, based on sound science and harmonised methodologies, in all fields within EFSA's remit.

One of the main tasks of the Advisory Forum is to forge close links between the Member States' food safety institutions working in the fields of risk assessment and communication. The aim is to maximise the sharing of scientific information, to collaborate whenever possible to avoid diverging opinions, promote coherence in risk communications, identify emerging risks as early as possible, and last but not least coordinate and avoid duplication of work.

4.1.2 ESCO Working Groups

In response to EFSA Management Board recommendations, given in June 2006, Working Groups and networks for carrying out scientific cooperation projects, the so-called EFSA Scientific Cooperation (**ESCO**) Working Groups, have been set up following consultations with the Advisory Forum and the Scientific Committee of EFSA. ESCO Working Groups focus on food and feed safety issues of interest for both EFSA and the Member States. To date, seven ESCO projects have been set up on topics like botanicals, emerging risks, the Expert Database, folic acid, harmonised risk assessment approaches, isoflavones, and non-plastic food contact materials. Participants in the ESCO projects include national experts proposed by the Member States' competent authorities through the Advisory Forum, members of the Scientific Panels or Scientific Committee, and EFSA scientific staff. The reports resulting from these ESCO projects are submitted to the Executive Director of EFSA, who may decide to bring it to the attention of EFSA's Panels and Scientific Committee for information and further consideration.

The issue of botanicals is a good example, where different scientific cooperation tools complemented each other: experts worked together in an ESCO Working Group to advise on the adequacy of the proposed approach for the safety assessment of botanicals and botanical preparations. The ESCO Working Group considered six botanical preparations to test the science-based framework described in the guidance document that had previously been published by the Scientific Committee, following a public consultation.

Made up of members of the Scientific Committee and the Advisory Forum, the Steering Group on Cooperation (**SGC**) has been established to provide oversight on these joint projects.

4.1.3 Looking ahead

Given the growing number of dedicated networks, including one of EFSA's Scientific Committee, the need for ESCO projects will be reduced and consequently the mandate of the SGC will need reconsideration.

4.2 Focal Points

4.2.1 Taking stock

Whilst the Advisory Forum focuses on strategic aspects regarding scientific cooperation, a network of Focal Points has been established in all Member States to support the Advisory Forum members in

their work. The Focal Points are engaged in the day-to-day business to build up and strengthen networking and cooperation at national level.

Since their establishment in 2007/2008 the Focal Point network continuously developed and during this time became a key player in cooperation activities in Member States. Following a positive evaluation of the work (carried out in 2009 by members of the Advisory Forum and EFSA), all Focal Points, and observers continued their valuable work with the support of the Scientific Cooperation Unit (**SCO**). New Focal Point Agreements, signed in 2009, provided for a slightly increased funding and allowed for a more permanent character of the Focal Points. The Agreements were renewed with all Member States in 2010. In addition to the current Member State Agreeemnts, in 2011 Agreements will also be signed with Island and Norway. In September 2009 representatives from Croatia, the Former Yugoslav Republic of Macedonia, and Turkey (EU candidate countries) joined the Focal Point network as observers.

Focal Points collected and shared information amongst themselves and with EFSA on a number of topics. They play an important role in collecting national data for EFSA's risk assessment. Questionnaires and specific requests, such as those on Bisphenol A, nanotechnology or maximum levels of uranium in food and water, supported the work of EFSA's Scientific Committee and Scientific Panels. In other cases, the information requested and compiled was crucial to decide on further cooperation activities between competent authorities in Member States and EFSA, including national training initiatives and the exchange of planned activities in the area of risk assessment of food and feed.

Focal Points are the main drivers of the Information Exchange Platform, for which they collect and upload documents in the area of risk assessment. Many Focal Points have also shared annual, strategic, and multi-annual work plans as well as planned activities with other Member States and EFSA, thus contributing to a more coordinated planning of risk assessment activities and avoiding duplication of work.

Focal Points have further strengthened their national networks with Article 36 organisations, in particular through organising dedicated meetings with potential new and already participating organisations. They supported EFSA in ensuring that the Article 36 list is up-to-date and functional, both in terms of contact details and structural changes in the Article 36 organisations themselves. Focal Points encouraged the Article 36 organisations in their country to apply for published Article 36 calls. Nearly all Focal Points participated in a training organised by EFSA on how to apply and take part in Article 36 grants, thus enabling them to support organisations in their countries in the application process as well as throughout the project cycle. All of these activities have improved the networking between and among Article 36 organisations and with EFSA.

Focal Points supported EFSA in populating its Expert Database. In addition to presenting, distributing or publishing information on this Expert Database, Focal Points have been active in identifying national expert databases and network of experts and encourage scientists to apply.

Supported by the national Focal Points, the German Bundesinstitut für Risikobewertung (**BfR**) prepared an "EU Food Safety Almanac", which provides an overview of the competent public authorities and the structures regarding food and feed safety within the European Union[13]. The almanac focuses on risk assessment and supports scientific cooperation in Europe, e.g. by facilitating the search for European partners and also helps avoiding duplication of work.

To further increase awareness, understanding, and outreach of the work done by EFSA, the Advisory Forum and Focal Points disseminated information through a variety of communication channels and new tools, and through extending target audience networks within Member States. E.g. in 2009 they contributed to national and international events with over 100 presentations, posters, and written contributions, thus raising the awareness of the Focal Point network and of EFSA. In the same time period, Focal Points have organised over 50 events in their countries, ranging from targeted

[13] The EU Food Safety Almanac is available on the BfR website at http://www.bfr.bund.de/cm/255/eu_food_safety_almanac.pdf

workshops to international conferences. At many of them, Focal Points from other countries as well as EFSA staff were invited to present their work and cooperation activities.

4.2.2 Looking ahead

To further strengthen the scientific cooperation between EFSA and Member States, a set of priorities for the Focal Point network has been identified for 2010[14]. These include:

- maintaining the Article 36 list of organisations up-to-date, thereby ensuring its functionality;
- stimulating Article 36 organisations to apply for Article 36 calls, in particular in the context of the medium-term planning of the scientific cooperation between Member States and EFSA;
- fostering the network of Article 36 organisations by using the newly developed IT tools: database of Article 36 organisations , extranet[15] space for Article 36 organisations;
- developing the IEP further and uploading all relevant documents, including planned activities in the area of risk assessment;
- facilitating the cooperation between EFSA and national lists/databases of scientific experts with a view to enlarge EFSA's Expert Database, in particular in scientific and geographical areas currently underrepresented;
- continuing efforts in 2010 to further leverage the cooperation with the Advisory Forum Communication Working Group and EFSA to support communication plans for 2010; and
- organising national events to raise the visibility of Focal Points' and EFSA's work, to address (scientific) issues of concern in their countries, and to foster the various scientific cooperation projects between Member States and EFSA.

4.3 EFSA Networks

4.3.1 Taking stock

As defined in Article 23 (g) of Regulation (EC) No 178/2002, EFSA shall establish networks of organisations operating in the fields within its mission and shall be responsible for their operation. In addition, various specific sectoral legislations, e.g. in the process of evaluation of feed additives and GMOs, foresee a variety of networking activities between EFSA and the Member States' competent authorities. The main aim of the networks is to facilitate scientific cooperation through the coordination of activities; the exchange of information (e.g. on recent risk assessment activities or on data sharing); the development and implementation of joint projects (e.g. scientific events and workshops); and the exchange of expertise and best practice in the fields within EFSA's mission.

The "Decision concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission"[16], which aims to clarify the setting-up and operation of these networks, has been adopted by the EFSA Management Board in 2010. According to this decision, an EFSA network consists of appointed representatives from Member State scientific organisations, normally one per country. Over time, EFSA has created and successfully operated several of such networks. The following networks currently exist:

- Expert Group on Chemical Occurrence;
- Pesticide Steering Committee;
- Networking Group on Pesticide Monitoring;
- Task Force on Zoonoses Data Collection;
- Expert Group on Food Consumption;

[14] The report on Focal Point Activities 2009 has been endorsed at the Advisory Forum meeting in Seville on 11 February 2010 and is available at http://www.efsa.europa.eu/en/networks/fp.htm
[15] The extranet of EFSA is an electronic platform with restricted access.
[16] The Decision is available on the EFSA website at http://www.efsa.europa.eu/en/keydocs/docs/networksoperation.pdf .

- 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; and
- Scientific Network on BSE/TSE
- Network on Emerging risks;
- Scientific Network for Risk Assessment of Nanotechnologies in Food and Feed.

4.3.2 Looking ahead

In order to further strengthen cooperation between EFSA and Member States, the Advisory Forum has indicated that it wants to further foster an efficient and structured collaboration in harmonising existing, and testing and applying new risk assessment methodologies and in the monitoring of emerging risks.

With the experience gained, and given the growing number and importance of these networks, it is necessary that best practices be formalised, considering the legal framework and the nature of these networks. The Advisory Forum supported the proposal that the operation of these networks be clarified and documented on an annual basis. In addition, regular feedback from the activities of these networks is planned at Advisory Forum meetings.

4.4 Article 36 Networking

4.4.1 Taking stock

According to Article 36 of EFSA's Founding Regulation (in the following "Article 36"), EFSA shall promote the European networking of organisations operating in the fields within the Authority's mission.

A list of organisations capable of assisting EFSA in its tasks has been established in December 2006 by EFSA's Management Board. The list is based on nominations made to EFSA by Member States' Permanent Representations. At the beginning, 234 organisations were included in the list which was considerably enlarged in 2008, reaching a total number of 371 organisations. By the end of 2010 almost 400 organisations were included in the list. The expanded list of organisations with its wider knowledge base facilitates the cooperation between EFSA and Member States significantly.

Based on the Strategy for Cooperation and Networking, EFSA has implemented grants and procurement schemes to support scientific cooperation projects with scientific organisations in Member States. For both schemes the detailed administrative procedures stem from EFSA's Financial Regulation and its Implementing Rules, which are based on the **EU** financial framework[17]. The budget allocated for grant or procurement activities in the different scientific areas is set out in EFSA's Annual Work Programmes[18]. These plans take into consideration the research and scientific needs of EFSA and are prepared in consultation with Member States competent authorities via the Advisory Forum in order to identify common priorities and avoid the duplication of activities.

The total amount of EFSA funds for cooperation projects with organisations in Member States to support EFSA in its scientific tasks has considerably increased. From 2007 to 2009, EFSA has spent approximately 16 million € in funds for grant and procurement activities (approximately 6.7 million € on grants and 9.3 million € on procurement projects, including agreements). Besides EFSA, Member States also contribute to the project funding.

[17] Council Regulation (EC, EURATOM) No. 1605/2002 of 25 June 2002 on the Financial Regulation applicable to the general budget of the European Communities, (OJ L 248, 16.9.2002, P. 1-48), and as amended by Commission Regulation (EC, EUROTAM), http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:248:0001:0048:EN:PDF.
[18] More on Annual Work Programmes for grants is available on the EFSA website at http://www.efsa.europa.eu/en/networks/art36.htm

Due to the increasing importance of procurement contracts and grants to assist EFSA, two new IT support tools have been launched: a database of Article 36 organisations in December 2009 and an extranet workspace for all members of the Article 36 network in May 2010. Besides facilitating the networking and participation in EFSA calls for proposals, the Article 36 network extranet space includes useful information for the organisations and provides them with the opportunity to actively network, e.g. via sharing information and initiating discussion fora in view of participating to EFSA calls for proposals. The Article 36 Database was developed to assist the Member States' competent authorities and EFSA in the management, particularly in the maintenance and updating of the Article 36 organisations list, and equally to support the networking among the Article 36 organisations, and between these organisations and EFSA. One of the Database main features is the search tool for organisations' contact information and fields of competence.

In 2009 EFSA carried out an assessment of the efficiency and effectiveness of the grants and procurement schemes and provided recommendations for improvements to the schemes. The evaluation was based on a survey, in which both the partner organisations and EFSA scientific units participated.

Both EFSA and the organisations, to which a grant or procurement contract has been awarded, rate the cooperation and the process of project implementation positively. The assessment underpinned the complementary role of the two schemes. Based on the different legal provisions governing the two tools, procurement projects are of a more targeted nature, and mainly serve to directly support EFSA's specific activities and needs. On the other hand, grant projects are well suited to bringing together the expertise available in Member States' organisations. These have indicated that grants also have a positive effect on strengthening scientific cooperation and networking among each other and EFSA.

Procurement projects have mainly been used to support the evaluation of authorisation dossiers, whereas most of the grant projects have been deployed for cooperation projects in general risk assessment. Both grant and procurement projects have equally been used for projects on data collection and analysis. Given the fact that the administrative burden of the grant and procurement schemes is relatively high, for reasons of efficiency larger projects are preferred by the scientific organisations. For grants, the extensive documentation requirements were also highlighted.

Since 2007, almost 100 different Member State organisations have applied for a grant or procurement project. The applicants cover a broad range of scientific fields and geographical areas of Europe. Interestingly, around 70% of the procurement projects are carried out by organisations that are included in the Article 36 list for grants.

In conclusion, the evaluation suggests that the schemes are effective in achieving their objectives; supporting EFSA's scientific work as well as benefiting organisations through fostering networking and further collaboration opportunities. This assessment also confirms the complementary role of the two schemes.

4.4.2 Looking ahead

Based on experience gained and considering the results of the assessment, possible areas of improvement were identified. Therefore priority needs to be given to the following tasks:

- better addressing EFSA's scientific needs and Member State organisations' capacities to participate in projects by improved planning, e.g. by using more framework contracts and the launching of larger projects with longer duration;
- improving the project implementation by simplifying the administrative procedures in use, optimising the application process while continuously improving guidance and training; and
- developing networking activities further, by stimulating the use of the IT tools, and the consolidation of the Article 36 list.

4.5 EFSA Expert Database

4.5.1 Taking stock

EFSA's Expert Database was launched in June 2008. Its main objective is to allow scientists working in the remit of EFSA to register in a database of external scientific experts that can be queried to support the activities carried out by EFSA and competent authorities in Member States.

Since its launch, the database has grown steadily, with 100 applications received on an average per month, and a total of 3000 applications by December 2010. Following a thorough evaluation process, 2600 experts have been included in the Expert Database (status: 31 December 2010), 92% of which have agreed to be also searchable by Member States *i.e.* by the Advisory Forum members and Focal Points.

The experts included in the database are affiliated with a variety of scientific organisations (92%). Few have declared to be self-employed (4%), retired (3%) or unemployed (1%). Within the pool of employed experts, 38% work at universities/academic institutions, 32% in governmental organisations (e.g. national risk assessment agencies) and 17% in other public institutes. The remaining employed experts work in private organisations (7%), Non Governmental Organisations (**NGO**) (3%), foundations (1%), intergovernmental institutions (1%) or other types of organisations (1%)[19].

Since its establishment in 2008, the Expert Database has successfully been promoted at national level by Focal Points and more widely by international organisations. Whilst scientific experts from all Member States and European Economic Area / European Free Trade Association (**EEA/EFTA)** countries are represented in the Expert Database, with the exception of Liechtenstein, some countries have a lower representation considering the country population. Consequently, these countries may benefit from targeted promotion activities on the Expert Database.

All main areas of expertise that fall within EFSA's remit are covered by the Expert Database "New Technologies" and "Plant Health" were identified as areas that require further strengthening, and also "GMO", "Toxicology", and "Exposure assessment" may need further promotion support.

User surveys on the Expert Database were carried out in autumn 2009, one for EFSA staff and one for external users (*i.e.* representatives of the Advisory Forum and Focal Points from Member States and EEA/EFTA countries). EFSA scientific units and more than half of the Member States and EEA/EFTA countries have used the Database during 2009. The other Member States' competent authorities indicated not having needed it at the time. The Expert Database tool was generally considered user-friendly by both, internal and external users. However, further improvements are required, in particular on the speed of the search tool and on the keyword search features. The survey also revealed that the required expertise was not always identified in the Database, therefore continuous promotion is required to increase the number of experts and broaden the expertise available.

4.5.2 Looking ahead

Jointly with Focal Points, efforts will be ongoing to increase the awareness of the EDB within the national scientific organisations carrying out risk assessment activities and thus ensure that EFSA and competent authorities in Member States will continue to benefit from a growing pool of qualified experts.

In the light of the outcome of the surveys and based on the Expert Database 2009 Evaluation Report, the following priority areas for action were identified during the course of 2010:

- continuing to increase the overall number of experts via the current promotion activities with Focal Points and international organisations; paying particular attention to promotion activities in Member States with a relatively low number of experts in the Database;

[19] Due to data protection reasons, further information on individual applicant experts, namely on time spent working for EFSA, is not collected in the EDB and thus related information cannot be provided in this report.

- continuing (or initiating) cooperation activities with Focal Points and international organisations, in particular in underrepresented scientific areas or areas of expertise requested to be further increased on the Expert Database; and
- improving the search tool, namely its user-friendliness, speed for delivering results of queries and accuracy in the identification of sought expertise.

5 THE MAIN SCIENTIFIC COOPERATION ACTIVITIES

5.1 Risk assessments

Providing the best possible and most comprehensive scientific advice to risk managers requires a multidisciplinary and integrated approach. This is being achieved not only by the contribution of expertise from all around Europe, but also by cooperating closely with scientific organisations in Member States on issues related to risk assessment.

5.1.1 The work of EFSA's Scientific Committee

5.1.1.1 Taking stock

The Scientific Committee (**SC**) has the task of supporting the work of EFSA's Scientific Panels on scientific matters of a horizontal nature and providing strategic advice to EFSA's Executive Director. It is also responsible for general coordination to ensure consistency in the scientific opinions prepared by the Scientific Panels. The SC focuses on developing harmonised risk assessment methodologies in fields where EU-wide approaches are not already defined. Examples are its opinions in the area of emerging risks, exposure assessment, the margin of exposure approach for the risk assessment of substances that are both genotoxic and carcinogenic, as well as procedural and scientific aspects to ensure transparency in the way EFSA is conducting its risk assessments[20].

Most of these activities are aimed at ensuring the application of consistent approaches for risk assessment by the experts contributing to EFSA's scientific work. Other activities were aimed at advising EFSA's management on general risk assessment practices to be further implemented within EFSA such as in the area of data collection, data analysis, and scientific cooperation in the area of exposure assessment and identification and evaluation of emerging risks. Cooperation between the Scientific Committee and Member States' competent authorities is enhanced by outsourcing, e.g. the recent contracts on risk assessment terminology and applicability of physico-chemical data, Quantitative Structure Activity Relationship (**QSAR**) and read across in Threshold of Toxicological Concern (**TTC**) assessment.

5.1.1.2 Looking ahead

The EFSA's Scientific Committee and Advisory Forum Unit (**SCAF**) is currently setting up a network on nanotechnology. The SC and its Working Groups are further working on various subjects of horizontal nature where cooperation with Member States, international risk assessment organisations and stakeholders during the preparation and the wider implementation of the guidance will be essential. This includes, among other subjects, the preparation of guidance for 90-day feeding studies, the wider application of the TTC concept, the use of default values in risk assessment and the use of statistical approaches in risk assessment.

5.1.2 The work of EFSA's Scientific Panels

5.1.2.1 Taking stock

Whilst the SC is focusing on matters of general scientific nature, the Scientific Panels are responsible for their own scientific remits. ANNEX 1 summarises scientific cooperation activities between EFSA and Member States in these areas, both taking stock and looking ahead. To meet the challenge of the increasing workload and to leverage the wide body of knowledge available within EFSA, pooling of pan-European scientific resources is crucial. Scientific Panels produce opinions on applications, opinions on generic risk assessment issues and/or guidance opinions. Since the regulatory basis is different for these three main areas of work, also cooperation with Member States is organised in different ways.

[20] Transparency in risk assessment carried out by EFSA: Guidance Document procedural aspects: http://www.efsa.europa.eu/en/efsajournal/doc/353.pdf and Guidance of the Scientific Committee on transparency in the scientific aspects of risk assessment carried out by EFSA. Part 2 general principles: http://www.efsa.europa.eu/en/efsajournal/scdoc/1051.htm

Scientific cooperation in support of general risk assessments is supported by outsourcing, especially through grants, sharing accepted mandates within networks, organising workshops to discuss the approach to be taken to tackle mandates or to discuss the draft scientific opinions. EFSA also organises mandate-specific data collection to guarantee that the best possible data from Member States' scientific organisations and stakeholders is made available to the Scientific Panels and invites Member States competent authorities to share their risk assessments through the Information Exchange platform. In addition, Member States competent authorities are invited to participate in targeted and public consultations on draft opinions. The final opinions may be presented at the Standing Committee on the Food Chain and Animal Health (**SCFCAH**) for discussion, which further enhances the mutual understanding between Member States and EFSA. Specific networks provide discussion fora between EFSA Panels, units and competent authorities' experts. These have resulted in self-mandates by Panels within the areas of mutual interests.

Evaluating products, substances, and claims that need to be assessed or re-evaluated under EU law represent an area that has steadily grown and has become a large part of EFSA's workload; in 2009, this work represented 68 % of EFSA's scientific outputs and consumed a growing amount of its resources. Besides the provisions in the EFSA Founding Regulation, this work is generally also described in specific sectoral legislation. Strengthened cooperation and networking between EFSA and its counterparts in Member States has provided valuable tools to engage pan-European expertise and allocate tasks. Cooperation in this area is supported by (1) outsourcing (especially through procurements); (2) preparatory work carried out by Member States' competent authorities, if provided for by the sectoral legislation as well as data-collection from specific substances where no applicants are involved (especially for re-evaluations); and (3) assessing the comments received from Member States' competent authorities on these applications.

Sharing and developing together risk assessment practices is a third important area of cooperation with Member States' competent authorities in the area of risk assessment. This is supported by outsourcing (especially through grants), organising workshops to discuss the approach to be taken to tackle mandates or to discuss the draft scientific guidance opinions. In addition, Member States' competent authorities are invited to participate in targeted and public consultations on draft opinions concerning guidelines. The final opinions are often presented in SCFCAH for Member State endorsement or implemented via regulatory process to sectoral regulations. This further highlights the importance of mutual understanding between Member States and EFSA on the approaches taken in developing guidance opinions.

5.1.2.2 Looking ahead

As for the SC, scientific cooperation with Member States' competent authorities in the preparation of new harmonised methodologies and approaches for risk assessment is crucial to ensure consistency. Diverging views can never be excluded, but can be kept to the minimum. It is here where EFSA and the Member States should work further together to clarify each others methods and to identify where further harmonisation could be reached.

EFSA is also currently running a project analysing all regulatory workflows related to applications. Any involvement of Member States, foreseen by the respective regulations and directives, will also be included in a report in order to enable to find ways to further enhance the collaboration.

5.2 Regular data collection programmes

5.2.1 Taking stock

EFSA's Founding Regulation as well as specific Community legislation[21] establish EFSA's data collection mandate in relation to food and feed safety including nutrition, zoonotic organisms, food-

[21] E.g. 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, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:325:0031:0040:EN:PDF and 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

borne outbreaks, antimicrobial resistance, chemical contaminants and residues, animal health and welfare, and plant health. Networks with representatives from Member State institutions have been set up to coordinate the collection of the data. Appropriate methods to analyse data is essential. Besides the European Commission (including the statistical office of the European Union - **EUROSTAT**), representatives from non-EU European countries[22] and international organisations often participate as observers, as EFSA's Founding Regulation 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 this mandate.

EFSA is also tasked with providing recommendations to the Member States and the European Commission on how to improve the technical comparability of the data it has received. EFSA's Founding Regulation emphasises the need for technical comparability, which pertains both to the monitoring and data collection in the Member States, as well as to data transfer, storage, and retrieval in EFSA. To ensure a solid basis for drawing conclusions, high-quality data is essential. Therefore the data collection needs a pre-defined, uniform methodology. Working Groups have been established for the development of harmonised protocols for data collection on specific topics.

General guidance is provided by EFSA concerning the annual reporting on zoonoses, antimicrobial resistance, and food-borne outbreaks. EFSA has also published harmonised monitoring and reporting specifications for antimicrobial resistance data for zoonotic agents from food and animal populations; for food-borne outbreaks; as well as for verotoxigenic *Escherichia coli* and *Yersinia enterocolitica* in animal populations. In addition, Article 36 projects provide further guidance for harmonised monitoring and reporting of zoonotic parasites, Q fever, rabies etc.

EFSA has established a data collection programme and issues a variety of reports, some of which are published annually e.g. the Community Zoonoses Report (in collaboration with the European Centre for Disease Control and Prevention (**ECDC**) or the Annual Report on Pesticide Residues in Food. Others are produced on an *ad hoc* basis on microorganisms and chemical contaminants. These reports enable both the characterisation and the monitoring of risks; thus, they support risk assessments and can also serve to monitor compliance with risk management measures.

The process of risk assessment comprises four distinct but closely linked activities: hazard identification; hazard characterisation; exposure assessment; and risk characterisation. The 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 to be combined with data on the quantity of the food consumed. Hence, the quality of the risk assessment is directly influenced by the accuracy, comprehensiveness, and comparability of the available consumption data. As laid down in Article 32 of Regulation (EC) No 396/2005, EFSA is also responsible for preparing the Annual Report on Pesticide Residues. This task comprises the collection of the results of pesticide monitoring analysis performed in Member States and EEA countries, the analysis of the collected data, and an assessment of the actual exposure of European consumers to pesticide residues. In contrast to the risk assessment performed in the framework of Maximum Residue Level (**MRL)**-setting, which use the residue concentration measured in supervised field trials, the actual exposure assessment scenario uses the "real" residues quantified in products placed on the European market. In 2010, EFSA received the data of the results of the 2009 monitoring activities in a new format. This allows for the reporting of data and information at the level of each individual analytical determination. More than 60,000 samples of fruit, vegetables, cereals and other food commodities of plant or animal origin were analysed for residues of approximately 600 different pesticides, amounting to a total of 17 million determinations. The annual data collection on pesticide

on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2005:070:0001:0016:EN:PDF.

[22] Based on EEA Joint Committee Decision No 134/2007, published in OJ L 100, 10.4.2008, p.33 (http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:100:0033:0043:EN:PDF), the term "Member State(s)" contained in the Regulation (EC) No 178/2002 shall be understood to include, in addition to its meaning in the Regulation, Norway and Iceland

residue monitoring will establish a data pool that will also allow trend analysis with regard to residue occurrence and consumer exposure.

EFSA has also produced protocols and analysed data from a series of EU-wide baseline surveys on zoonotic agents in animal populations and foods. The results of which are used to set EU targets for reduction of the prevalence of *Salmonella* in various animal species; or to support considerations, if risk management measures for other zoonotic agents are necessary.

In 2005 the SC recommended the establishment of a harmonised EU food consumption database and a Scientific Colloquium[23] recommended that EFSA coordinate a pan-European dietary survey. With the support of Member States, EFSA established a Concise European Food Consumption Database, operational since the end of February 2008. 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. Consequently 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. In 2008, EFSA also launched a call for proposals focused on children. Both initiatives have been successfully concluded and the new Comprehensive Database includes data on food consumption by adults and children submitted by 20 and 15 Member States, respectively. A summary of the data in the new database is to be published on the EFSA website together with guidelines on how to use the information to calculate exposure.

5.2.2 Looking ahead

The current activities on data collection focus on exposure through food consumption of microbiological and chemical contaminants as well as pesticide and veterinary medicinal residues. New activities are emerging particularly with regard to post-marketing monitoring of regulated substances. Examples are the food additive legislation which requires Member States to collect data on consumption of food additives and report them to EFSA; and monitoring data for environmental exposure of GMOs.

For the purpose of conducting exposure assessments and quantitative risk assessments, it is necessary to be able to combine data on occurrence of chemical contaminants, residues, or microbiological agents 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.

As outlined above, the consumption data used by EFSA in its exposure assessments are the most comprehensive and up-to-date currently available in the EU. However, they include important methodological differences between the collaborating Member States' scientific organisations, 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 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**.

While harmonisation of data collection is progressing, it is important to monitor its implementation. Quality control and assurance in this area has been initiated and will be developed further.

[23] EFSA (European Food Safety Authority), 2005. EFSA 3rd Scientific Colloquium Report European Food Consumption Database - Current and medium to long-term strategies http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178628824484.htm

Since data are often 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' competent authorities 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.

5.3 Information exchange

5.3.1 Information Exchange Platform

5.3.1.1 Taking stock

The Information Exchange Platform was launched in 2008 to facilitate the exchange of information on risk assessment activities between Member States and EFSA. The Platform is populated with documents on risk assessment activities produced by national risk assessment bodies. They include risk assessment mandates, outputs, work plans, quality manuals, crisis manuals, and country profiles. By December 2010, over 830 documents have been uploaded by Focal Points, including almost 700 risk assessments.

A Focal Point Working Group on the Information Exchange Platform was established in September 2008 tasked with providing proposals for developing the IEP. Following a six months pilot period, the IEP was reviewed in spring 2009 and hereafter a number of improvements were made to the Platform. These included the launch of an advanced search tool and a reporting and statistics tool. These enable users to search for documents effectively and provide the option of producing customised reports on uploaded documents, respectively. During 2009, access to the Information Exchange Platform was broadened to EFSA Panel Members and selected individuals nominated by Advisory Forum members, in addition to the Focal Points.

As part of the evaluation of the Information Exchange Platform, a questionnaire was distributed to all users to gain a better understanding of how it is used and what improvements were needed to the site. The findings suggest that the Platform is a useful site in facilitating the exchange of information. In particular, the monthly reports are viewed as an important and useful feature. The main purpose identified for using the Information Exchange Platform was to keep informed on risk assessment activities in a particular scientific area.

The Working Group identified the need to promote the Information Exchange Platform better amongst its users. In addition, technical improvements are needed to the site; these include the layout, structure and improvements to some features. Also, additional scientists could benefit from having access to the site.

The Working Group members will also advise on how to further develop the Platform.

5.3.1.2 Looking ahead

The Evaluation Report of the Working Group on the Information Exchange Platform will be consulted with Member States' competent authorities. The recommendations, e.g. promotion activities, will then be implemented. In parallel, discussions will continue within the Working Group to provide suggestions on the improvements needed.

5.3.2 Sharing Work Plans of Member States' competent authorities

5.3.2.1 Taking stock

The overall objective of this initiative is to enhance the knowledge of planned activities at national level and, at the same time, to avoid possible duplication of work. In 2009, 16 Focal Points have shared a total of 21 plans, 12 of which were strategic plans and nine annual plans, as well as other types of documents on planned activities. The documents uploaded to the Information Exchange

Platform varied in type, form, target audience, and content - from very short lists of activities to long general presentations of goals and objectives, brochures and multi-annual national control plans. Due to their broad scope, it was impossible to summarise the documents and to make a comprehensive assessment of planned activities. Therefore, a harmonised reporting format has been developed by the SCO Unit in collaboration with the Focal Points. A simple table now allows the listing of information on planned risk assessment as well as of research and data collection activities. Its usability has been successfully tested during a pilot phase by eight Focal Points. The new reporting table seems to be a promising approach to complement the sharing of the full annual/strategic work plans by Member States' competent authorities via the Information Exchange Platform. It not only generates a harmonised way of sharing information, but it also offers a format through which the competent authorities are able to report, also those which cannot easily share their annual and/or strategic work plans. In addition, it facilitates the search for specific activities in Member States. Thus, Member States' competent authorities have now two possibilities to share planned activities: either by uploading their work plans on the Information Exchange Platform or by filling in the standard reporting table. By using one or both tools, altogether 18 countries have provided information on planned activities in 2009.

5.3.2.2 Looking ahead

Member States' competent authorities will continue to be invited to share their planned activities. To facilitate the information exchange, it is planned to integrate the standard reporting table into the IEP.

5.3.3 Workshops and meetings with Member States' competent authorities

5.3.3.1 Taking stock

If and when appropriate, EFSA invites national experts with relevant scientific knowledge, nominated by Member States' competent authorities, to meetings to discuss and share scientific experience, including on sensitive or controversial topics. This supports EFSA's work by exchanging views and getting input on scientific topics from highly qualified experts.

One example concerns the special meetings on the safety assessment of aspartame, a sweetener that has been authorised in foods for many years in many countries and for which EFSA has published a scientific opinion in 2006. At the initiative of EFSA, together with its Advisory Forum, 18 national experts from ten countries' risk assessment bodies, that could provide scientific knowledge relevant to aspartame, were invited to three meetings (in April and November 2009 and January 2010).

Another example of joint events between EFSA and Member States' competent authorities is the workshop on "Science Supporting Risk Surveillance of Imports", jointly organised by EFSA and the Spanish Food Agency (**AESAN**) in February 2010 in Seville. This EFSA-AESAN event followed up on the outcomes of a conference that the French Food Safety Agency (now **ANSES**) and EFSA jointly organised on 3 October 2008 on "Assessment of the health risks of food, animal and plant imports in the European Union".

Finally, a follow-up of a joint even between EFSA and the Dutch Food and Consumer Product Safety Authority (**VWA**) in 2008, a special issue of the International Journal on Food Microbiology (Vol.139, Suppl.1, 2010) has been published early 2010, gathering several scientific papers in the area of **MRA**.

5.3.3.2 Looking ahead

EFSA will continue to use the valuable tool of exchanging views on scientific topics and seeking input from competent authorities. For example, more than nine EFSA units have already foreseen meetings and/or workshops organised together with Member States or with participation of national scientific experts (see Appendix 1 for more details).

5.3.4 EFSA Scientific Colloquia

5.3.4.1 Taking stock

Initiated in 2004, EFSA Scientific Colloquia aim to create a forum for open scientific debate with experts in Member States on subjects central to the work of EFSA for which the scientific thinking is not yet concluded. Ideas on topics for Colloquia emerge from the SC, Advisory Forum, as well as EFSA Scientific Panels and units. The objective of Colloquia is to convene scientists to have an open exchange of views on a certain topic. Colloquia are structured in discussion groups after a short plenary session with introductory presentations. The outcomes of the discussion groups are presented and discussed in a final plenary session to formulate conclusions of the Colloquium and to make recommendations, as appropriate. The output of each Colloquium is summarised in an overall Summary Report which is published on the EFSA website[24]. Colloquia have provided recommendations to EFSA, e.g. the Colloquium on acrylamide concluded that there was no need to revise the risk assessment; the colloquium "Cumulative Risk Assessment of Pesticides to Human Health" proved very successful with useful considerations for the Panel on Plant protection products and their residues (**PPR**) as well as for Cumulative Risk Assessment (**CRA**) outside the pesticides remit.

5.3.4.2 Possible future topics

As feedback on EFSA's Scientific Colloquia has been very positive and because of their importance for EFSA's scientific work as well as for the sharing of knowledge with experts in Member States and beyond, the intention is to continue with this type of meetings.

5.3.5 Training needs

5.3.5.1 Taking stock

The Strategy for Cooperation and Networking of 2006 indicated that EFSA should establish a programme of courses in risk assessment, involving experts from Member States. This was reiterated in 2008 in the Interim Review of the Strategy for Cooperation and Networking between EU Member States and EFSA, where particularly newer Member States requested to further increase training activities. Thus, training belonged to the three main areas where improvement was suggested.

Following up on the recommendations in the Strategy of Cooperation and Networking, an initiative was taken to identify the training needs in the Member States. In close cooperation with Focal Points, the SCO Unit analysed training opportunities in food safety risk assessment offered by the relevant European and international institutions as well as at national level by Member State authorities. A wide variety of training is on offer.

Since 2006 the European Commission has a training programme on Food Safety ("Better Training for Safer Food") in place, which focuses on risk management and control and is targeted at staff from national competent authorities in Member States and candidate countries. Another programme receiving co-funding from the European Commission, the European Toxicology Risk Assessment Training (**TRISK)** [25] project, is offering training courses in the field of toxicology risk assessment.

Considerable training opportunities are available at national level: the Focal Points reported more than 500 entries corresponding to even more courses and workshops organised by the Member States over the past three years. These training events cover a wide range of topics, many of which target risk managers and controllers. Investigations, which training needs scientists in Member States would have, showed that, in fact, several fields would be of interest; however only general risk assessment training was regularly requested.

Apart from ECDC in Stockholm, there appear to be few other European or international organisations that have a designated programme on risk assessment training. Instead, most organisations offer training on *ad hoc* basis through seminars and workshops. Similarly, EFSA has offered seminars

[24] EFSA Scientific Colloquia Reports can be found at http://www.efsa.europa.eu/en/scpublications/colloquiareports.htm.
[25] More on the European Toxicology Risk Assessment Training can be found at http://www.trisk-project.eu/ .

addressed to experts from Member States, EEA/EFTA countries, as well as candidate countries in the fields that fall under EFSA's remit. EFSA has organised exercises in collaboration with Member States' competent authorities and the European Commission to practice and test collaboration when answering to urgent requests. These often take the form of a crisis exercise. In order to further improve this training, EFSA is working with a contractor to establish a multi-annual training program.

Also, on the occasion of the 2009 renewal of the EFSA SC and Scientific Panels, EFSA Management Board recommended activities to be initiated by EFSA to help balance the number of applications from scientists from Member States that have joined the European Union in or after 2004. Subsequently, in autumn 2008, EFSA organised two seminars (in Budapest and in Warsaw) with the support from Focal Points. The aim was to inform scientists in the new Member States about EFSA's scientific work and to explain and discuss the benefits and implications of EFSA SC and/or Panel membership.

In conclusion, although quite a number of training opportunities are provided by different organisations, offers for training on general principles and/or steps in food safety risk assessment are limited.

Recently a Working Group of EFSA has been set up to develop a module for training on general principles and methods of risk assessment. These modules will be implemented for EFSA's staff and external scientific experts.

5.3.5.2 Looking ahead

Taking into account EFSA's Strategic Plan 2009-2013, the recommendations of the Advisory Forum and the EFSA Management Board and the findings of the report on training needs, it can be concluded that additional training on risk assessment, addressed to scientists from national authorities, is needed and wished by Member States. However, EFSA is not mandated to organise training for non-EFSA staff experts, whereas the European Commission already has a programme in this area. In this context, EFSA liaises with the European Commission service, responsible for training programmes in the area of food safety.

5.3.6 Identification and handling of research priorities

5.3.6.1 Taking stock

The SC and Panels as well as the scientific units and the Advisory Forum frequently highlight research needs and concrete research proposals. Target addressees for such proposals are the Directorate General for Research & Innovation (**DG RTD**) of the European Commission (through its Framework Programmes), the Joint Research Centre (**JRC**) of the European Commission as well as other potential research funding organisations.

5.3.6.2 Looking ahead

To streamline the process for collecting and reviewing research proposals and to enable EFSA to highlight the identified research priority areas an Internal Task Force has been established. Input has also been provided by the Advisory Forum Members, the SC, the Advisory Group on Risk Communications (**AGRC**)[26], and the Advisory Forum Communications Working Group (**AFCWG**).

A consolidated proposal on key research priorities, by EFSA will be submitted to DG RTD and other key funding organisations.

5.3.7 Public consultations

5.3.7.1 Taking stock

EFSA's approach regarding public consultations on scientific outputs reflects its commitment to transparency, accountability, high scientific quality, and efficiency. It fosters the interaction between EFSA, EU citizens, consumers, and all relevant stakeholders, including national food safety

[26] Information on the AGRC is available on the EFSA website at http://www.efsa.europa.eu/en/riskcommunication/agrc.htm

authorities. Although public consultation is not formally part of scientific cooperation with Member States, as it is primarily targeted towards EFSA stakeholders, Member State organisations often contribute feedback through this process.

Public consultation on scientific outputs aims at an effective exchange on a draft scientific output based on a decision of EFSA to seek comments from the public. In addition to public consultation, EFSA also regularly consults with its institutional partners.

Identification of the need for a consultation is based on coherent and clear criteria. A public consultation may be considered, when EFSA receives a new type of question. This could be in areas, where EFSA has not issued opinions previously, and where a public consultation would ensure that the knowledge on different types of approaches and information is available for risk assessment or for developing risk assessment methodologies. Complex or emerging scientific issues can be another subject of a public consultation; e.g. in case where science has progressed substantially in the past or new technologies for which information and approaches in risk assessment still need to be developed. Finally, risk assessment methodologies, principles, and processes are areas that can benefit from a public consultation. On the other hand, there are areas in which public consultations are not carried out systematically, e.g. scientific opinions on regulated substances; statements of the SC and/or Panels that were adopted in response to an urgent request or under emergency situations.

Since the introduction of public consultations in 2005, nearly 50 public consultations have been conducted through August 2010. Examples are draft guidance documents such as the one on safety assessments of botanicals and botanical preparations intended for use as food supplement (2008); draft scientific opinions regarding Dietary Reference Values (formerly Population Reference Intakes) (2009), on food borne antimicrobial resistance as a biological hazard (2008) or on the welfare aspects of genetic selection in broilers (2010). A complete overview can be retrieved from EFSA's corporate website[27].

5.3.7.2 Looking ahead

In the coming years, EFSA will continue to use the useful instrument of a public consultation. Public consultations are planned e.g. by the GMO Panel on the Guidance on genetically modified animals; by the NDA Panel on draft opinions related to Dietary Reference Values for protein, energy and certain micronutrients, and on draft guidance documents on scientific requirements for the substantiation of health claims in selected areas (e.g. gut and immune function; post-prandial blood glucose responses/blood glucose control; weight management, energy intake and satiety; protection against oxidative damage; cardiovascular health; bone, joint and oral health; neurological and psychological functions; and physical performance); as well as by the DATEX Unit on the new food classification proposal.

[27] For open consultations visit http://www.efsa.europa.eu/en/calls/consultations.htm; for closed consultations http://www.efsa.europa.eu/en/consultations/consultationsclosed.htm .

6 COOPERATION ACTIVITIES IN RISK COMMUNICATIONS

The promotion of coherence in risk communications is identified as one of the four priority areas for strengthening the co-operation and networking between the EU Member States and EFSA. Co-operation and coherence in communications has been implemented through the AFCWG, established in 2003. EFSA initiated a review of the group's Terms of Reference in 2007 which were endorsed by the Advisory Forum. This update focused on strengthening co-operation and coherence in practical ways[28].

6.1 Advisory Forum Communications Working Group

The AFCWG provides an important mechanism for exchange of information and experiences and is a basis for strengthening the coherence and co-ordination of communications activities between the national authorities and EFSA. Close involvement and participation of the European Commission also ensures more consistent communication and clearer messages on food safety taking into account the different but complementary roles of risk assessors and risk managers.

The group also aims to support Advisory Forum members, national authorities, and designated national Focal Points in identifying appropriate opportunities and audiences for promoting scientific cooperation and communication on EFSA's work, food safety issues within Member States and the wider European food safety system.

The AFCWG's meetings and work programme address the following key objectives:

- develop co-operation and co-ordination of communications on all areas within EFSA's remit;
- support the development of best practices and guidelines in risk communications;
- facilitate acquisition of knowledge and training in communications;
- exchange information and experiences gained both at Member State and European levels both through the network of AFCWG members and their respective teams;
- share information and knowledge on public perception on food and feed safety, nutrition, plant health, and animal health and welfare; and
- evaluate communications activities and results in view of identifying lessons learned.

6.2 Risk Communication: State of Play

Coherence in risk communications has been strengthened through: continued pre-notification of public announcements on EFSA's scientific work; proactive exchanges on key issues such as GMOs, food colours and nanotechnology; and the exchange of information on "emerging issues" in individual Member States, focusing on the implications for communications.

In order to further support co-ordination and planning of communications activities related to risk assessment advice issued by EFSA and Member States, EFSA is looking into the development of an online tool to optimise the exchange of information between EFSA and Member States. This would be a rolling, forward planning calendar that could be published on the extranet identifying upcoming publication/communications plans for both EFSA and Advisory Forum Members.

EFSA continues to work closely with Member States to foster coherent communications and greater outreach at national level through effective use of appropriate networks. A template was developed for Focal Points to report on their target audience networks and the impact of their activities in Member States. This will help EFSA better understand how its scientific work is being communicated and reported in Member States.

Cooperation through the AFCWG and Focal Point networks was reinforced, e.g. through joint communications activities, and the development of a tailored good practice guide for Focal Point website management. EFSA has also benefitted from the organisation and promotion of joint events

[28] http://www.efsa.europa.eu/en/afwgs/docs/afcwgtor.pdf.

with national food safety authorities, relevant Ministries and local/regional authorities, addressing risk assessment and risk communications (20 events organised to date since 2007).

In order to support development of best practices and share experience in risk communications, the presentation of case studies is a regular agenda item at meetings of the AFCWG. EFSA also organised training workshops on risk communications and crisis communications, respectively in 2005 and 2006. Building on from this work, the AFCWG is currently developing risk communications guidelines to underpin and support an effective and consistent approach to risk communications across the EU. This initiative that will be completed in 2010, aims to provide a framework to assist decision making about appropriate communication approaches in a wide variety of situations that can occur when assessing and communicating on risks in the European food safety system. The risk communication guideline initiative, benefits from the expert input from the AGRC[29]..

6.3 Looking ahead

Cooperation and networking between Member States and EFSA has already come a long way. The review of EFSA's communications strategy (2010-13 perspective) will provide further opportunity to strengthen both cooperation and effective outreach. Qualitative research amongst EFSA's key customers, partners, and stakeholders and the re-conduction of a Eurobarometer survey on EU consumer perception of food risks are providing important input to this process. EFSA will seek to reinforce involvement of Member State partners to support development of clear and meaningful messages and greater public outreach.

[29] More information on this group can be found at http://www.efsa.europa.eu/en/riskcommunication/agrc.htm .

7 DISCUSSION AND CONCLUSIONS

EFSA is committed to bringing together the extensive scientific expertise available across Europe and to ensure its efficient use. The Advisory Forum, the Focal Points and the dedicated networks make sure that the data and information exchange, consultations, and work sharing between EFSA and Member States' competent authorities takes place. Other mechanisms for cooperation have also been successfully established: the Expert Database, the Information Exchange Platform, and the network of Article 36 organisations.

In addition, cooperation tools such as targeted and public consultations, the cooperation via workshops and scientific colloquia have further evolved. Furthermore seminars have been organised in Member States to raise awareness of EFSA's work.

All these activities, which have been started or solidified in recent years, have resulted in clear benefits:

- ability to deal with an increasing workload, while increasing quality and efficiency;
- building on existing work and reduction of duplication of efforts;
- increased consistency and quality of data; and
- harmonisation of risk assessment requirements and convergence in the interpretation of scientific information.

EFSA will further build on the progress made in recent years and further engage with partners and stakeholders at national and European levels. Looking at 2011 and beyond, EFSA will continue to see its workload increase, particularly in the area of authorisations. Therefore increasing efficiency is key, boosting risk assessment capacity in Europe[30] is equally important.

The information provided in this Report is meant to inform the Advisory Forum, competent authorities, and organisations included in the Article 36 list on EFSA's activities planned for the coming years. It provides the basis for a broader discussion and prioritisation in Member States. The members of the Advisory Forum, supported by their Focal Point, have a crucial role in initiating and steering this discussion. This will also help identifying the capacity and core competences of each Member State. Bilateral meetings between Member States' competent authorities and EFSA will then define individual contributions. These will be used to ensure that EFSA can cope with the increasing workload and fulfil its mission.

To support this process and to be able to better plan for the next years, EFSA will continue its dialogue with the European Commission to anticipate the upcoming tasks.

[30] "Moving ahead from cooperation between EFSA and Member States to boosting the capacity of risk assessment in Europe" discussed at the EFSA Management Board meeting of 18 June 2009, available at http://www.efsa.europa.eu/en/090618/docs/mb090618-ax7.pdf

ANNEX 1: SCIENTIFIC COOPERATION BETWEEN EFSA PANELS/ UNITS AND EU MEMBER STATES

All Community legislation referenced in Annex 1 can be found under the respective year and number at EUR-lex at http://eur-lex.europa.eu/RECH_naturel.do?ihmlang=en.

ANIMAL HELTH AND WELFARE (AHAW)

General risk assessment

Taking stock

A scientific network for risk assessment in animal health and welfare has been being established with the overall objective to streamline and intensify the scientific cooperation in this specific area. The network will allow for regular interaction between the AHAW Panel/Unit and the Member States' organisations dealing with risk assessment on animal health and welfare through their representatives. The overall objectives are to build mutual understanding of risk assessment principles and to promote exchange of data for risk assessments in the field of animal health and welfare.

The first meeting of the newly created scientific network for risk assessment in animal health and welfare was held in November 2010. This meeting also provided an opportunity to discuss practical implementation of modelling in animal health risk assessments, based on the guidance document developed by the AHAW Panel. The draft opinion on increased mortality of Pacific oysters was shared with members of the scientific network for comments.

Public consultations are regularly carried out before final adoption and publication of mandates, where a particular interest or justification has been identified. Technical meetings with Member States and/or stakeholders are conducted whenever particular needs for additional data are identified.

In 2010, two consultations have been completed on health and welfare aspects of genetic selection in broilers and concerning the practice of harvesting feathers from live geese for down production. Two technical meetings with Member States and/or stakeholders were conducted on practices of harvesting feathers from live geese for down production, and on the welfare of animals during transport.

In the AHAW area, cooperation with Member States takes also place through the SCFCAH. The AHAW Unit regularly attended SCFCAH meetings of interest to EFSA, in particular, when a possible mandate to EFSA has been discussed and also following adoption of an opinion in order to present the opinion to Member States and to answer related questions. In 2010, AHAW opinions on brucellosis, Classical Swine Fever (**CSF**), African Swine Fever (**ASF**), and Q fever were presented during the SCFCAH meetings. These meetings were also utilised to seek permission to use Member States' data (e.g. Q fever, CSF in wild boars) to enable EFSA to reply to requests for scientific opinions from the European Commission.

Cooperation with Member States is also promoted through grants by outsourcing parts of the initial work needed to develop major generic opinions and risk assessments. In 2010 there were two calls:

- specification of data collection on animal diseases to increase the preparedness of the AHAW Panel to answer future mandates
- contribution of meat inspection to animal health surveillance

Looking ahead

The AHAW Unit and the Panel are seeking further collaboration with Member States in the area of epidemiological data on animal diseases. Currently, data specification is being developed in collaboration with Member States through a grant. Because of specific requests from the European Commission, collaboration with Member States on data collection is to be further strengthened.

AHAW cooperation with Member States will be further reinforced and enhanced through the AHAW scientific network. Planned activities include a workshop on the use of models in animal health risk assessments.

Public consultations and/or technical meetings are planned for a number of mandates including animal health and welfare aspects of genetically modified animals, welfare of animals during transport, use of animal based measures to assess the welfare of dairy cows, and public health hazards to be covered by meat inspection of domestic swine, taking into account implications for animal health and welfare.

Collaboration with Member States through SCFCAH is to be continued and further strengthened.

FOOD ADDITIVES AND NUTRIENT SOURCES ADDED TO FOOD (ANS)

Risk assessment within the authorisation process

Taking stock

The ANS Panel carries out risk assessment of food additives (new applications for authorisation, as well as re-evaluation of all food additives, which were permitted before 20/01/2009), nutrient sources added to food (e.g. sources of vitamins and minerals) and other substances added for nutritional purposes to food, as well as other deliberately added substances, including substances added for purposes other than technological ones e.g. with functional properties, but excluding flavourings and enzymes. Most of the Panel's work is carried out in the context of authorisation procedures. In addition, the Panel develops scientific guidance to the industry for preparing new applications. The currently applicable regulations for food additives lay down that EFSA is responsible for carrying out the risk assessment based on technical dossiers provided by the applicants. Therefore, the direct role of Member States is limited, although they can provide additional information and are in a limited number of cases interested, because they have granted a temporary national authorisation. However, temporary national authorisations will soon not be possible any more.

For the evaluation of nutrient sources, the situation is similar for new applications but different for sources that have been granted a temporary national derogation. This has been the case in the past for the nutrient sources for food supplements and there is currently an ongoing national derogation period for the sources for the fortification of food. In these cases, the applications are provided by the Member States to the European Commission; the Member States have an interface role between EFSA and the applicants.

For the re-evaluation of the already permitted food additives, the situation is different and EFSA relies on the information made available by interested parties in response to public calls for data. The Member States are of course important potential providers of data.

Another important contribution of the Member States to the risk assessment activities is their sharing with EFSA of food consumption data through EFSA concise database. This is very important for the exposure assessment activities of the ANS Panel. A very important contribution has been made with the participation of several national organisations to the Article 36 consortium Project on individual food consumption data and exposure assessment studies for children (**EXPOCHI)** and especially its program on food colours.

Looking ahead

In addition to the existing contribution of Member States, a reinforced role with the entry into force of the new regulatory framework for food additives can be foreseen.

Food additives – new applications

Having regard to the Article 3(1) of Regulation (EC) No 1331/2008 on the main stages of the common application procedure for updating the Community list in the area of food additives, new applications may be made by a Member State in accordance with the conditions provided for by the implementing measures referred to in Article 9(1). In addition, according to the Article 27 (monitoring of food additive intake) of the Regulation (EC) No 1333/2008 on food additives, the Member States shall maintain systems to monitor the consumption and use of food additives on a risk-based approach and report their findings with appropriate frequency to the European Commission and EFSA.

Addition of vitamins and minerals and other substances to food

Another important role of the Member States is also defined in Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to food, especially for "other substances". Actually, Article 8 of this Regulation indicates that Member States can provide information on potentially harmful effects on health of such substances.

BIOLOGICAL HAZARDS (BIOHAZ)

Risk assessment within the authorisation process

Concerning the Animal By-Products (**ABP**) area, the BIOHAZ Panel cooperates with Member States in the assessment of applications for new alternative methods for disposal of use of ABP.

Taking stock

Although under the current ABP regulation (Regulation (EC) No 1774/2002) no specific rules are foreseen for collaboration with Member States in this area, a joint DG SANCO EFSA non-binding guideline was issued in 2006 and then updated in 2008.

According to these guidelines the Member States are encouraged to perform a preliminary assessment of the alternative methods for ABPs that private applicants would like to submit to EFSA according to a specific framework described in the guidelines. Since 2006 all the mandates for assessment for new alternative methods for ABPs received by the BIOHAZ Unit from Member States were following this procedure. In 2009, a workshop was jointly organised by the Directorate General for Health & Consumers (DG SANCO) and EFSA to explain and share views with Member States on the main difficulties encountered in the applications.

Looking ahead

The revised ABP Regulation (EC) No 1069/2009, entering into force in March 2011, has introduced a formalised procedure for applications for new alternative methods for disposal of use of ABP. The BIOHAZ Panel has adopted a scientific opinion (guidance) with the aim to help the European Commission to define a standard format for these applications. This standard format will be inserted in future in the revised ABP Regulation as implementing measure. Under this new framework the competent authorities of the Member States concerned will have to evaluate, whether the dossier that the applicant wishes to submit to an EFSA assessment, complies with the aforementioned standard format. A workshop with Member States and DG SANCO on biogas and compost processes took place in November 2010.

So far, neither in the area of TSE tests area nor regarding decontamination treatments, cooperation activities are planned with Member States.

General risk assessment

Taking stock

In the BIOHAZ area, cooperation with Member States takes place through the BSE-TSE and the MRA networks, which were established some years ago, but also through the SCFCAH. EFSA regularly attended SCFCAH meetings of interest to EFSA, in particular, when a possible mandate to EFSA has been discussed and also following adoption of an opinion in order to present the opinion to Member States and to answer related questions. The SCFCAH meetings were also utilised to seek permission to use Member States' data on food borne pathogens, collected through mandatory exercises, to enable EFSA to reply to requests for scientific opinions from the European Commission.

The BIOHAZ networks have been crucial to identify emerging issues and triggered several self-tasking opinions (e.g. food borne viruses, biogenic amines, and antimicrobial resistance issues), following discussion at the Panel. The networks also facilitated learning about activities being carried out in Member States in the area of risk assessment and, subsequently, avoiding divergence of opinions. TSE infectivity in small ruminants is mentioned representatively for many other examples.

Looking ahead

The BIOHAZ Unit and the Panel are seeking further collaboration with Member States in the area of QMRA of food borne pathogens, particularly Salmonella and Campylobacter. Recently, QMRA models on those pathogens have been developed through outsourcing activities (grants and procurements) and the models could be used by Member States to estimate different scenarios regarding risk reduction of a number of human cases.

The BIOHAZ Unit has launched a procurement procedure with an overall objective to develop a user-friendly interface version of the QMRA model, which the Member States could use for their specific situation and needs. The Panel recommended that Member States should have the possibility to assess their national pig meat food chains using this QMRA model. In fact, Member States already expressed their interest in using the model for their specific situations at meetings such as EFSA's MRA Network meeting in June 2010 and the Advisory Forum Meeting in February 2010.

Collaboration with Member States through the networks and through SCFCAH is to be continued and further strengthened.

FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS AND PROCESSING AIDS (CEF)

Risk assessment within the authorisation process

Taking stock

The CEF Unit is collaborating with Member States in all its fields of activities.

In the area of Food Contact Materials (**FCM**) under Regulation (EC) No. 1935/2004, the preparation of summaries of toxicity data of substances used to manufacture plastic FCM is outsourced to the German BfR.

In the area of flavouring substances, the Unit has taken over and intensified the close collaboration of the former EFSA Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) with **FLAVIS**, a centre of excellence of the Danish Technical University assisting EFSA for the collection and the compilation of information needed for the evaluations.

Looking ahead

The collaborations for plastic FCM substances and for flavourings are expected to be continued in the frame of ongoing contracts.

Substances used to manufacture non-plastic parts of FCM have generated crises in the past (like Isopropyl thioxanthone (ITX) and methylbenzophenone). In order to be able to provide quick answers in case of urgent questions on such materials, an ESCO Working Group has been set up at the end of 2009, on recommendation of the Advisory Forum. The Working Group is collecting experience available in Member States from evaluations they carried out for these materials. This work will be finalised in 2011.

In order to prepare the evaluations of the hundreds of applications for food enzymes expected to be submitted in 2012 [under Regulation (EC) No 1332/2008], the CEF Unit has made contact with the Danish and French authorities, who performed risk assessment of food enzymes in the past. Both authorities should provide the CEF Unit with general information on the evaluations they performed. Based on the experience of the Member Sates, the CEF Panel will classify incoming applications and determine the most urgent needs for the evaluations.

General risk assessment

Taking stock

The evaluation of Bisphenol A (**BPA**) is a sensitive topic, not only because of high expectations of society, but also because of conflicting views expressed in the scientific community about evaluation of this substance (low dose effects, endocrine disruption mechanisms, etc). The CEF Unit organised a meeting on BPA at which the draft opinion of the CEF Panel was presented and open for discussion to Member States. The participants were experts designated by Member States. A wide variety of views were expressed and the Panel has considered the comments received.

After adoption and publication, the CEF Panel opinion on BPA was open for discussion with Member States at a Working Group meeting on food contact materials organised by the European Commission in Brussels.

Looking ahead

Within the ESCO Working Group on non-plastics Food Contact Materials, experts from Member States are considering and discussing screening approaches for the thousands of substances used by industry and which have not been evaluated. After discussions with the TTC Working Group of the SC, proposals will be made to the Executive Director of EFSA in 2011.

According to Regulation (EC) No 1935/2004, Member States play a crucial role in establishing the mandates for all applications in the area of food contact materials. In cooperation with Member States, the unit will propose harmonised approaches for identifying the key questions for the evaluations.

CONTAMINANTS IN THE FOOD CHAIN (CONTAM)

General risk assessment

Taking stock

In the CONTAM area, cooperation with Member States takes place via the submission of occurrence data for various contaminants (e.g. heavy metals, persistent organic pollutants, marine biotoxins) in food and/or feed. Generally, Member States submit these data to EFSA's DATEX Unit to compile these data, which are then in the scientific opinions of the CONTAM Panel. In addition, the CONTAM Panel makes frequent use of the EFSA's "Concise European Food Consumption Database" in its risk assessments. This database contains information regarding the average daily consumption of foods per person sourced from the Member States.

A good example is a series of risk assessments related to marine biotoxins carried out by the CONTAM Panel. To this purpose the DATEX Unit collected data from EU Member States on both toxins occurrence and shellfish portions consumed in single meals. In order to protect consumers with a high consumption of shellfish against acute effects of marine biotoxins, the CONTAM Panel identified 400 g of shellfish meat as an appropriate estimate of a large portion size consumed in Europe to be used in the risk assessments. Recently, EFSA received new data on the shellfish portion sizes consumed from Belgium, France, Portugal and Spain. A re-assessment of the shellfish consumption figure was therefore carried out by the CONTAM Panel. For this purpose also data from the new Comprehensive European Food Consumption Database were used for the first time. Based on the new data the CONTAM Panel concluded that the earlier established estimate of the consumption figure of 400 g shellfish meat is appropriate for protecting high consumers against acute effects of marine biotoxins.

In anticipation of European risk assessments in the area of mycotoxins and natural plant toxicants, the CONTAM Unit has issued several Article 36 calls and scientific procurements. For example, one Article 36 project compiled scientific information on morphine in poppy seeds and mycotoxins such as alternaria toxins, moniliformin, diacetoxyscirpenol, sterigmatocystin, phomopsis, ergot alkaloids and nivalenol in food and feed. This collaboration with Member States demonstrated an effective way to facilitate the risk assessments in the area of mycotoxins, which are carried out by the CONTAM Panel between 2010 and 2012.

In addition, the expert database and national risk assessment available via the IEP are very useful tools and sources of information for the ongoing work of the CONTAM Panel.

Looking ahead

The CONTAM Unit and Panel are seeking further collaboration with Member States in the area of mycotoxins, natural plant toxicants and process contaminants e.g. 3-monochloropropane-1,2-diol (**3-MCPD)** esters. Thus, in July 2010 EFSA signed an Article 36 agreement which will provide occurrence data on ergot alkaloids in food and feed. These data will provide a useful source of information for this risk assessment which has to by finalised by the CONTAM Panel in 2011. In addition, an Article 36 grant agreement related to a toxicity study of 3-MCPD esters in rats, which will be available in 2011, will provide useful toxicity data which may be used in the risk assessments by the CONTAM Panel, national or international bodies. In addition, the CONTAM Unit will follow up the outcome of adopted CONTAM opinions by data needs identified in order to refine risk assessment. For example, in relation to the outcome of the risk assessments on marine biotoxins, the gathering of experimental data related to the influence of processing (e.g. cooking, steaming, and autoclaving) on the level of marine biotoxins in shellfish. Related to the risk assessment on nitrate in vegetables, the influence of processing on the nitrate content in vegetables will be studied. It is also anticipated that the series of risk assessments related to brominated flame retardants will identify data needs which should be addressed to have a more refined risk assessment. For 2012 the CONTAM Unit plans a workshop on contaminants with Member States and the European Commission.

Member State collaboration via scientific procurement is also needed when addressing questions related to chemical contaminates within the meat inspection mandate which EFSA recently received.

In case urgent requests arrive to EFSA the continuation of effective co-operation with Member States is crucial for the scientific outputs conducted by EFSA. Examples of successful cooperation with Member States in the area of contaminants are statements related to e.g. public and animal health in the European Union posed by possible contamination of the feed and food chain due to ash-fall following the eruption of the Eyjafjallajökull volcano in Iceland, and risks for public health due to the presence of dioxins in pork from Ireland.

DATA COLLECTION AND EXPOSURE (DATEX)

Data collection, analysis and reporting

Taking stock and looking ahead

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 European Commission on the current situation along with the proposed sampling plan for the following year. The European Commission performs the data collection and EFSA's DATEX Unit accesses results in the Commission's database, analyses them and produces the report. The first annual report was issued by EFSA in November 2009 based on Member State data submissions for 2008. Every following year a new report will be produced on the results of the previous year.

EFSA has also been given the task to periodically collect data provided by the Member States and produce occurrence reports on a number of environmental contaminants, process contaminants and other undesirable substances in food and feed. Some of these continuing collections are already ongoing; many others are in the process of being formalised.

EFSA started in 2008 to collect data on two process contaminants, acrylamide and furan. Acrylamide is a genotoxic and carcinogenic contaminant that may be formed in food, particularly plant-based food rich in carbohydrate, during cooking, frying, baking or roasting, at temperatures of 120°C or higher. Furan is a carcinogenic organic compound that can be formed in food during commercial or domestic heat treatment, including home cooking. The European Commission initiated recommendations 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.

As part of the European Commission strategy to reduce the presence of dioxins in food and feed, data collected by the Member States through the European Commission were sent to EFSA in 2009 for statistical analysis. Dioxins are widely distributed contaminants with different toxic effects including dermal toxicity, immunotoxicity, carcinogenicity, reproductive and developmental toxicity. They are formed during incomplete industrial and natural combustion processes and tend to accumulate in the fatty portion of food. The first 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 (**PCB**s) included in the dioxin and dioxin-like compound group. Starting in 2010, continuous collection from the Member States of data on dioxins and dioxin-like PCBs and annual reporting on their occurrence is one of the new tasks of EFSA.

Similarly, data collection and reporting on non dioxin-like PCBs has started with a first report published in 2010.

Additional continued data collections with periodical reporting will start in 2011 for many groups of contaminants:

- inorganic contaminants (including nitrates, arsenic, cadmium, lead and others) in food and feed;
- mycotoxins (including aflatoxins, ochratoxins, fumonisins, nivalenol and others) in food and feed;
- inherent plant toxins (including pyrrolizidine, opium alkaloids, tropane alkaloids and others) in food and/or feed; and
- organochlorine compounds in feed.

Apart from the continued data collections described above, the European Commission has occasionally requested that EFSA provide a topical occurrence report for specified contaminants. In these cases EFSA, in close collaboration with the European Commission, issues calls for contaminant data from Member States and other interested parties, as needed, and produces the report. An example of this category is polycyclic aromatic hydrocarbons (**PAHs**) that can be formed from a variety of

combustion and pyrolysis processes and of which a number have been shown to be genotoxic carcinogens. A topical report requested by the European Commission was issued in 2007 covering these compounds.

Many data collection activities on occurrence of specific substances also involve assessment of human dietary exposure.

Harmonising testing methodology

Taking stock and looking ahead

There are some significant attempts already in place across the EU to harmonise testing methodology for contaminants. Regulation (EC) No 882/2004 establishes European Union Reference Laboratories (**EU-RL**) in food and feed for marine biotoxins; mycotoxins; heavy metals in food and feed; dioxins and PCBs; PAHs; residues of veterinary medicines and contaminants in food of animal origin; animal proteins in feeding-stuffs; and additives for use in animal nutrition.

Regulation (EC) No 32/2002 deals with undesirable substances intended for animal feed. For example it defines the maximum content in feedstuff for some natural plant toxins such as free gossypol, theobromine, and ricin (derived from the Castor Oil plant). Further, there are also a number of European Commission Regulations specifying in detail sampling and analytical protocols to follow for the official control of selected contaminants. Moreover, European Commission Regulation (EC) No 1881/2006 specifies contaminants that should be regularly tested. However, the number of tests to be performed is not specified. Thus implementation varies across Member States. For example, monitoring of nitrate in vegetables is compulsory with regular reporting to the European Commission but the frequency of testing would vary between Member States.

Despite the official specifications some incongruence in the reporting of analytes has been experienced. Specificity and sensitivity of the methods used are not always given. Sensitivity is more commonly geared to maximum limits in the legislation rather than the levels required for the exposure assessment.

Concerning chemical occurrence data, an Expert Group (Network) endorsed by the EFSA Advisory Forum, assists since 2008 in harmonising data collection efforts across the Member States. Contact has also been established with several of the EU-RL for important contaminant areas to discuss harmonisation of analytical methodology and sensitivity.

The Technical Working Group on Data Collection (**TWG-DC**) was introduced by EFSA in 2009 to develop a proposal to harmonise the collection of analytical measurement data for the presence of harmful or beneficial chemical substances in food, feed and water. The TWG-DC was expected to produce documents on two separate aspects:

1. the harmonised description of data on analytical measurements in food and feed samples (Guidance on Standard Sample Description for Food and Feed), including a list of standardised data elements (items describing characteristics of samples or analytical results such as country of origin, product, analytical method, limit of detection, result, etc.), controlled terminologies and validation rules to enhance data quality; and
2. the procedures to efficiently transmit and exchange data between Member States and EFSA (Guidance on data exchange) taking care of selecting specific file formats for data transmission (e.g. Extensible Markup Language (**XML**), Microsoft Excel etc.) and specific data transmission protocols to support electronic data exchange.

The Guidance on Standard Sample Description for Food and Feed has been published in January 2010 after peer review of the Expert Group on Chemical Occurrence. The Guidance on Data Transmission will follow at the end of 2010.

Two other harmonisation initiatives need to be mentioned.

a) 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 assigned to the DATEX Unit an internal 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 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.

b) 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 provided recommendations for the handling of such data in March 2010. The outcome will facilitate harmonisation across Member States and laboratories of the details reported for a range of contaminants.

ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP)

Risk assessment within the authorisation process

Taking stock and looking ahead

Most of the work dealing with authorisations in the FEEDAP Unit is related to the authorisation of feed additives, which is regulated by Regulation (EC) No 1831/2003. This regulation lays down that EFSA is responsible for carrying out the risk assessment of feed additives, based on technical dossiers provided by the applicants. In the past, this work was done by Member States in the framework of the SCFCAH.

The FEEDAP Unit/Panel has been cooperating with Member States since 2004, when the Regulation (EC) No 1831/2003 came into force. The Regulation states that EFSA must "make any information supplied by the applicant available to the Member States" (Art. 7.2.b). By using the electronic platform on the extranet, Member States can access all documentation related to any application for authorisation of feed additives.

In order to make best use of the available experience in the Member States, experts of the Member States are invited to review the dossiers for authorisation of feed additives, and provide comments related to the risk assessment during the first three months, after the dossier has been considered valid. The comments submitted by Member States are taken into consideration during the assessment, performed by the Working Group and the Panel.

GENETICALLY MODIFIED ORGANISMS (GMO)

Risk assessment within the authorisation process

Taking stock

EFSA carries out the risk assessment of GMOs in the EU. Member States participate throughout the risk assessment process, while EFSA's GMO Panel is responsible for preparing and adopting the GMO risk assessments. Based on the GMO Panel's risk assessment, Member States and the European Commission decide on GMO authorisation applications.

In the regulatory procedure for GMO risk assessment, Member States either carry out the initial risk assessment themselves (under Directive 2001/18/EC) or, under Regulation (EC) No 1829/2003, have the opportunity to examine all GMO applications in detail and provide input to EFSA, while it is carrying out the risk assessment. When cultivation of the GMO is involved, Member States are asked to volunteer to carry out and provide EFSA with the ERA.

Member States have the opportunity to see all GMO applications and provide input, where appropriate, through a dedicated extranet called "EFSAnet". EFSA has developed this platform to provide Member States with a channel of communication on the risk assessment process. While carrying out its risk assessments, EFSA is regularly in contact with the competent authorities in Member States, which are offered a weekly update from EFSA on the progress of open applications.

EFSA's GMO opinions take into consideration all scientific comments received from Member States on GMO applications. Moreover, since June 2006, in the interest of transparency, EFSA has undertaken to indicate how specific comments have been addressed in its opinions on GMOs, by including a list of comments and responses in an annex of the overall opinion on the respective GMO.

EFSA also ensures a close collaboration with Member States in the framework of the GMOs applications for cultivation (submitted under Regulation (EC) No 1829/2003) since 2005. EFSA collaborates with competent authorities of Member States who have volunteered to take charge of the initial ERA of GMO applications for cultivation. Three meetings are systematically organised during the risk assessment process between the Member States competent authorities and their scientific bodies and EFSA and its GMO Panel and the Member State competent authorities is always invited to a GMO plenary to present the outcome of the ERA to the GMO panel.

Up to now EFSA and its GMO Panel has collaborated/is collaborating on 17 cultivation applications with Czech Republic, France, Germany, Spain, Sweden, UK and The Netherlands.

Looking ahead

Performing the initial ERA is a major undertaking for Member States. Up to now, a few Member States have been able to take on this responsibility. Whilst the regulation stipulates that EFSA "shall" delegate the ERA EFSA encounters difficulties in finding Member States that volunteer.

Preparation of guidance

Taking stock

Member States have in general been less involved in the generation of guidance to applicants than they have been in the assessment of applications (see above). The main activity for Member States' participation has been through the obligatory public consultation of each guidance adopted by the GMO Panel. Very valuable input has been collected from Member States as well as from the scientific community at large. During the last 30 months, EFSA has been updating its ERA guidance for applicants. The work is based on a self-tasking mandate as well as on a mandate from the European Commission. The European Commission's mandate specifically states that EFSA shall strive to develop this guidance in close cooperation with Member States. Thus, Member States have been

involved by EFSA in two ways: by being kept informed and by being invited to provide input at various occasions.

Specifically, the following activities have taken place: EFSA has twice met and discussed the general outline of the work in the regulatory committee for Directive 2001/18/EC, in March and November 2009. A summary of the work in progress was also presented during the European conference - EFSA and GMO Risk Assessment for human and animal health and the environment - in September 2009.

Furthermore, an in depth discussion between Member States representatives and the experts of the EFSA GMO Panel was organised twice *i.e.* in June 2009 and 2010. The latter meeting was webcasted to provide an opportunity for all interested parties to view the proceedings live. During the public consultation of the updated ERA guidance in mid 2010, a total of 494 comments were submitted, 254 from 10 Member States, Switzerland and Norway. Many useful comments were received.

Looking ahead

EFSA will arrange the first meeting of the EFSA scientific risk assessment network for GMOs. The participants come from the Member States and include experts from the area of molecular characterization/food and feed safety and from the area of environmental safety. The aim is to create an environment, where risk assessment practices and priorities can be discussed with invited GMO Panel members.

DIETETIC PRODUCTS, NUTRITION AND ALLERGIES (NDA)

Risk assessment within the authorisation process

Health Claims

Taking stock

In 2008, EFSA had received from the European Commission a list of 4,185 function claims for scientific evaluation, as foreseen in Article 13.1 of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods. The list was received in the form of a database, which had been compiled by the European Commission based on the submissions from Member States. In this process, Member States had had the responsibility to provide references to the totality of available scientific evidence for each health claim on the list, upon which the EFSA NDA Panel bases its assessments. This list was complemented by an addendum of 452 health claims, which has been submitted to EFSA in March 2010. EFSA screened all health claims contained in the original list using six criteria established by the NDA Panel to identify claims, for which EFSA considered sufficient information had been provided for evaluation, and those, for which more information or clarification was needed, before evaluation could be carried out. This led to the identification of around 2,000 health claims, which were referred back to the European Commission and the Member States for further clarification.

Subsequently, the European Commission coordinated with Member States the provision of the information or clarification, which was requested by EFSA; EFSA received this information in November 2009.

The original database of Article 13.1 health claims contained a number of "misplaced claims", where information on similar claims had been accidentally placed under a wrong health claim entry. Upon request of the European Commission and Member States, EFSA re-allocated those "misplaced claims". During this process, some Member States also identified a number of missing similar health claims, which still needed to be submitted to EFSA ("missing claims"), which were added to the database.

The assessment of health claims, based on newly developed scientific data or proprietary data (Article 13.5) and health claims referring to the development and health of children or disease risk reduction claims (Article 14), is based on the information provided by the applicant in the form of a dossier. Regulation (EC) No 1924/2006 foresees that the applicant submits the application for authorisation to a competent authority of a Member State, which is responsible for performing a validity check of the application.

Once EFSA receives the application, it informs the European Commission and all Member States and makes the application and any supplementary information, supplied by the applicant, available to them. The respective competent authority of the Member State, who submitted an application, is also kept informed about any communication with the applicant and EFSA may address the competent authority of the Member State directly, in case a question regarding the scope of an application is identified.

All Member States are notified, as soon an application health claim opinion has been published. EFSA also ensures that Member States are always informed about EFSA's scientific assessments in the area of health claims. EFSA regularly attends the meetings of the European Commission Working Group on Health Claims as well as the relevant meetings of the SCFCAH and assists Member States in any scientific questions which arise.

In October 2009, EFSA organised a technical meeting with representatives of the Member States and the European Commission in order to explain the approach of the NDA Panel in the evaluation of Article 13.1 function claims and to clarify some procedural aspects. This was followed by a technical meeting in June 2010, which was not only open to Member States, but also to all other stakeholders and covered not only the assessment of Article 13.1 function claims, but also the assessment of claims, which are based on newly developed scientific data or proprietary data (Article 13.5) and

health claims referring to the development and health of children or disease risk reduction claims (Article 14).

Looking ahead

EFSA is striving to maintain the close cooperation with Member States which it currently has in place in the area of health claim. It is expected, that the evaluation of Article 13.1 function claims (excluding botanicals) will be finalised (adopted) by end of June 2011, unless other priorities emerge.

Changes to the Community list of function claims, once adopted by the European Commission, may be made after consultation of EFSA on the European Commission's own initiative or following a request by a Member State. Therefore, further cooperation with Member States will emerge in this area, once the Community list of function claims has entered into force.

The authorisation of Article 13.5 and 14 claims is an ongoing process, depending on the applications received. Therefore also the communication with Member States can be considered as an ongoing process.

Based on experiences gained with evaluation of claims and to further assist applicants in preparing and submitting their applications for authorisation of health claims, the NDA Panel has been asked to develop guidance documents on the scientific requirements for health claims (e.g. gut and immune function; post-prandial blood glucose responses/blood glucose control; weight management, energy intake and satiety; protection against oxidative damage; cardiovascular health; bone, joint and oral health; neurological and psychological functions; and physical performance). Each guidance document will be subject for public consultation and may be followed-up as appropriate by scientific meetings with experts in the field.

Novel Foods

Taking stock

Under the current legislation [Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients] a Novel Food application is first assessed by a Member State, which drafts the "Initial Assessment Report (**IAR**)". The European Commission forwards the application and the IAR to all other Member States, which are given 60 days to provide comments. In the case that one or more Member States express objections related to the safety of the proposed Novel Food, the European Commission tasks EFSA to provide a "second opinion".

While in the early years of EFSA, this applied only in approximately one third of the applications, in recent years, EFSA has had to reassess the majority of the Novel Food applications. For its assessment, EFSA takes into account the IAR and all scientific comments from all Member States, which constitute very valuable input for EFSA.

Looking ahead

In early July 2010, the European Parliament adopted amendments on an European Commission's proposal for a new Novel Food Regulation. It is anticipated, that this proposal will be subjected to a conciliation procedure, in order to reach agreement between the European Parliament, the European Commission and the Council, and that the new regulation will come into force in April or May 2011. The new regulation foresees a centralised authorisation procedure and EFSA to carry out the safety evaluations. Related to the new regulation, which will also introduce the concept of history of (safe) use for "traditional foods from third countries", EFSA expects to receive a mandate to provide guidance to applicants, on how to prepare and present an application. EFSA is committed to work together with Member States and to take into account their input for such a guidance document. This will happen via the Advisory Forum and consultation on a draft guidance document.

General risk assessment

Taking stock

In 2005 EFSA has been asked by the European Commission to review and update the last report on recommended nutrient and energy intakes for the EU population prepared in 1993 by the Scientific Committee on Food (**SCF**). In doing so, the NDA Panel is taking into account new scientific evidence and more recent national intake data and recommendations as well as the existing advice of the Scientific Committee on Food on Population Reference Intakes for energy, nutrients, and other substances with a nutritional or physiological effect.

By now, EFSA issued five scientific opinions related to Dietary Reference Values (**DRVs**): principles for deriving and applying DRVs; DRVs for water; DRVs for fats, including saturated fatty acids, polyunsaturated fatty acids, monounsaturated fatty acids, trans fatty acids, and cholesterol; DRVs for carbohydrates and dietary fibre; guidance for food-based dietary guidelines.

All draft opinions on DRVs, were subject to public consultation with Member States, the scientific community, and other stakeholders. In September 2009, a meeting with Member States to place, to discuss the draft opinions as well as comments received during the public consultations with national experts.

Looking ahead

The draft opinions on DRVs for Energy and Proteins, which are currently under preparation, will be subject to public consultation by end 2010/beginning 2011. The work on DRVs for micronutrient will start in 2011. All opinions will be again subject to public consultation and maybe also discussed, as appropriate, at dedicated meetings with national experts.

PLANT HEALTH (PLH)

General risk assessment

Taking stock

A scientific network for risk assessment in plant health has been established with the overall objective to build mutual understanding of risk assessment principles in the plant health sector and to provide increased transparency in the current process among Member States and EFSA. The 1st network meeting has taken place on 14-15 October 2010. The specific objectives of the scientific network for risk assessment in plant health are:

- to facilitate harmonisation of pest risk assessment practices and methodologies;
- to enhance exchange of information and data between EFSA and Member States; and
- to achieve synergies in pest risk assessment activities.

Following the preparation and endorsement of draft guidance documents by the PLH Panel, a public consultation was launched which aimed at collecting the views and comments of the stakeholders including the Member States. Information submitted within the public consultation is taken into account during the finalisation of the guidance document. The PLH Panel is currently developing a guidance document for the assessment of environmental risks which is planned to be launched for public consultation in June 2011.

The ongoing project "*Prima phacie*" aims at developing methodologies for pest risk assessments and was granted in 2009 to a consortium of 11 partners from 8 Member States. The grant will conclude in 2012. A new call for proposals has been launched in June 2010 on "Plant health pest surveys for the EU territory: an analysis of data quality and methodologies and the resulting uncertainties for pest risk assessment".

Looking ahead

PLH cooperation with Member States will be further reinforced and enhanced through the PLH scientific network and collection of data. The way in which Focal Points could assist in data collection will be further explored.

Data for pest risk assessments for the EU territory often need to be collected from Member States through questionnaires particularly on pest occurrence/prevalence and on phytosanitary measures. For example, in 2009 a request was made to the Advisory Forum representatives on Plant Health on control measures taken against the oak processionary moth *Thaumetopoea processionea*[31]. In 2010-2011, questionnaires to Member States are planned on solanaceous pospiviroids and *Monilinia fructicola* f1. This information, together with results of EU projects (such as EUPHRESCO[32]) and results of Member States' surveys, will be used by the PLH Panel to conduct pest risk assessment for the EU territory.

[31] EFSA Panel on Plant Health. Scientific Opinion on a pest risk analysis on *Thaumetopoea processionea* L., the oak processionary moth, prepared by the UK and extension of its scope to the EU territory. The EFSA Journal (2009) 1195, 1-64.

[32] A European Research Area - Network (ERA-NET) project for research policy development and implementation in the field of statutory and emerging plant pests, diseases and invasive species (but not: GMO's)

Pesticide Risk Assessment Peer Review (PRAPeR) and Plant protection products and their residues (PPR)

Risk assessment within the authorisation process

Taking stock

The following legislations are relevant for the authorisation process of pesticides:

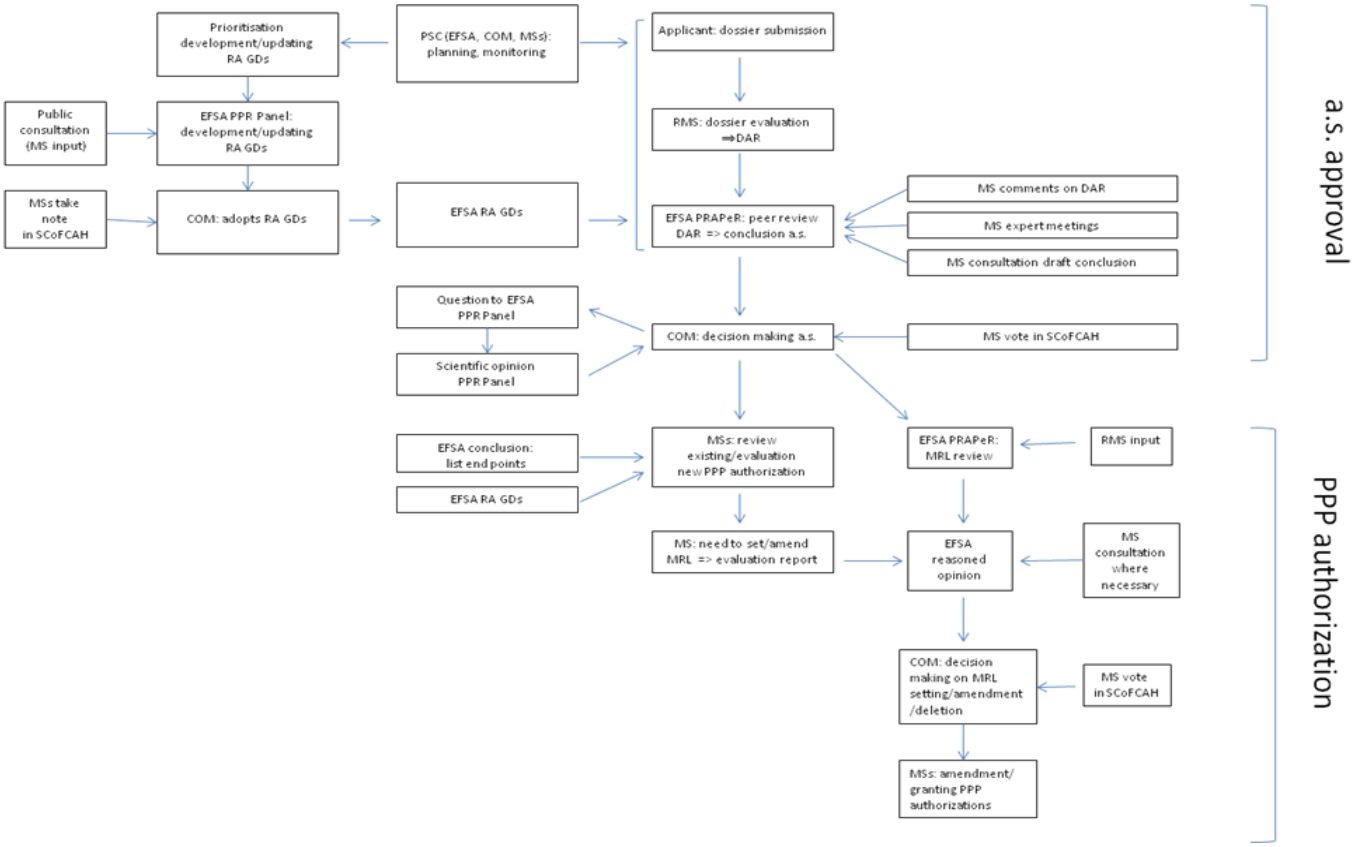
- Directive 91/414/EEC and Regulation (EC) No 1107/2009 concerning the placing of Plant Protection Product (**PPP**) on the market (the Regulation will replace the Directive as of 14 June 2011);
- Regulation (EC) No 369/2005 on Maximum Residue Levels (MRLs) of pesticides in or on food and feed of plant and animal origin.

This authorisation process is a two step procedure:

- the active substance approval at EU level;
- the PPP authorisation at Member State level.

However, both steps involve the participation of several partners, representing both the national level (Member States) and the EU level (European Commission and EFSA). Fig. 1 illustrates the whole process.

Fig 1: Active substance (**a.s.**) approval and PPP authorisation: interactions between EFSA, European Commission and Member States



The cooperation between EFSA and the Member States is particularly important with regard to:

- the EFSA peer review of the Draft Assessment Report (**DAR**) produced by the Rapporteur Member State, including commenting on the DAR by all Member States and participation of Member States' experts in the EFSA expert meetings, and leading to the EFSA conclusion on the active substance;
- the management of the process in the Pesticide Steering Committee (**PSC**), i.e. EFSA's networking with Member States in the area of pesticides;
- the drafting of reasoned opinions on MRLs by EFSA on the basis of Member States' input.

Within EFSA, the organisation of the peer review, the drafting of the conclusions and the drafting of the reasoned opinions are allocated to the PRAPeR Unit. The PPR Panel is contributing to the process in two ways:

- by producing Risk Assessment Guidance Document used throughout the process (both for the active substance approval and the PPP authorisation); and
- by answering specific scientific questions that could not be solved during the peer review process or raised by the European Commission.

The following aspects are contributing to the efficiency of the process:

- the involvement of Member States, both in the scientific evaluation and in the management of the process (through the PSC), contributing to understanding of scientific and procedural issues;
- the work distribution between PRAPeR and PPR, with the PRAPeR Unit performing the routine evaluations in line with risk assessment methodologies developed by the PPR Panel experts supported by the PPR Unit;
- a good cooperation within the Pesticide Steering Committee between EFSA, the European Commission and Member States in the identification of needs regarding guidance documents, the appropriate prioritisation of the development of these guidance documents and a high degree of implementation when they are finalised;
- participation of Member States' risk assessors in scientific workshops organised by the PPR Unit;
- systematic public consultation on EFSA's website on draft guidance documents at the beginning and/or the end of the process; Member States are the main contributors; and
- information of Member States on the ongoing work of the PPR Panel on guidance documents is regularly done by presentations at the PSC and the Standing Committee of DG SANCO of the European Commission.

Looking ahead

Some areas could be considered for improvement:

- the complexity of the peer review of DARs in PRAPeR Unit is such that it only functions smoothly when all partners involved deliver their input timely and according to a high quality standard; the resource situation to meet these expectations is variable between Member States;
- for new active substances the selection of the Rapporteur Member State is done by industry: where national organisations may need the fee, there is a potential for competition for such tasks between Rapporteur Member States.

Post-marketing Monitoring

Taking stock

According to Regulation (EC) No 396/2005 on MRLs of pesticides in or on food and feed of plant and animal origin, Member States have the obligation to control compliance of MRLs in food and feed samples by official controls and to submit the results of the control activities to the European Commission and to EFSA. Article 32 of Regulation (EC) No 396/2005 requests EFSA to prepare an Annual Report on Pesticide Residues. The report shall give an overview of the control activities performed by Member States and EFTA countries in order to ensure compliance of food with the MRLs established at EU level, to summarise the results provided by the reporting countries, to identify critical areas of concern regarding MRL compliance, to assess the actual consumer exposure to pesticide residues, and to perform an analysis of potential chronic and acute consumer health risks related to the intake of pesticide residues.

In June 2009 and June 2010 EFSA published its annual reports on pesticide residues in food which was on the market in 2007 and 2008, respectively. Each year more than 70,000 samples were analysed by the competent authorities in Member States and EFTA countries (Norway and Iceland).

Following its first annual report, EFSA identified deficiencies in the formats used by the reporting countries to return the results of the control activities to EFSA; these deficiencies impede performing all the evaluations as requested by the Regulation, including an accurate exposure assessment analysis. In agreement with the experts of the Networking Group on Pesticide Residues, EFSA started the initiative to develop a new data collection system aimed at facilitating the data transfer and validation to restructure the submitted data to allow more powerful data analysis and more accurate risk assessment. In 2009, a pilot project was launched to test the suitability of the new data model with real data submission. Six Member States (Austria, Denmark, Germany, Ireland, Slovenia, and The Netherlands) submitted the results of the monitoring activities performed in 2008 using the new format ("Standard Sample Description"): pesticide residue results from ca. 27,000 samples (corresponding to almost 6 million determinations) were submitted to EFSA. Taking into account the experiences gained in the pilot project, the data model was discussed in the Networking Group on Pesticide Residues and modified accordingly. The amended Standard Sample Description was used by all Member States and the EFTA countries for reporting the results of the pesticide residue control activities of 2009. In total more than 60,000 samples with results covering more than 800 different pesticides (for a total of more than 10,000,000 data points) were submitted in accordance with the agreed "Standard Sample Description" model. Thus, this data collection will be the major input source for building the EFSA data warehouse.

Looking ahead

The submission of detailed monitoring results by Member States and EFTA countries using the EFSA format ("Standard Sample Description") will allow more powerful analysis of the data. EFSA will be able to identify potential consumer risks related to certain pesticides, food commodities or the origin of the food. In addition, the submission of detailed results will provide the information to analyse reasons and risks related to multiple residues, co-occurrence of certain active substances which share a common mode-of-action or specific problems related to organic food, baby food and processed food.

Regulation (EC) No 396/2005 stresses the importance to assess cumulative and synergistic effects resulting from the exposure to pesticide residues. The PPR Panel is currently working on the development of a methodology. In order to perform these assessments the availability of monitoring data at sample level as collected in the new data format is essential. Further work is needed to collect detailed food consumption data in a format appropriate for probabilistic analysis (see chapter 5.2). However, as soon as the missing tools (methodology for cumulative risk assessment and food consumption data) are available, EFSA will be in a position to perform this analysis.

The development of the EFSA data warehouse will be a further important step regarding the information exchange with Member States and the European Commission services.

ANNEX 2 ACRONYMS

3-MCPD	3-monochloropropane-1,2-diol
ABP	Animal By-Products
AESAN	Agencia Española de Seguridad Alimentaria y Nutrición (Spanish Agency on Food Safety and Nutrition)
AFCWG	Advisory Forum Communication Working Group
AGRC	Advisory Group on Risk Communications
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (French Agency for Food, Environmental and Occupational Health & Safety)
a.s.	Active substance
ASF	African Swine Fever
BfR	Bundesinstitut für Risikobewertung
BPA	Bisphenol A
BSE/TSE	Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy
CRA	Cumulative Risk Assessment
CSF`	Classical Swine Fever
DAR	Draft Assessment Report
DG RTD	Directorate General for Research & Innovation
DG SANCO	Directorate General for Health & Consumers
DRV	Dietary Reference Value
FCM	Food Contact Material
GMOs	Genetically Modified Organisms
ECDC	European Centre for Disease Control and Prevention
EEA/EFTA	European Economic Area/ European Free Trade Association
ERA	Environmental Risk Assessment
ESCO	EFSA Scientific Cooperation Working Groups
EU	European Union
EU-RL	European Union Reference Laboratory
FCM	Food Contact Material
FDA	US Food and Drug Administration
IAR	Initial Assessment Report
ITX	Isopropylthioxanthone
JRC	Joint Research Centre
MRA	Microbiological Risk Assessment
MRL	Maximum Residue Level
NGO	Non-governmental Organisations
PAH	Polycyclic Aromatic Hydrocarbon
PCB	Polychlorinated biphenyl
PPP	Plant Protection Product
PSC	Pesticide Steering Committee
QMRA	Quantitative Microbiological Risk Assessment
QSAR	Quantitative Structure Activity Relationship
SC	Scientific Committee
SCF	Scientific Committee on Food
SCFCAH	Standing Committee on the Food Chain and Animal Health

SGC	Steering Group on Cooperation
TDS	Total Diet Study
TRISK	European Toxicology Risk Assessment Training
TTC	Threshold of Toxicological Concern
TWG-DC	Technical Working Group on Data Collection
UN	United Nations
VWA	Voedsel en Waren Autoriteit (Dutch Food and Consumer Product Safety Authority)
WHO	World Health Organisation
XML	Extensible Markup Language

EFSA Panels/Units

AFC	The former EFSA Panel on food additives, flavourings, processing aids and materials in contact with food
AHAW	Animal Health and Welfare
ANS	Food Additives and Nutrient Sources added to Food
BIOHAZ	Biological Hazards
CEF	Food Contact Materials, Enzymes, Flavourings and Processing Aids
CONTAM	Contaminants in the Food Chain
DATEX	Data Collection and Exposure
FEEDAP	Additives and Products or Substances used in Animal Feed
GMO	Genetically Modified Organisms
NDA	Dietetic Products, Nutrition and Allergies
PLH	Plant Health
PPR	Plant Protection Products and their Residues
PRAPeR	Pesticide Risk Assessment Peer Review
SC	Scientific Committee
SCAF	Scientific Committee and Advisory Forum
SCO	Scientific Cooperation
ZOONOSES	Zoonoses Data Collection

Appendix: Medium-term Activities Plan
2010-2013

EFSA is not bound to launch these calls or activities as specified.

Directorate	Science Unit	Planned activities			Framework contracts, Multiannual service contract	Direct Article 36 / Procurement calls - planned to be launched in 2011, 2012, 2013 *(year specified in brackets)*	Support by Networks	Workshop/Seminars with MS	Data/Information collection	Public consultation	Other
		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
	AHAW		1	Animal Health Strategy (4th pillar - science) - Vector-borne diseases		Updating, upgrading and sustaining critical systematic reviews on vector borne diseases (to be initiated in 2011 – should be active over the next 3-5 years).	-	-	-	-	-
			x	Animal Health Strategy/animal health law: Preparedness for mandates from the Commission		1. Data collection on specific animal diseases (follow-up of the Art 36 call CFP AHAW 2010-01 - to be initiated in 2012 – probably active over the next 3 years) in accordance with mandates received. 2. Data collection on commodity based risk assessment (follow-up of the Art 36 call CFP AMU 2010-01 - to be initiated in 2012 – probably active over the next 3 years) in accordance with mandates received	YES	-	YES	-	-
			1	Reg 1/2005 (transport of fish)							technical meeting with stakeholders
			2	Council Directive 98/58 - development of welfare indicators: pigs and poultry		procurement on review of new scientific evidence					
						Preparatory work for the future development of animal based measures for assessing the welfare of pigs. (2011)					
						Developing theoretical models for quantitative assessment of animal welfare (2011)					
			1	Guidance on animal health and welfare aspects of GM animals						YES	
			1	Scientific Network for Risk Assessment in Animal Health and Welfare			Coordination, collaboration and organisation of meetings and other means for the exchange of information and data within the Scientific Network for Risk Assessment in Animal Health and Welfare	YES (possibly - workshop with MS organised together with ECDC and the European Commission)			
	ANS	3		(EC)1333/2008 Food additives (will become fully applicable in 2011)			YES: (networks were involved in the distribution of the information on the public call for data)	-	YES: via four public calls for data were launched (preservatives, emulsifiers, waxes and miscellaneous food additives)	-	
		208		(EC) 257/2010 programme for the re-evaluation of food additives	Food additives - preparation of pre-evaluation documents on misc. food additives (other groups to be specified), Multiple framework contract with cascade (2011-2014). Food additives - • Preparation of pre-evaluation documents, including toxicological and non-toxicological data, for the re-evaluation of food additives permitted in the European Union (2010-2014).	Specific contracts under two FWCs (2011, 2012 and 2013).	-	-	-	-	-
		16		(EEC)89/107 Food additives (framework directive)			-	-	-	-	-
		10		(EC)02/46 Food supplements			-	-	-	-	-
		17		(EC)01/15 Fortification of food			-	-	-	-	-
			6	Revision meat inspection regime in the EU		Support (data collection) for a risk based meat inspection (2011). Preparation of background document for meat inspection mandate (2011). Technical report on risk based meat inspection (2011).	YES	YES (later in 2011 for poultry meat inspection)	YES	YES	Stakeholders meeting in 2010.
			x	Evaluation of antimicrobial treatments for carcasses (decontamination agents)			YES	-	-	-	-
			1	Work on antimicrobial resistance			YES	-	-	-	-
		4		(EC) 999/2001 - Art. 5.3, 6.1, Annex X TSE regulation			YES	-	-	-	-

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
	BIOHAZ	8		Reg (EC) 1774/2002 - Art. 4, 2. (e); Art. 5, 2. (g); Art. 6, 2. (i) Animal By-Products not intended for human consumption			YES	YES (workshop with MS organised together with the European Commission will take place in Nov 2010)	-	-	-
			1	Estimate public health impact of new targets for *Salmonella* in turkeys			YES	-	-	-	-
			1	Biogenic amines in fermented foods			YES	-	YES	YES	-
			1	Foorborne viruses			YES	-	YES	YES	-
			1	QMRA Campylobacter in broiler meat - control options			YES	-	-	-	-
	CEF	80		Recycled packaging processes			-	-	-	Only for guidelines in general	-
				(EC)1331/2008 Additives, enzymes, flavourings (procedure)			-	-	-	Only for guidelines in general	-
		75		(EC)1334/2008 - Art.3 Food flavourings	Summarize new dossiers on flavourings according to the new regulation, Multiannual service contract (2010-2014).	Collection, preparation and updating of data on flavourings and flavourings substances, specific contract under the FWC (2011).	-	-	-	Only for guidelines in general	-
		5		(EC)2065/2003 - Art. 7 Smoke flavourings used or intended for use in or on foods			-	-	-	Only for guidelines in general	-
		140		(EC)1332/2008 - Art. 3 Food enzymes		Screening and establishment of a database for safety evaluations of enzymes carried out by Member States (tbc).	-	-	-	Only for guidelines in general	-
		74		(EC)282/2008 Recycled plastic materials and articles intended to come into contact with foods		Support the risk assessment of recycling processes of plastics (year tbc)	-	-	-	Only for guidelines in general	-
		30 (for plastics) x (for active and intellingent materials)		(EC)1935/2004 - Art.9 Materials to come in contact with food 2002/72/EC - relating to plastic materials and articles intended to come into contact with foodstuffs (EC)450/2009 - on active and intelligent materials and articles intended to come into contact with food	Examination and drafting of summary datasheets on toxicity data related to the evaluation by the CEF panel of substances to be used in food contact materials, Framework contract (2009-2013). Examination and drafting of summary datasheets on physical, chemical and exposure data (non-toxicity data) related to the evaluation by the CEF Panel of substances to be used in food contact materials, Framework contract (2009-2013).	Screening of literature on bisphenol A (2011).	-	-	-	Only for guidelines in general	-
						Data collection on current uses of plasticizers in food contact materials (2011).					
						Re-grouping of chemicals for non plastics food contact materials (already launched in 2010).	-	-	-	Only for guidelines in general	For FCM we have an ESCO WG on non-plastics FCM Stakeholder meeting in 2011.
						Specific contracts under Framework Contracts (2011-2013)					
			4	Opinions on mycotoxins for 2011			-	-	YES (occurance data, via Datex)	-	-
			1	Opinions on heavy metals for 2011			-	-	-	-	-
			3	Opinons on persistent organic pollutants for 2011		Data collection and analysis on brominated flame retardants (2011).	-	-	-	-	
			1	Opinions on inherent plant toxins for 2011			-	-	YES (occurance data, via Datex)	-	-
			1	Opinins on emerging contaminants for 2011			-	-	YES	-	-
			1	Opinion related to evaluation of substances on the EC list as acceptable previous cargoes for edible fats and oil for 2011-2013 (this involved app. 100 substances and leads to maybe more than 1 output		Support for evaluation of 100 sustances as acceptable previous cargoes. Collection of information related to criteria II (ADI/TDI) and criterium III (food allergenicity). Procurement in 2011. Specific contract under Framework contract CT/EFSA/AMU/2009/01).	-	-	YES (to companies)	-	-
						Support for evaluation of 100 substances as acceptable previous cargoes. Collection of information related to criterium IV (reactivity of substances) (2011).					
			5	Meat inspection mandate (BIOHAZ but - co-adoption by CONTAM) for 2011 to 2013		Preparatory work for contaminants evaluation in food chain (2011 procurement).	-	-	-	-	-

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
Risk Assessment Directorate	**CONTAM**		x	marine biotoxins - follow up of outcome of adopted opinions - data needs identified in order to refine risk assessment		Obtaining experimental data related to the influence of processing (e.g. cooking, steaming, autoclaving) on the level of marine biotoxins in shellfish (2011).	-	-	-	-	Belgian indicated that they will carry out such a project in 2011 pending approval. Proposal is to i) get more information from BE if the objectives (EFSA and BE) are identical and if BE gets funding for this project in 2011. In case BE objectives matches with EFSA and BE fundings are available, EFSA would not need such a call as it would be an overlap.
			x	nitrate in vegetables - follow up of outcome of adotped opinions - data needs identified in order to refine risk assessment		Influence of processing on nitrate content in vegetables (2012).	-	-	-	-	-
			x	Workshop on contaminants (2012)			-	YES (in 2012)	-	-	To have such a workshop was alreday proposed by EC for 2010
		1-2 per year		Pharmacologically active substaces (Regulation (EC) 470/2009, Art. 19)			-	-	-	-	-
	FEEDAP	92		(EC)1831/2003 - Art. 4 Additives in animal nutrition (1st evaluation and re-evaluation)	Preparation of background document for the re-evaluation of feed additives, Framework contract (2011-2012). Support to the statistical evaluation of dossiers on feed additives, Framework contract (2011 -2012).	Specific contracts under Framework Contracts (2011-2012)	-	-		"Guidance document for the assessment of biomasses for use in animal nutrition" will be published for public consultation by the end of 2010, and in 2011, the "Technical Guidance on the safety of use of Bacillus species in animal nutrition".-	-
		309		(EC)1831/2003 - Art. 10 Additives in animal nutrition (1st evaluation and re-evaluation)			-	YES (in 2011)	-	-	-
		probably 2		(EC)1831/2003 - Art. 13 Additives in animal nutrition (1st evaluation and re-evaluation)		Literature review and data collection on aspects related to the evaluation of the safety of certain categories of feed additives (2011).	-	-	-	-	-
		x		(EC)1831/2003 - Art. 14 Additives in animal nutrition (1st evaluation and re-evaluation)			-	-	-	-	-
		5		(EC)1831/2003 - Art. 15 Additives in animal nutrition (1st evaluation and re-evaluation)			-	-	-	-	-
		2		(EC)1831/2003 - Art. 25 Additives in animal nutrition (1st evaluation and re-evaluation)			-	-	-	-	-
		probably 1		(EC)767/2009 - Art. 10,13 Placing on the market and use of feed			-	-	-	-	-
	GMO	4 planned to be adopted in 2011 (1 Food/feed safety; 3 for environmental safety)		Guidelines for GM animals		Data collection and methodology support in GMO risk assessment in the area of GM animals (2011).	Possible discussion topic within "EFSA scientific network for risk assessment of GMOs" (network with MS experts; risk assessment approaches will be discussed)		relevant for: Data collection and methodology support in GMO risk assessment (2011)	4 public consultations on GD for GM animals foreseen during 2011	-
		1 ERA GD; 1 opinion on NTOs planned to be adopted in 2010		Guidelines for environmental risk assessment			Discussion topic within EFSA scientific network for risk assessment of GMOs" (network with MS experts; risk assessment approaches will be discussed)	2 consultation meetings with MS in 2009/2010 took place for the ERA GD development	-	2 public consultations (one for ERA GD, one for NTO document) were already done in 2010	-
		approx. 13- 14 received/year		(EC)1829/2003 - Art. 3-6, 15-18 GM food and feed *(1st evaluation and re-evaluation)*			EXTRAnet IT platform: comments from over 210 MS experts on all dossiers	-	-	-	-

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
		approx 140 to be received		EC 1331/2008 Food additives	Procurement for initial RA of applications to be received under 1331/2008 Food additives, Framework contract (2011-2015).	Specific contracts under Framework Contract (2012-2015)	-	-	-	-	-
	NDA		10	Population reference intakes for micronutrients and other essential substances		Literature review and data collection related to dietary reference values for micronutrients (2011).	-	-	-	10 public consultations on draft opinions related to Dietary Reference Values for protein, energy and certain micronutrients	-
			1	Guidance on assessing the safety of traditional food from third countries			-	-	-	-	-
			1	Guidance on the assessment of novel foods			-	-	-	-	-
		X (150 op - could be higher pending the EC decision on grey list claims)		(EC) 1924/2006 - Art 13.5, 14 Nutrition and health claims on food			-	-	-	7 guidance documents related to the assessment of health claims in selected areas	-
		X (2500 claims - will be combined to form coherent opinions)		(EC) 1924/2006 - Art 13.1 Nutrition and health claims on food			-	-	-		-
		5		(EC) 2000/13 - Art. 6(11) Labelling, presentation and advertising of foodstuffs		Data collection on novel foods (history of use) (2012).	-	-	-	-	-
		40		(EC)1997/258 Art 7(1) Novel food & ingredients			-	-	YES	-	-
		5		(EC)2006/141 - Art. 15 Infant formulae and follow-on formulae			-	-	-	-	-
	PLH		x	Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community		Preparatory work for developing methodologies and guidances and collection of data in support of risk assessment in plant health (2011).	-	-	-	-	-
						Data collection and preparatory data analysis to support the pan-European pest risk assessment for the PLH Panel scientific opinions.	-	-	-	-	-
			x	Pest risk assessment for the European Community plant health: a comparative approach with case studies (2009-2012)			YES	YES	YES	-	-
			x	Plant health pest surveys for the EU territory			-	YES	YES	-	-
			1	Guidance on environmental risk assessment of plant pests (2010-2011)			-	-	-	YES	-
			1	Risk to plant health of the solanaceous pospiviroids for the EU territory (2010-2011)			-	-	YES	-	-
			1	Risk to plant health of the plum pox virus for the EU territory (2010-2011)			-	-	YES	-	-
			1	Risk to plant health of *Monilinia fructicola* for the EU territory (2010-2011)			-	-	YES	-	-
	PPR	1		Directive 91/414/EEC and Regulation (EC) No 1107/2009 (both for placing plant protection products on the market, the Regulation will replace the Directive mid 2011)		Literature research on Endocrine Disruptors (2011)	no	-	YES	-	-
		1				Case study on Soil Ecoregions – extension from EU 3 to EU 27 (2011)		-	YES	-	-
		1				Review of the state of the art regarding toxicological (and ecotoxicological) risk assessment of microorganisms used as active substances (2012) - Specific contract under the Framework Contract CT/EFSA/AMU/2009/01).		-	-	YES	-
		2				Support to review of Draft EU Guidance Document for AOEL (2011)		-	-	YES	
		1				Literature research for updating the EU Ecotoxicolgy GD (Aquatic and Terrestrial) (2011).		-	YES	YES	-
		3				Preparatory work for the follow up questions requested by Risk Managers on guidance of birds and mammals (2012 or 2013).		-	-	-	-
		2				Modeling and calculations for development and implementation of PPR fate guidance under Regulation 1107/2009 (2011).		-	-	-	
			2	Technical reports on endocrine active substances (EAS) and environmental risk assessment (ERA)		Collection and analysis of data on specific subjects of relevance for the Scientific Committee (e.g. TTC) (2011)*.	-	-	-	-	-

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2010-2013

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
	SC		1	Technical report illustrating how to use of available software to derive a BMD			-	1 workshop for EFSA Staff and Panel Experts, December 2010 or early 2011	-	-	-
			1	Guidance on RA concerning potential risks arising from applications of nanoscience and nanotechnologies to feed, food and pesticides		Monitoring trends and developments in the area of applications of nanotechnology in food and feed (2014).	YES, Nano Network	-	-	-	-
			1	Protocol for 90-day feeding trials with whole food/feed			-	-	-	-	-
			1	Genotoxicity testing strategies			-	-	-	YES	
			1	Guidance on statistical approaches to assess adverse or biologically relevant effects		QSAR and other types of computational toxicology: Monitoring trends and developments, followed by development and practical demonstration of the usefulness. Direct contract (2011)* Development of quantitative methods for describing uncertainties, Direct contract (2012).	-	-	-	-	-
			1	Possible human health risk based on the concept of thresholds of toxicological concern			-	-	-	-	-
			1	Compendium of Botanicals			-	-	-	-	-
			1	Risk Assessment terminology in food and feed safety			-	-	-	-	-
			1	Guidance on Default Assumptions							
			1	Experimental animals		Impact assessment of the use of experimental animals to fulfill regulatory requirements in food and feed risk assessment (2011).	-	-	-	-	Consultation of relevant EFSA Panels and Units before adoption
						(*) Pending further prioritisation by the Scientific Committee, to include one of these projects in the WP 2011					
	AMU		x	Development of approaches to detect and predict emerging risks in animal health and plant health		Further method development for the assessment of emerging risks on animal and plant health (2011).	-	-	-	-	-
			x	Information retrieval from literature and classical library services		Training to EFSA experts and staff on systematic literature review (already launched in 2010).	-	YES	-	-	-
			x	Quantitative decision support and statistical data analysis	Multiple Framework Contract on statistics for statistical analyses and ad hoc consultation upon request (2011 - 2014)	Specific contracts under FWC (2011-14)	-	-	-	-	-
	DATEX		x	Access to product level market share of foods as sold in the 27 EU Member States	Food market intelligence services, Framework contract (2010 - 2013).	Food market intelligence services specific contract under FWC (2011 - 2013)	YES	-	YES	-	-
			x	Update on food composition database using the latest information available from selected participants in the EuroFIR network		Nutritional intake calculations using an updated food composition database and comprehensive food consumption information (2011).	YES	-	YES	-	-
			x	A systematic and harmonised approach for collecting food consumption data in EU Member States (EU Menu project)		Preparation for the EUMenu project food consumption data collection methods (2011). EU Menu IARC support (2011).	YES -	YES - Consultation on progress for the EUMenu project with the Expert Group for food consumption data -	YES -	- -	- -
			x	A new food classification system that can serve most of EFSA's areas and allow the use of the food consumption information in a direct match to the respective chemical or microbiological data collection		Development of a tool for entering food description details from the classification system to interface with laboratory LIMS system to simplify data entry (2011). *	YES	YES - Workshops on new food classification method (impementation of recommendations from WG)	-	-	EFSA colloquium on food classification held on 23-24 June 2010. Working Group appointed with reporting deadline in 2011.
			x	Review and refinement of exposure assessment methodology for acute and chronic exposure situations using deterministic and probabilistic methods		Development of a module to estimate model distributions of dietary exposure using Bayesian statistics (2011). Access to high performance probabilistic calculation computer service (2011).	-	-	-	-	YES - involvement by

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							***Please specify***
						Probability risk assessments: methodological development and testing in different areas (e.g. contaminants, additives, etc.) (2011).					Scientific Committee
			x	Collection of chemical occurrence data covering major foods in the diet (90%) in individual countries using the total diet study approach (TDS) with a statistically representative number of samples. Samples would undergo testing for a set range of chemicals			YES	YES	YES - Data collected using the TDS approach initially through the DG RTD funded activity	YES - New food classification proposal during 2011	YES - Activity supported by a DG RTD project to define the coverage and parameters to be used
			x	Standardisation of data collection and data transfer methodology		Assistance to Member States to map database structures to EFSA requirements and to submit data using the xml protocol (2011).	YES	YES	YES	-	-
				Guideline for using the comprehensive food consumption database		Updating the comprehensive food consumption database by incorporating recently collected data in adults and children (2011).	YES	-	YES	-	YES - Working Group appointed to develop guideline (2010)
		(*) additional call, for consideration pending budget availability during implementation									
	EMRISK		x	Crisis simulation exercise	Food and feed safety crisis preparedness training, Framework contract with one contractor (2010-2014).	Specific contracts under FWC (2011-2014)	-	-	-	-	-
			x	Identification of data sources and methods for identification of emerging risks		Foresight study on emerging risks in a particular area within EFSA`s remit to identify through a structured expert elicitation methodology, potential emerging risks in a specific area within EFSA's mandate (2011).	-	-	-	-	EFSA colloquium on emerging risks. Parma, 12-13 October 2010
						Data collection on consumptin of energy drinks under specific scenarios (2011)*					
						Development of a database for emerging risks (2011).					
			x	1st Annual report on emerging risks			Network will meet for the first time in November 2010	-	-	-	-
			x	Support to the AF on emerging issues			-	-	Stakeholders to be contacted for information concerning consumption of energy drinks	-	-
	PRAPeR	62		Directive 91/414/EEC - EFSA`s role as peer reviewer of the RMS`s initial evaluation drafting a conclusion on new active substances			YES	-	YES: Rapporteur Member State to provide assessment report	YES (on the RMS' Draft assessment report)	expert meetings with national experts
		27		Regulation (EC) 1107/2009- Art. 12 Conclusion on active substances			YES	-	YES: Rapporteur Member State to provide assessment report	YES (on the RMS' Draft assessment report)	expert meetings with national experts
		4		Regulation (EC) 1107/2009 - Art. 23 Opinion on basic substances			YES	-	YES: Rapporteur Member State to provide assessment report		
		16		Regulation (EC) 33/2008 - Art. 10, 20 Conclusions on resubmission of non-included substances			YES	-	YES: Rapporteur Member State to provide assessment report	YES (on the RMS' draft assessment report)	expert meetings with national experts
		58		Regulation (EC) 2229/2004 - Art 25a Conclusions on "green track" active substances of stage 4			YES	-	YES: Rapporteur Member State to provide assessment report	YES (on the RMS' draft assessment report)	expert meetings with national experts
		31		Draft AIR II Regulation - Art.12 Renewal annex I inclusion			YES	-	YES: Rapporteur Member State to provide assessment report	YES (on the RMS' draft assessment report)	expert meetings with national experts
		300		Regulation (EC) 396/2005 - art. 9-11 (setting new/amending existing MRLs)			-	-	YES: Rapporteur Member State to provide assessment report	-	-
		250		Regulation (EC) 396/2005 - art. 12(1) (MRL review following Annex I (non-)inclusion of the active substance- entry into force after September 2008)	Scientific and technical assistance on the review of existing MRLs pursuant to Article 12 of Regulation (EC) No 396/2005, Framework contract lots 1, 2, 3, 5, 6 (2010-2014).	Specific contracts under FWCs (2011-2014)	-	-	YES: MS are requested to provide the information supporting the MRLs in a format defined by EFSA (PROFile) (Excel file with integrated data validation implementing the data requirements and guidance documents applicable for assesment of residues in food	-	-
					Scientific and technical assistance on the review of existing MRLs pursuant to Article 12 of Regulation (EC) No 396/2005, Framework contract lot 4 (2011-2015).						
		167		Regulation (EC) 396/2005 - art. 12(2) (MRL review following Annex I inclusion of the active substance - entry into force before September 2008)	Scientific and technical assistance regarding the assessment of maximum residue levels (MRLs) for pesticides – Lot 1: ad hoc collection of CXLs and other information essential for a European risk assessment, Framework contract launched in 2009.						

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		Estimated amount of outputs on **authorisation dossiers** (x indicating amount of outputs difficult to estimate)	Estimated amount of outputs on **general risk assessment** (x indicating amount of outputs difficult to estimate)	Regulation/Subject							*Please specify*
		3		Annual Reports on Pesticide Residues	Scientific and technical assistance on the drafting of the Annual (2009-2012) Report on Pesticide Residues, Framework contract (2010-2014).	Specific contracts under Framework Contract (2011-1014)	YES	YES	YES: data are collected from all MS and EFTA countries by means of EFSA Standard Sample Descriptor. Information of ca. 70.000 samples, 10 million determinations.	-	YES: Member States consultation
	SCO		x	Scientific Cooperation with Member States	Focal Point multi-annual agreement.	Focal Point agreements, renewable yearly - 2010, 2011, 2012 and 2013.	YES	Focal Points organise national/international events with EFSA participation	Focal Points faciliate data and information collection from Member States regularly	-	-
			x	Information Excange Platform			YES	-	The IEP is collection of information	-	-
			x	Article 36 network			YES	in cooperation with Focal Points, many workshops/training modules to take place	-	Conslutation with AF and selected other EU agencies	-
			x	Expert database			YES	-	The Expert database is collection of information	-	-
			x	Scientific colloquia			YES	Colloquia are special types of seminars/workshops	-	Colloquia are a type of consultation with selected experts from MS	-
			x	EFSA Journal			-	-	-	-	-
			x	General training on risk assessment		Possibly organisation of a training module will be outsourced in 2012 or later (tbd).	-	YES	-	-	-
				Editing and proofreading	Framework contract 2011-2015.	Specific contracts under the FWC.					
	ZOONOSES		x	Annual Community Summary Reports on antimicrobial resistance (AMR) in collaboration with ECDC, EFSA's contractor and the Task Force on Zoonoses Data Collection; analyses of antimicrobial resistance data	Preparation of EU summary report on antimicrobial resistance, Framework contract (2010-2014).	Specific contracts: Preparation of EU summary report on antimicrobial resistance (2011).	Zoonoses Task Force is consulted about the analyses of AMR data and of the final report each year	A workshop on AMR data analyses in 2012	Member States will submit the data on AMR each year through EFSA's web application	-	A WG to make a proposal on analyses of AMR data to be set up for years 2010-2011
			x	Annual Community Summary Reports on Zoonoses and food-borne outbreaks in EU in collaboration with ECDC , EFSA's contractor and the Task Force on Zoonoses Data Collection; analyses of the data	Preparation of Community Summary Report on zoonoses, zoonotic agents and food-borne outbreaks, Framework contract (2010-2014).	Specific contracts under Framework contract (2011-2014)	Zoonoses Task Force is consulted about the analyses of the data and of the final report each year	A workshop on zoonoses and foodborne outbreak data analyses in 2012	Member States will submit the data on zoonoses and foodborne outbreaks each year through EFSA's web application	-	-
						Proposals for improved ways to analyse and present the annual data collected from Member States on zoonoses in the Community Summary Report (2011).					
						Reader survey among the recipients of the Community Summary Reports on zoonosis and anti-microbial resistance (2011).*					
						Support in statistical analyses of trends and targets of annual zoonoses data (2011), Specific contract under the Framework Contract CFT/EFSA/AMU/2007/01.					
			x	Coordination of the annual reporting on zoonoses, antimicrobial resistance and food-borne outbreaks		Assistance in the annual zoonoses data reporting due to transfer to a new database (2011), specific contract planned under a new Framework Contract to be launched by EFSA's ITOP unit.	Consultation of the Zoonoses Task Force on the reporting rules each year	-	Annual reporting through the web application; data validation	-	-
			x	Analyses of EU-wide baseline survey (Listeria in ready-to-eat foods)		Assistance in statistical analyses of Listeria baseline survey (2011) (specific contract under Framework Contract on statistical analysis launched in 2007).	Zoonoses Task Force is consulted about the analyses of the data and of the final report in 2011-13	-	Member States will be contacted about the data validation in 2011-2012	-	A WG to assist in the data analyses to be set up for years 2011-2013
			x	Meat inspection; setting on epidemiological criteria for certain zoonotic hazards targeted in meat inspection		Support in statitistical analyses of the data (2012) (specific contract under Framework Contract on statistical analysis launched in 2009).	Zoonoses Task Force is consulted about the analyses of the data and of the final reports in 2011-2013	-	Member States may be contacted about the data validation or for additional data n 2010-2013		WGs to assist in the data analyses to be set up for years 2010-2013
						Literature searches for data on zoonotic agents to support the meat inspection mandate. Direct Contracts (2010 and 2012).					
						(*) additional call, for consideration pending budget availability during implementation					

Last update: 25 October 2010