



MOVING AHEAD FROM COOPERATION BETWEEN EFSA AND THE MEMBER STATES TO BOOSTING THE CAPACITY OF RISK ASSESSMENT IN EUROPE

Introduction

1. EFSA's Strategy on Cooperation and Networking¹ developed in conjunction with the Advisory Forum (AF) was adopted by the Management Board (Board) in December 2006. An interim report on its implementation was endorsed by the AF in November and the Board² in December, 2008. In its meeting of 29 January, 2009 the Board discussed with four members of the AF, EFSA's cooperation activities with Member States (MSs). The Board emphasised the need to continue to further build cooperation, recognising the importance of the engagement of all MSs in such activities, so as to make optimal use of resources, available information and expertise. The Board agreed that it would like to come back to this matter during the year.
2. Reflecting on the discussions in the Board, the AF in February 2009 and subsequently on the 23rd of April, continued to develop their views for deepening and consolidating cooperation. Members of the AF highlighted the overall support for building cooperation further while also reflecting on some of the issues that may have to be addressed to build an optimal mutually-beneficial cooperation system within the EFSA regulatory framework. Discussions revolved around the different cooperation models that exist under the different legislations within EFSA's fields of competence and the varying capacities of MSs to assist in joint initiatives. Longer term planning for cooperation was identified as an aspect that may enable greater participation of MSs in EFSA's work.
3. In its Strategic Plan 2009 – 2013³ EFSA recognises the importance of a continuing and further strengthened cooperation and networking between EFSA and the MSs' food safety agencies and national scientific activities.
4. This paper updates the Board on the evolution of these discussions, seeking guidance on the issues raised in this paper concerning the deepening and consolidation of existing cooperation through future initiatives. This will enable EFSA with the AF and Scientific Committee to reflect further on this matter and take appropriate action.

¹ MB 19.12.2006 – 6a Strategy for cooperation and networking

² MB 18 12 08 item 8 doc 6a interim review

³ MB 18 12 08 item 6 doc 4 –Strategic Plan 2009-2013

I COOPERATION WITHIN EFSA'S LEGAL AND GOVERNANCE FRAMEWORK

5. Cooperation between MSs and EFSA is an integral part of EFSA's Founding Regulation (EC) No 178/2002⁴, which recognises this as a core principle in several parts of the Regulation e.g. in Article 22(7) and (9) and reflected in recitals 40, 44, 51, 53, 55. Article 22(9) is particularly clear where it affirms that MSs shall cooperate with the Authority to ensure the accomplishment of its mission. Article 22(7) of EFSA's Founding Regulation imposes a duty on EFSA to network and cooperate with National Competent Authorities and there are comparable articles reflecting mutual requirements which are implemented by a range of institutionalised tools⁵. These tools define roles that are based on a collaborative approach between MSs and EFSA.
6. Article 27 provides for the creation of the AF comprising the nominated representatives of the national food safety authorities of all 27 EU MSs to advise the Executive Director of EFSA on such matters as drawing up the Authority's work programme, the prioritisation of requests for scientific opinions, exchanging information on potential risks and pooling knowledge. The Article also foresees close cooperation with MSs to avoid duplication of the Authority's scientific studies, reduce divergence and promote European networking of competent organisations (Article 36(1)).
7. The Founding Regulation also describes the role of MSs in EFSA's specific tasks. Article 33(2) and (3) places a reciprocal duty on EFSA and MSs' organisations working in the field of data collection to cooperate, and also an obligation for the MSs to enable certain categories of data to be transmitted to EFSA. In the area of emerging risks, Article 34 requires MSs to treat as a matter of urgency requests for additional information received from EFSA. Information exchange is also ensured via the rapid alert system network in which EFSA participates and where MSs have a notification obligation.
8. Article 36 provides for the creation of a network of competent organizations operating in the fields within EFSA's mission. The list which is based on nominations from MSs is adopted by the Board and provides an essential tool in the implementation of the Strategy for Cooperation and Networking. In addition, EFSA's cooperation with MSs is further underlined by the fact that under Article 29 MSs may request an EFSA scientific opinion.
9. Since EFSA's establishment, new legislation has placed an emphasis on cooperation with MSs via increased use of centralised procedures e.g. for Novel foods⁶, Feed additives⁷ and through the Regulations establishing a common authorisation procedure for Food Additives, Food Enzymes and Food Flavourings⁸. These legal acts provide for a transparent information flow between EFSA and the national competent bodies; applications are shared at the beginning of the procedure and opinions after adoption.

⁴ 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 as last amended.

⁵ Articles 22(8), 27(4), 29, 30, 32, 33, 34, 36, 40 and 55 of Regulation (EC) No 178/2002 as last amended.

⁶ Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.

⁷ Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition.

⁸ Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings.

10. For instance, in the Genetically Modified Organisms (GMO) area⁹, the legislator opted for a separation of tasks between EFSA and MS competent bodies. MSs are responsible for undertaking environmental risk assessments and safety assessments may also be performed by a MS. In addition to its legal obligation, EFSA also reflects MSs comments in its GMO opinions.
11. In the authorisation procedure for active substances of plant protection products¹⁰, MS carry out the risk assessment of the dossiers submitted by petitioners as rapporteurs. EFSA's role is to peer review these. Together with MSs and the European Commission, EFSA put in place in 2009 a Pesticide Steering Committee, to further strengthen its role in reviewing the safety of active substances used in pesticides.
12. In the area of zoonoses¹¹ EFSA, in collaboration with the MSs and the European Commission, prepares an annual Community summary report on Zoonoses collecting and collating data from the MSs.
13. Therefore in EFSA's Founding Regulation and subsequent legislation, the legislator has ensured that EFSA and the MSs are fully embedded in cooperation activities, exchanging data and information and building scientific activities to underpin risk assessment. In finding the balance between cooperation with MSs and the need for EFSA to be independent, the legislator reflected in EFSA's governance certain core structures and requirements. EFSA's governance in fact presents a unique model enabling it to be independent while fulfilling its mission to make full use of the cooperation tools provided for it.
14. The first distinctive element is the independency of the members of its Board as described by Article 25 of the Founding Regulation, who are appointed exclusively in their personal capacity. The Board has one representative from the European Commission.
15. The second element in EFSA's governance is the independency of the members of its Scientific Committee and Scientific Panels who are tasked with providing the scientific opinions of EFSA. Members respond to an open call and are selected on the basis of their experience and expertise. Scientific Panels of other EU agencies (e.g. European Medicines Agency, European Chemicals Agency¹²) active in domains comparable to food and feed safety are composed of expert representatives of MSs
16. The third characterizing element is the creation of a specific advisory body, the AF, in which MSs representatives play an important role in advising the Executive Director of EFSA in the performance of her duties. As previously described, the main thrust of its work is to promote cooperation and networking, assist with identifying emerging risk and priorities, sharing scientific information, pooling resources, avoiding unnecessary duplication of efforts, and co-ordinating work programmes.
17. The legislator thus organised EFSA into separate and distinct components, each with its own responsibilities and roles, balancing independence with cooperation, enabling it through networking to harness and build information and expertise for the mutual benefit of both national and European risk assessors and managers. And ultimately, through adhering to its governance structures and tools EFSA can ensure the

⁹ Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed; Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.

¹⁰ Council Directive of 15 July 1991 concerning the placing of plant protection products on the market (91/414/EEC); Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC.

¹¹ Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents

¹² (Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency) and to the European Chemicals Agency (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency.

overall independence of its work. In building further initiatives on cooperation and networking, EFSA will need to reflect on these checks and balances foreseen in its Founding Regulation.

II COOPERATION ACTIVITIES INITIATED SINCE 2006

18. EFSA's Strategy on Cooperation and Networking (hereinafter called the Strategy) has enabled EFSA to progress towards building with the MSs and the Scientific Committee a comprehensive framework for cooperation activities. In 2008 EFSA created a Scientific Cooperation and Assistance Directorate to support networking and cooperation activities.
19. The Strategy called for a strengthening of MSs' cooperation through the AF in collaboration with the Scientific Committee, both of which are key in the strategic coordination of cooperation. The Strategy foresaw four priority areas:
 - Exchanging and collecting scientific data and information;
 - Sharing risk assessment practices;
 - Contributing to the harmonization of methodologies for risk assessment;
 - Promoting coherence in risk communications.
20. As a result of the implementation of the Strategy, a Focal Point network was established in 2008 to support the members of the AF. The AF has indicated that it is keen to ensure that this network continues to function efficiently and since its establishment EFSA and the AF have worked to build its capabilities and strengths.
21. MS networks have also been established in other areas i.e. data collection and specific area of risk assessment (GMO, BIOHAZ) To strengthen these further EFSA has considered giving these a more permanent character.
22. Strengthening cooperation with Article 36 organisations continues to be a priority for EFSA. The network is now established and functional, supporting EFSA in its tasks on specific projects. In order to optimise the necessary expertise in this network, taking into account the changing scientific needs as well as changes occurring in research organisations in MSs, the Board updated this list of Article 36 organisations¹³ in December 2008.
23. An Interim Review of the Strategy was conducted in 2008. An AF survey revealed that MSs supported the approach EFSA had taken in building the cooperation, its approach to grants and projects under Article 36, its building of an expert database and in its support to the AF members through the Focal Points initiative. The Interim Review, endorsed by the Board in December 2008, followed discussion within the Scientific Committee and AF highlighting progress made.
24. For the four priority areas the review identified the following top priorities:
 - Exchanging scientific data and information – continued streamlining of data collection and data exchange to ensure the quality and overall prioritisation for cooperation activities.
 - Sharing risk assessment practices - Working Groups have been established to carry out Scientific Cooperation Projects (ESCOs) on issues of interest to the Scientific Committee and Panels as well as the MSs. The review of the Groups was overall positive and cooperation had been successful in projects e.g. on botanicals, emerging risks, building an expert database. It was concluded that for maximum efficiency there was a need for clear, concise mandates which could deliver outcomes in the allocated time. In addition, further long-term training on risk assessment for experts working in different fields of food safety, especially for new MSs was identified as important.

¹³ MB 18 12 08 item 8 doc 6b - Update on Art. 36 list of organisation

- Harmonisation of risk assessment methodologies - The harmonisation of risk assessment approaches between MSs was judged to have high priority and be essential to building confidence and trust in each others risk assessments. Priorities for harmonisation on which specific elements of risk assessment to address had been identified and working groups will commence in 2009.
- Promoting Coherence in Risk Communication – The Advisory Forum's Working Group on Communication has increased activities in pre-notifying opinions and press materials which in turn have enhanced cooperation. A revision of the Terms of Reference of this Group had assisted in re-focussing cooperation activities. Through continued sharing of best practices, co-ordinated information and communications on emerging and topical issues, the development of targeted newsletters, joint events, and dedicated linked web-pages, progress had been made.

25. In conclusion, the Interim Review showed that substantial progress has been made in the cooperation between MSs and EFSA in a short time and cooperation and networking should be continued in general and strengthened further some specific areas.

III BOOSTING RISK ASSESSMENT CAPACITY ACROSS EUROPE

26. EFSA is not only determined to further build cooperation with national agencies and other national scientific bodies; it is equally committed to supporting their work. Along with EFSA, national bodies engaged in risk assessment and other scientific work, provide the basis for the risk assessment capacity in the European food safety system. Their data collection, research and evaluation activities underpin much of EFSA's work. Among other, it is their information which EFSA collects and collates that in many cases enables EFSA to deliver Pan-European advice on which European level risk management decisions can be made to protect all EU citizens.

27. Many of EFSA's experts have built and will continue to build their experience through national activities enabling them to participate at the European level as recognised experts. Therefore national expertise is a vital element of EFSA's capabilities, and indeed building this further through offering the opportunity for experts to become familiar with European risk assessment practices would both strengthen the national bodies as well as increase the pool of experts to which EFSA may have access. Strengthening expertise in national agencies, including those who actively participate to EFSA's scientific activities, as well as those who currently do not, and those in other national scientific organisations and institutes, would serve to boost the overall available risk assessment capacity around Europe for the benefit of both national and European risk assessment activities. Networking with MSs allows for the sharing of expertise between MSs, enabling all involved in the network to benefit from the totality of expertise available across Europe.

28. When considering the relationship between EFSA and the national agencies represented in the AF it is noted that many of the national agencies have responsibilities that differ from one another and from EFSA. These variations include organisations with both risk assessment and management roles, research responsibilities, different coverage of the field to plate chain, and agency size. Inevitably EFSA's relationship with each and their ability to participate in joint activities, their needs, expectations and often aspirations towards EFSA vary accordingly.

29. The range of scientific expertise that is available within an individual MS may vary depending on a range of factors, including historical interest in different fields, MS size and overall risk assessment or data collection capacity. National experts may not be able to give time to European initiatives or there may be language or other obstacles to full participation. Thus, even those MSs with significant risk assessment capabilities are not always able to contribute to all European cooperation projects.

30. Financial and other resource aspects may also discourage active participation for some MSs. In a time of financial constraint, national agencies are under even more scrutiny to justify their activities and to provide

benefit from their European engagement at the national level. It is therefore vital to ensure that MSs maximise their involvement in EFSA's activities in a way which enhances information and data exchanges and work on risk assessments which will be of value at the national level as well as at the European level.

31. Currently EFSA develops its annual work programme in consultation with national agencies and in turn they are encouraged to share theirs with EFSA. One possible initiative voiced by and discussed with the MSs to address this issue was the necessity to anticipate in the longer term EFSA's cooperation initiatives to enable better planning of activities at the national level. Expertise could be built, data and other information collected as a national priority to feed into European level cooperation. EFSA initiatives could then be built into the national bodies' own planning cycles. This more strategic, open and transparent approach to programming of the cooperation work in the longer term would be beneficial as it would enable better planning by MSs, enhancing their ability to be involved in the cooperation activities they wish to be involved in and identify areas of mutual benefit.
32. With more advanced planning MSs could thus make informed choices about growing, maintaining or not specific capabilities depending on whether they wish to be involved in particular future joint activities. MSs could thus focus on building expertise in a specific area rather than trying to span all areas with limited resources and become centres of excellence, coordinating European level activities with other MSs (e.g. like Denmark does currently coordinating European level work on flavours in the FLAVIS project).
33. Overall, this requires an identification of activities for cooperation on a 3 - 5 year horizon including the areas concerned, their (anticipated) regulatory framework, and possible workload. The MSs could reflect on the areas they wish to be involved in and the AF could discuss whether all areas are sufficiently covered at the EU level. This process would involve the Scientific Committee to ensure that EFSA's cooperation activities dovetail into the overall risk assessment work and also the Commission so that the overall process can take into account possible future changes in legislation.
34. Another specific initiative (mentioned in Chapter II) would be to give the existing cooperation networks a permanent basis enabling enhanced programming and mutually beneficial exchanges in areas such as e.g. GMOs and Biohazards.

IV DISCUSSION

35. The Strategy on Cooperation and Networking has enabled EFSA to achieve major progress in the cooperation with MSs, while maintaining the independence of EFSA's scientific opinions. The initiative has increased the exchanges of scientific information and assisted EFSA face its workload and strengthen the coherence of its communication. Conversely, experts have been able to benefit from this work in terms of building an understanding of an issue with colleagues from across Europe and have gained experience in many aspects of risk assessment at the European level. Although successful, the initiative, up until now, has focused on short term activities and has been planned with that time frame in mind. New impetus is needed to look at issues in a longer time frame to enable MSs to anticipate and plan better their own input accordingly.
36. Through its Strategic Plan 2009-2013, EFSA has now put in place a multi-annual plan. To face the challenges of the Strategic Plan 2009 – 2013, EFSA and the MSs need to build further on existing cooperation and address any unnecessary obstacles to participation enabling all MSs to work effectively with EFSA.
37. In discussion with the AF and with guidance of the Scientific Committee, EFSA could consider planning of cooperation activities in the mid to long term. Such a framework could be a useful tool in ensuring continued active participation from a broad range of MSs. MSs may thus be able to focus on developing specific

expertise or build complementary activities into their own national work programmes which would in turn enable them to participate further at the European level in those areas they have chosen to be involved in.

38. Boosting overall capacity of risk assessment expertise as outlined in part III could be considered to be mutually beneficial at both European and national level thus enhancing the overall European food safety system.
39. EFSA, the AF and the Scientific Committee may also need to reflect further on which other initiatives would assist in building or maintaining sufficient risk assessment expertise, evidence collection and evaluation capacity to enable broader participation in the longer term. In this respect building tomorrow's risk assessment expertise within MSs' national agencies, other bodies and institutes may be a useful initiative.
40. Initiatives such as working directly with MSs' experts to build experience in European level risk assessment methodologies, data collection and evaluation techniques etc, may prove beneficial and indeed has been raised by the MSs in the AF discussions. Such initiatives as developing risk assessment information materials, the placement of national level scientific experts in EFSA for short term secondments, enabling national level scientists to participate as observers to working group discussions and encouraging the full use of European Commission risk assessment training programmes, may assist in building greater capacity and expertise across the EU at national level which in turn would build capacity to assist in European-level work.
41. The Board is asked to consider the issues raised in this paper and reflect on the possible development of the framework outlined in Sections II and III. This will provide guidance for future reflection and initiatives that will be discussed with the AF and Scientific Committee.