



## Previous and Current Scientific Cooperation with Member States

### INTRODUCTION

1. Since EFSA's operational start-up in May 2003, scientific experts from the EU Member States, with a high reputation in peer reviewing scientific information, are gathered in the Scientific Panels and Scientific Committee to conduct the risk assessments on request of the European Commission, the European Parliament, the Member States and on its own initiative, in the area of food and feed safety. In addition, scientific cooperation has been pursued frequently with experts from EU Member States, third countries, international organisations and stakeholders and such cooperation has indeed materialised in many areas of EFSA's work. Cooperation has been established, either on an *ad hoc* basis or in a more formalised manner, in the areas of science, communication and information technology (IT). In order to facilitate the discussions of the Advisory Forum on scientific coordination and networking amongst Member States and EFSA, this document provides, as background information, details of past and current scientific and other cooperation with Member States' experts and institutions. Scientific cooperation with third countries, international organisations and stakeholders will be addressed in a separate paper for a future discussion.

2. There is a high workload in the various areas covered by the Scientific Panels and Scientific Committee. The management and prioritisation of EFSA's scientific work has therefore been subject of discussions in meetings of the Management Board, the Advisory Forum and EFSA's Scientific Committee. It has increasingly become clear that in the interest of the Community it is important to identify ways to make a more efficient use of the sparse resources and scientific competence, both nationally and at European level, to conduct the scientific assessments needed at European level.

3. In June 2006, the Management Board adopted priorities for key recommendations derived from the EFSA Evaluation (carried out in agreement with Article 61 of Regulation 178/2002) and concluded that "furthering the development of active networking with Member States and strengthening the involvement/cooperation with national competent authorities" should be high on EFSA's agenda. Therefore, initiatives of the Advisory Forum to commit itself, together with EFSA, to further increase scientific cooperation by formalising the exchange of scientific information (see document AF

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29.09.2006-5 prepared for discussion and agreement at this meeting) are greatly appreciated.

4. In addition to these initiatives, EFSA wishes to explore with the Advisory Forum further options for close cooperation with the Member States at all levels. Whereas the focus will be on scientific cooperation, other areas such as communication and IT are also to be considered. To assist the Advisory Forum with its discussions on cooperation, two papers have been developed:

- Document AF 29.09.2006-4 providing an overview of current and past activities involving Member States, (this document), and
- Document AF 29.09.2006-5 providing financial and legal aspects for funding external cooperation and options for networking.

5. An overview of current and past activities with Member States' expert cooperation providing details of the work area, the legal basis for cooperation and the financial implications are provided in the table below.

### **SUMMARY OF PREVIOUS AND CURRENT SCIENTIFIC COOPERATION WITH MEMBER STATES**

6. A first analysis of the information included in the table leads to the following types of scientific collaboration that can be distinguished:

a) contracts with external experts or scientific research organisations for the preparation of scientific documents in the framework of regulatory risk assessments (for authorisations in particular) to be carried out by the respective Scientific Panels and Committee; typical examples are the dossiers in the area of flavourings, food contact materials, and more recently, the food colours; in some cases the preparation of a working document may be based on new experimental work to provide information required for the improvement of the risk assessment (e.g. semicarbazide);

b) collaboration with Member States' experts on request of EFSA or on request of a Scientific Panel in the framework of (the preparation of, the follow-up of) a risk assessment for an EU-wide collection and analysis of scientific data; costs involved are generally related to the preparation and organisation of the meetings, the preparation of a template to ensure a harmonised data submission and to provide the appropriate facilities for the transmission/sharing of the data (e.g. development of a suitable IT infrastructure for the sharing of data and related documents); examples are the activities in the area of zoonoses and BSE/TSE, and the collection of occurrence data on methylmercury, PAHs and furan; in some cases the active participation of the AF was requested to facilitate the data collection process;

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- c) formal consultation of the Member States in the framework of specific authorisation processes, as laid down in the respective specific Regulations such as in the area of feed additives (1831/2003), GMO's (1829/2003), and Pesticides (1490/2002 for existing, and 91/414 for new pesticides); bilateral meetings with Member States in the area of GMO's also belong to this category;
- d) collaborations with Member States, on initiative of EFSA's or one or more Member States, to follow and exchange information on newly identified or emerging subjects of common interest in the area of food and feed safety; examples are: nanotechnology, risk-benefit analysis of foods, marine biotoxins, quantitative microbiological risk assessment, BSE/TSE risk assessment.
7. The Advisory Forum was directly involved in various cases of the scientific collaborations as indicated in the table and summarised above. The table is also including other kinds of collaborations EFSA has established so far. The members of the Advisory Forum are invited to take note of the various activities and kinds of collaborations. The EFSA Secretariat would also appreciate the assistance of the members in developing an appropriate strategy to strengthen the co-operation with the Member States, and in particular their own role in this process.

Table: Overview of activities with Member States' cooperation

Scientific activities			
Description	Dates	Level and kind of cooperation	Legal basis
<b>AFC Panel</b>			
Assessment of the Ramazzini Foundation study on aspartame	December 2005-May 2006	Close involvement and information exchange with MS's through AF. France and the Netherlands hosted WG meetings	EFSA initiative followed by request from the Commission
Risk assessment of semicarbazide (SEM)	July 2003 to June 2005	Close involvement and information exchange with MS through AF  Contract with Dutch research institute for testing of genotoxicity of SEM	Reg. 178/2002: Formal request from Commission
1 <sup>st</sup> Flavis work and contract	2003-2006	Contract with Danish Government institute. Some MS have provided expert assistance to the working group, meeting in Copenhagen	Regulation 1565/2000 of 18 July 2000
2 <sup>nd</sup> Flavis work and contract	From April 2006	Contract with Danish Government institute. Some MS have offered expert assistance to the working group, meeting in Copenhagen	Regulation 1565/2000 of 18 July 2000
Re-evaluation of food colours	2006-2007	Contract with Dutch Government institute to prepare reviews of permitted colours.	Formal request from Commission

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Preparation of working documents on FCM substances for the Panel under contract	February 2004 – present	Preparation of evaluation reports on data other than toxicity (mainly migration into food) and discussion in the working group, done by Dutch public interest organisation	Directive 89/109 and Regulation 1935/2004
Preparation of working documents on FCM substances for the Panel under contract	February 2004 – present	Preparation of evaluation reports on toxicity data and discussion in the working group. Work carried out by: Danish and Italian Government institutes and by a German university.	Directive 89/109 and Regulation 1935/2004
Nanotechnology initiatives	2006-	Initial discussion with AF. On the agenda of a next AF Meeting to discuss: initiatives, RA approaches and close cooperation with MS's	EFSA initiative
<b>AHAW Panel</b>			
Development of animal welfare Risk Assessment Guidelines	2007-2008	Contract with Italian scientists. Meetings with MS should take place in the second half of 2007	EFSA initiative
<b>BIOHAZ Panel</b>			
Establishing network of national contacts points of MS involved in the coordination of BSE/TSE Risk analysis.	2006-	Contacts in MS's are currently been nominated (2 meetings/year)	EFSA initiative
Update methodology for GBR assessment	2006 -	Request for surveillance data from Member States	EFSA initiative
(Quantitative) RA for BSE in Goats	Goats 2005	Request for data from MSs – (for goats received) not done for sheep	EFSA initiative

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Developing an approach for QMRA	2005 -	Request for input from MSs (questionnaire); outsourcing to MS expert	EFSA initiative
<b>CONTAM Panel</b>			
Opinion on the safety assessment of wild and farmed fish (SWAFF)	February-April 2005	Request for occurrence data from MSs through the Advisory Forum	Reg.178/2002 question from the Parliament
Methylmercury and mercury	April 2004 – ongoing	Request for occurrence data from MSs through the Advisory Forum	Reg. 178/2002
Assessment of the risks for human and animal health of contaminants in food and feed	2003-	Request for occurrence data on contaminants in food and feed from MSs through Expert WGs on Industrial and Agricultural Contaminants of the SCFCAH	Reg. 178/2002
<b>FEEDAP Panel</b>			
Authorisation process for placing on the market and use of feed additives.	3-month consultation with MS for each valid application	Formal consultation of the MS in the authorisation process of feed additives (30 applications/year).	Regulation (EC) 1831/2003
Identification of new data on the effects of the use of a feed additive (iodine)	19 <sup>th</sup> December 2005 – 17 <sup>th</sup> may 2006	Bilateral cooperation with the UK Food Standards Agency	Regulation (EC) 178 /2002
Development of Guidance documents on Environmental Risk Assessment of Feed Additives.	July-October	Public Consultation in EFSA's website including Member States	Self-tasking activity
<b>GMO Panel</b>			
Provide opinion on MS assessment of GMO application dossier, addressing scientific divergence between MS's (12 questions received from DG ENV)	July 2004	Bilateral meeting with national experts of France on scientific divergence	Dir. 2001/18/EC, at request of Commission

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	End 2004- early 2005	Communication exchange with national experts of the Netherlands	
Provide scientific opinion on the safeguard clause invoked by: =(1) Austria =(2) Hungary =(3) Greece	=(1) March 2004 =(2) During 2005 =(3) July 2006	=(1) bilateral meeting with national experts of Austria =(2) exchange of views between panel members and national experts of Hungary =(3) bilateral meeting with national experts of Greece	Dir.2001/18/EC, Article 23
Authorisation process for placing on the market and use of GMOs	3 months consultation MS's for each application	Formal consultation of the MS's as part of the authorisation process (35 applications thus far)	Reg. 1829/2003
Initial environmental risk assessment of application including cultivation: =(1) Spain (2 appl.) =(2) The Netherlands (1 appl.) =(3) Germany (1 appl.) =(4) France (1 appl.) =(5) 4 pending applications including cultivation	=(1): Nov 2005; May 2006 =(2): June 2006 =(3): June 2006 =(4): not yet fixed	In accordance with the Regulation, MS competent authorities carry out the environmental RA's. EFSA organises meetings with national experts of MS's involved (CA's) to coordinate the work (3 meetings for each application)	Reg. 1829/2003
Development of Guidance Document on RA of GMO plants	April-May 2004	Public written consultation including Member States Stakeholder consultation (1 day meeting)	Reg. 1829/2003
Development of guidance on general surveillance of GM plants	20 Jan and July-September 2005	Consultation meeting with experts from MS (1 day meeting). Public written consultation including Member States	Reg. 1829/2003
Development of guidance on GM micro-organisms	July- September 2005	Public written consultation including Member States	Reg. 1829/2003

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Development of guidance on GM events combined by crossing	July- September 2006	Public written consultation including Member States	Reg. 1829/2003
Forum Meeting with MS Experts	15 May 2006	Meeting with technical experts from MSs on RA approaches, strength and weaknesses	EFSA initiative
GMO EFSA net launch	16 March 2005	Meeting with technical experts from MSs	EFSA initiative
<b>NDA Panel</b>			
Defining procedures for application of claim dossiers	2006-	Establish contact points with MS's and arrange for at least one meeting with MS's experts	New Regulation
Set-up EFSA Extranet communication procedures	2006-	Involvement and training of MS's contact points; one meeting with technical experts from MS's; software instalment and IT support for training	EFSA initiative
Conference on Nutrition and Health Claims	8-10 November 2006	MS's representatives are invited	EFSA initiative
<b>PLH Panel</b>			
Meeting with MS Chief Officers of Plant Health Services	November – December 2006	Representatives of MS COPHS	Council Working Party on Plant Health/EFSA
Collection and availability of data on organisms harmful to plants and plant products	Early 2007	Seminar or colloquium. Representatives of MS competent services.	EFSA initiative
<b>PPR Panel</b>			
Prioritisation of the revision/development of Guidance Documents in the field of pesticide risk assessment	Summer/autumn 2006	Consultation of MS within the SCFCAH	Linked indirectly to Council Directive 91/414/EEC

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Revision/development of Guidance Documents on risk assessment of pesticides	Ongoing	Consultation of MS within the SCFCAH and designated national authorities (contact points for the evaluation of existing active substances under Dir. 91/414/EEC)	Linked indirectly to Council Directive 91/414/EEC
<b>Scientific Committee</b>			
Safety assessment of botanicals and botanical preparations	October 2004-present	Preparation of a questionnaire to obtain from MS's a clear picture of the national concerns, current regulatory approach, and the extent of the issue in Europe. Analysis of the answers.  In the coming months, one to one meetings with MS who have a special interest in the issue to exchange on the lists of botanicals	EFSA initiative
Emerging risks	November 2004 – April 2006	Contract with the Food and Consumer Product Safety Authority – VWA in the Netherlands to identify and create a network of key sources (e.g. networks, university groups, research institutes, national food authorities, consumer organisations, industry associations) and procedures for transmission of information on emerging food-related risks to support EFSA in the identification of emerging risks within the limits of Regulation (EC) No. 178/2002.	Reg. 178/2002

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Interface Risk Assessment-Risk Management (RA-RM)	May-December 2005	Contract with an external expert for the preparation of a working document on the interface between RA and RM	EFSA initiative
<b>SES Zoonoses</b>			
Annual data collection on zoonoses, antimicrobial resistance and food-borne outbreaks and preparation of Community Summary Report on Zoonoses	Annually: March-November	Reporting of national data to EFSA (March-May) Validation and reporting on the data (June-November) Consultation of MSs in October Coordination by MSs' representation in Zoonoses Task Force (2 meetings /year) and ad hoc working groups (4 meetings/year)	Directive 2003/99/EC
Zoonoses contract with Danish Research Institute	Annually: June-November	Contract on drafting the Community Summary Report under supervision of EFSA 3 coordination meetings/ year	EFSA's initiative
Improvement of the Annual Zoonoses Report	2004-2005	2 Working Groups comprised by MS experts (10 meetings) and MS' representation in Zoonosis Task Force; 1 meeting	Directive 2003/99/EC
Harmonisation of monitoring and reporting schemes for zoonoses, antimicrobial resistance and food-borne outbreaks	Continuously until at least 2010	Working Groups comprised from MS experts (20 meetings/year ) and MS' representation in Zoonoses Task Force	Directive 2003/99/EC Regulation 2160/2003
Salmonella/Campylobacter Baseline studies	2005 until at least 2010	Analyses and reporting of data collected from the MS, consultation of MS on the report Working Groups comprised from MS experts to support the analyses (5 meetings /year)	Regulation 2160/2003

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		MS' presentation in Zoonoses Task Force	
Contract on assistance on food-borne outbreaks with German Risk Assessment Institute	2006-2007	Contract on assistance in revising the reporting on food-borne outbreaks 3 coordination meetings	EFSA's initiative
<b>SES Pesticides RA</b>			
Peer review of existing and new pesticides	Continuously until at least 2008 (for existing substances)	Consultation of MS's on the draft assessment report (DAR) (prepared by rapporteur MS)	Reg. 1490/2002 for existing active substances; EFSA initiative for new pesticides
Peer review of existing and new pesticides	Continuously until at least 2008 (for existing substances)	Consultation of MS's on the rapporteur MS's response to comments	EFSA initiative
Peer review of existing and new pesticides	Continuously until at least 2008 (for existing substances)	MS's participate in expert meetings addressing outstanding issues (approx. 20 meetings/year)	Reg. 1490/2002 for existing pesticides (optional); EFSA initiative for new pesticides
Peer review of existing and new pesticides	Continuously until at least 2008 (for existing pesticides)	Evaluation meeting with MS experts to agree on final EFSA conclusions (approx. 6 meetings/year)	EFSA initiative
<b>SES Exposure</b>			
Furan data collection	May 2006-December 2008	Request for occurrence data from member States	Reg. 178/2002 and Draft Commission recommendation on the monitoring of the presence of furan in food, which is based on

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			the EFSA CONTAM report on provisional findings of furan in food
Data collection of polycyclic aromatic hydrocarbons (PAH's)	March 2005-October 2006	Request for occurrence data from member States	Reg. 178/2002 and Commission Recommendation (2005/108/EC) on the further investigation into the levels of PAH's in certain foods.
Food consumption data	2005-2007	Cooperation with MS' on the collection of food consumption data from Member States for a Concise Food Consumption database. Network of food consumption database managers currently being established	Reg. 178/2002
<b>Other SES activities</b>			
Science colloquiums	2-3 per year	Close involvement and information exchange with MSs	EFSA initiative

The Advisory Forum and its Working Groups <sup>1</sup>			
Description	Dates	Level and kind of cooperation	Legal basis
Meetings of the Advisory Forum are held to foster greater collaboration and co-operation on food safety risk assessments across Europe.	From its start in 2003, the Forum has had 17 meetings (August 06)	The Forum advises EFSA on its WP, on assessments it wants to start, on involvement of other parties, etc. etc. Members of the Forum inform colleagues on emerging risks and explore tools to make the outside world known of RA processes and its outcomes. For that reasons it held in the (recent) past a crisis exercise and a huge public event.	178/2002
The Advisory Forum created an <i>ad hoc</i> Working Group in order to prepare recommendations on how to improve the exchange of scientific information between the national agencies and EFSA.	From its start in 2005, the Working Groups has met 4 times and finished its work mid 2006	In its deliberations the WG particularly discussed: <u>what</u> information would be of interest to be exchanged, <u>when</u> in the risk assessment process this optimally should be done and, finally, by <u>whom</u> (or which means) this would be the most appropriate. The WG presented its report at the AF meeting on 19 <sup>th</sup> May in Vienna.	178/2002

<sup>1</sup> For the Communications and IT Working Group of the Advisory Forum , see ‘Communication activities’ and ‘IT activities’, respectively.

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<b>Communication activities</b>			
<b>Description</b>	<b>Dates</b>	<b>Level and kind of cooperation</b>	<b>Legal basis</b>
Advisory Forum Communications Working Group	Meetings four times per year	Regular discussion of forthcoming scientific issues of communications importance	Reg 178/2002 + Advisory Forum decision.
Task Force on Crisis Communications Requirements	2005-2006	Development of a proposal for information exchange (Extranet)	Reg 178/2002
Task Force on Collaboration in Communications	2006-2007	Development of joint communication activities	Reg 178/2002
Workshop on relevant communications issues (Risk Communications 2005 / Crisis Communication 2006)	Once a year	Enhancing level of knowledge and co-operation	Reg 178/2002
Ad hoc liaison with national communication and science experts on scientific issues	On-going	Liaison on case specific scientific issues when impacting on communication, particularly when national angle, e.g. salmonella, aspartame, AI	Reg 178/2002

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IT activities			
Description	Dates	Level and kind of cooperation	Legal basis
Advisory Forum IT Working Group	Since 2004	Meetings of the IT WG are held to create electronic tools to facilitate the exchange of documents, messages on emergencies, meeting registrations, etc.  In particular the Group has created an AF Extranet that secures documents access; provides event registration and facilitates in the collaboration on urgent food issues.	178/2002
Zoonoses Data Collection Application	Since 2005	Project steered (approval of specifications, deadlines, features, etc...) by a group composed of representatives of MS's. Application tested representative of MS.	Reg. 178/2002
Establishment of a Framework for Data Collection Application	August 06– December 06	Project steered by a group composed of representatives of DG SANCO, Ireland, Latvia, and Sweden. Application tested by representative of MS.	EFSA initiative
FURANs Data Collection application	September 06 – December 06	Project steered by a group composed of representatives of DG SANCO, Ireland, Latvia, and Sweden. Application tested by representative of MS.	EFSA initiative
Videoconference Network	Since January 05	Videoconference equipment made available to 22 Member States, plus	EFSA initiative

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		audio, video and web conference services	
Advisory Forum Extranet	Since January 05	Extranet for collaborating and exchanging information among Member states	EFSA initiative