European Food Safety Authority

# EXPLANATORY NOTE TO THE BOARD

(Not part of the Management Plan)

a) The Board adopted provisionally the Management Plan for 2004 at its meeting in December 2004

b) Following the vote on the budget for 2004 in the European Parliament, the Board should note that there was no reduction made to the Budget requested. However as the European Council decided at its meeting of 13 December to place the Authority's head quarters in Parma there are some changes made to this programme to reflect this. It is probable that as the year progresses the impact of the move to Parma will again have to be assessed in relation to the overall Plan.

c) The Plan has been discussed by the Advisory Forum at its meeting 11 December 2003 and the Commission was consulted on 24th November 2003. At the time of sending this to members the Commission has not yet been able to respond although comments are anticipated.

d) The Board is asked to adopt formally the work programme for 2004 while bearing in mind that there is a need for flexibility to ensure the day to day management of the Authority by the Executive Director, particularly in light of the move to Parma. The Board will be consulted should there be a need to make any substantial changes to the plan during the year.

# DRAFT

## 2004 MANAGEMENT PLAN OF THE EUROPEAN FOOD SAFETY AUTHORITY

**Including :**
**Overview and objectives of the Authority for 2004**
**Areas of Growth for the Authority during 2004**
**Establishment Plan 2004**
**Work Programmes 2004 including detailed Work Programmes of the Scientific Committee and Panel**
**Legislation which may affect Authority**

*Submitted to the Management Board at its meeting of 20 January 2004*

Done at Brussels, on

Dr Stuart Slorach
Chair

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## Executive Summary

2004 will be a critical year for the growth of the European Food Safety Authority. Having established itself as an independent European Agency during 2003, the Authority will build capacity in all areas of competence so as to deliver its mandate and meet the expectations of European and national institutions, stakeholders and the public at large.

Most importantly the Authority will be preparing in 2004 to move to Parma in Italy. It is not clear yet, at the beginning of 2004, how the detail of this move will unfold and in particular when it will be completed. It is clear however that there will be significant planning, personnel and logistical issues to address both in-house, with the scientific panels and Committee members, Management Board and the Italian Authorities.

Furthermore, during 2004 there will be significant development of both its scientific and communications functions enabled by appropriate operational and administrative support, including the appropriate deployment of human and financial resources. Through its work programme and operational procedures, the Authority will strive to build its reputation as an organisation dedicated to scientific excellence, openness and transparency. In this respect, the Authority will build capacity within its scientific departments particularly to ensure that it is able to keep abreast of scientific developments and emerging issues and apply the highest standards of scientific rigour. The Authority will continue to work closely with its independent Scientific Committee and Panels.

The Authority will communicate its opinions and other advice in a clear and understandable manner to the European Commission, European Parliament, Member States, stakeholders and the public at large. The Authority will engage in dialogue and seek feedback from its key stakeholders and customers in order to ensure that its goals, priorities and outputs are clearly communicated and in line with expectations.

People will be the cornerstone of the Authority's development and growth in 2004: it is therefore essential that the Authority be able to recruit and retain the best staff possible, at all levels, in order to deliver successfully its objectives for 2004 and beyond.

These objectives together with the scheduled activities for 2004 are summarized below.

- *Provide scientific opinions and advice to questions formally addressed to the Authority or by self-tasking*

This objective is mainly to develop and communicate independent, scientifically sound opinions on emerging food and feed safety issues, either in response to questions formally addressed to the Authority or by self-tasking based on issues brought to the Authority's attention through its international network of experts, national food agencies, stakeholders or the public at large. For the year 2004, the Authority's Scientific Committee and 8 Scientific Panels together will have to develop scientific opinions on the safety of more than 150 food-related substances, including food additives and flavours, coccidiostats and other biological hazards, new and existing pesticides, nutrients and dietetic products, animal food and feed contaminants, and GMO crops and micro-organisms. In addition, a considerable number of generic questions are expected on food and feed safety issues and on animal health and welfare issues.

In order to deal adequately with the expected large number of questions and still allow for a number of self-tasking questions, criteria will be developed to set priorities for the development of opinions within and between Panels. These criteria will take into account,

among other aspects, anticipated public health impact, possible legal obligations, the level of urgency as indicated by the submitting entity, possible connections between the question and other questions or work items, the level of public interest and economic importance of the question. The number of Panel/Scientific Committee and Working Group meetings scheduled for 2004 is substantial but care will be taken not to exceed the capacity of the members of the Scientific Committee, the Panels and the various Working Groups.

- *Assess the risks and maximum residue levels of existing and new pesticides and monitor specific risk factors and diseases.*

In order to use existing resources as efficiently as possible, a significant portion of the assessment of existing pesticides will be outsourced; however, the final risk assessment conclusion for each pesticide will be made by the Authority. Preparatory work related to the setting of maximum residue levels may start already during the second half of 2004 in order to anticipate and meet the very short deadlines applicable provided that the new regulation will enter into force in January 2005. The monitoring of zoonoses and zoonotic agents will become EFSA's responsibility towards the end of 2004. In order to address this task, part of the work involved in reporting on trends and sources of zoonoses in Europe will be outsourced. The work related to geographical BSE risk assessment and BSE/TSE testing and validation will be done largely in house by a special Group of National Experts .

- *Promote and apply new and harmonised scientific approaches for hazard and risk assessment methodologies.*

It is one of the Authority's objectives to ensure that its scientific work is driven by the highest standards of scientific rigour. Therefore, the Authority should establish itself in a leading position at the forefront of scientific progress in hazard and risk assessment methodologies and techniques in food safety evaluations. Means to achieve this leading position will include: (i) Increasing the Authority's scientific expert staff in areas of hazard and risk assessment; (ii) increasing the Authority's capability for collection and assessment of scientific data and other information; (iii) close monitoring of relevant scientific activities in other national and international organisations, institutions and authorities; (iv) organising scientific workshops and conferences on new approaches and methodologies in hazard and risk assessment, and (iv) increasing the Authority's activities in relation to the identification of emerging risks through the development and implementation of an emerging risk strategy. In 2004, science units will be established with recognized expertise in toxicology, ecotoxicology, exposure assessment and epidemiology, alternatives to animal testing, analytical chemistry and statistical analysis. Projects and issues that are high on the priority list include: (i) the search for links between human toxicity and exposure to food and food-borne substances, (ii) the effect of simultaneous exposure to a variety of substances through food, (iii) obesity and (iv) identification of major microbiological risks and harmonisation of their detection methods.

- *Foster exchange and transfer of scientific expertise and knowledge*

The Authority will establish a formal network of national food safety authorities and national expert centres affiliated with national food safety authorities. The network is expected to become an efficient tool allowing the identification of the most relevant national experts in the case of an emerging food crisis. In addition, the network will facilitate bridging national or regional differences of opinion or approach and provide a source of information on national activities, priorities and concerns. In addition a programme will be started of expert exchange and secondment. The co-ordinated exchange of national experts amongst national authorities and the secondment of national experts to the Authority may well appear to be a very efficient way of improving the cross-boundary, cross-cultural and cross-social understanding of food safety issues.

- *Promote the Authority as an organisation dedicated to scientific excellence, openness and transparency whilst ensuring that communication messages are relevant, understandable and address food safety concerns.*

The Authority will carry out in the second half of 2004 an audit among key stakeholders as well as media in order to evaluate both their perception of and expectations for the Authority. It will also carry out an analysis of possible consumer concerns regarding food safety and evaluate the possibility of tracking consumer concerns over time in collaboration with Member States. The Authority's new website is expected to be available in February 2004 and will continue to evolve in order to ensure that it is authoritative and user friendly and contains all of the necessary and relevant information appropriate for each target audience. A series of measures will be implemented in the course of 2004 to ensure that the Authority operates to the highest standards of openness and transparency. These will involve the organisation of a series of meetings between the Authority and stakeholders as well as opening up the risk assessment process further to public comment, including the holding of public hearings where appropriate. The work of the Management Board of the Authority will also be opened up further through the initiation of meetings to which the public has access,. In addition to the open publication of the agendas and minutes of the Advisory Forum on the web, the work of the Forum will be made more widely known during 2004. Towards the end of 2004 the Forum will hold a public meeting at which it will present its work and encourage open discussion with administrations, stakeholders and the scientific community.

- *Develop an overall strategy on international relations for the Authority building on those relations already established during 2003*.

The Authority will increase its visibility in the international arena during 2004. As a European agency, the establishment of a strong international presence is essential to promote the global recognition of its work. The links established during 2003 will be developed further in an overall international strategy with emphasis on promoting the excellence of the Authority's scientific work through transparency of its methods of work.

- *Ensure a smooth and swift relocation of the Authority to Parma.*

The announcement from the Council of the European Union on 13th December 2003 that the headquarters of the Authority will be based in Parma has been welcomed by all involved in the Authority. However, there will be much to achieve in 2004 in order to prepare for the move to Parma by the Authority, its scientific panels, staff and their families. The Authority will transfer all of its existing Brussels based activities to Parma while avoiding as far as possible any disruption to its work and outputs. To this end dedicated resources will be assigned to manage the Authority's move to Parma, as comprehensive planning and appropriate preparation are necessary for the move to be successful. Discussions have already been launched with the Italian authorities, and in particular the authorities in Parma, to ensure that the move can take place as soon as practicable bearing in mind that the Authority will need to be able to carry out its full programme of work from its new base.

**In summary, the following structures and strategies will be established to support the implementation of the tasks of the Authority:**

- The creation of an in-house Scientific Expert Service Department to support the work of the Authority's Committee and 8 Panels and to provide an in-house source of scientific expertise in a variety of scientific areas.

- The further development of access to scientific information, through the establishment of a formal network of national food safety authorities and national expert centres affiliated with national food safety authorities,

- The creation of a risk communication strategy which will focus on appropriate communication on food and feed safety risk and the monitoring of the effectiveness of such communication. The communications strategy will be fully integrated with risk assessment activities and take into account consumer and key stakeholder requirements. The communications strategy and key initiatives undertaken will strive to ensure that the Authority is seen as an expert and trusted source of information on food safety issues among its stakeholders and the public at large

- The establishment of two Working Groups of the Advisory Forum with the active participation of national food agencies and authorities to enhance coherence on risk communication and to provide the practical information technology tools for this and other information exchanges.

- The creation of a nucleus for a permanent crisis team and the enhancement of in-house procedures for the work of the Authority in identifying crisis as well as its operating procedures in the event of crisis.

- The establishment of a programme of expert exchange and secondment of national experts to the Authority to improve the cross-boundary, cross-cultural and cross-social understanding of food safety issues.

The establishment and implementation of an appropriate organisational structure and the recruitment of appropriately qualified scientists and other personnel at junior and senior level in order to develop and implement successfully the Authority's Work Programmes. At the beginning of 2004 the staff will be approximately one fifth of the numbers envisaged for it to function at full capacity but the Authority will have a full range of responsibilities with comprehensive work programmes. Therefore during 2004 the Authority will recruit both senior and junior staff to put in place the appropriate structures to manage and carry out the Authority's tasks. As a young agency it is important to recruit the best staff possible at all levels with staff selected for their excellence and competence from all parts of the EU area including the Accession states. In the main, staff will be engaged with the status of temporary agents although other solutions will be considered, for example, Detached National Experts, Auxiliary and Interim staff.

## I. Introduction

1. The following document provides the predictive Work Programmes with supporting information and Establishment Plan of the European Food Safety Authority (hereinafter referred to as the Authority) for 2004. To illustrate the rationale behind the Work Programmes of the Authority, additional supportive and explanatory information is provided which indicates the overall direction of the growing Authority, its objectives and priorities during this period and beyond. Together these elements form the Management Plan for 2004.

2. The Financial Regulation of the Authority and the founding Regulation[1] require that the provisional estimates of the Authority's revenue and expenditure for the coming financial year and a provisional list of posts should be adopted by the Management Board by March of the previous year. These should be accompanied by Preliminary Draft Annual and Multi-Annual Work Programmes. Once adopted as preliminary documents these should be forwarded to the Commission and to those States with which the Community has concluded specific agreements covered by Article 49 of the Regulation[2]. The documents form part of the supporting explanatory information for the Authority's draft budget requests for discussion by the Budgetary Authority and provide a basis for the assessment of the Authority's performance at the end of the financial year.

3. It should be noted that only towards the end of 2003 was it possible to undertake any detailed planning for the 2004 period as during 2003 the Authority was in a period of growth and development. The Authority developed from a rudimentary and small organisation at the beginning of 2003 into a functional and operational independent European agency at the end of that year. It was not possible or appropriate in March of 2003 to estimate the detailed scientific and other work programmes until all components of the organisation were in place. This is especially true of the planning associated with the work of the Scientific Committee and Panels of the Authority which were not all operational until July 2003. It is also true to say that the primary customer of the Authority, the Commission, was not able to provide the Authority with an overview of its needs in relation to scientific opinions for 2004 and beyond until November 2003. However, provisional draft overviews have been made available earlier in the year.

4. In line with the requirements of the Regulation the Board, endorsed an outline of the key tasks for the Authority during 2004[3] [4] a draft budget, and Establishment Plan at its March 2003 meeting (Establishment Plan in Annex I). It was agreed at this meeting that the Board should consider a Decision on more detailed Work Programmes at a later stage in 2003. Therefore this Management Plan which contains such detail was submitted for endorsement at its December 2003 meeting, while remaining within the general framework established in the provisional document adopted in March 2003. It should also be noted that this document was subject to review once the Budgetary Authority had made its final decision on the budget for the 2004 period On 18th December 2003. . This document is submitted for to the Board's January 2004 meeting for final adoption.

1 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

2 EFTA - EEA countries – at present no such agreement has been made for the Authority

3 MB 19/20.03.2003 – 8 Draft Budget 2004 - Information Note - MB 19/20.03.2003 – 8

4 MB 29.04.2003 – 2 - Minutes of 19/20 March meeting. As adopted 29 April – Point 8 – 'It was communicated to the Commission that the Authority is unable to meet this timetable this year. The submitted Preliminary Draft Budget 2004 contribution therefore reflects the ongoing process at this moment in time and will be subject to change. The Board endorsed the information provided in document 8 with a view to prepare a decision of the board at a later stage in the year.'

5. It should also be noted that this document can only provide predictive planning information and there has to be significant flexibility for the day to day management of the Authority by the Executive Director and staff. It should also be noted that the Management Board of the Authority will have any substantive changes to the Work Programmes and demands for associated reallocation of budget brought to its attention throughout the year. Due to the nature of the work of the Authority, questions may be put to it at any time during 2004 some of which by their nature and level of complexity may have a significant effect on work in other areas. Heightened food safety concerns or a 'crisis' situation may also significantly alter the work programme presented here. This flexibility required for the day to day management of the Authority however is framed by the overall principles established in the Regulation, the objectives laid down here and in the Authority's Management Board document The Setting of Work Priorities[5] and other policy documents considered by the Board.

6 The founding Regulation gives guidance to the Board in relation to its adoption of the overall Work Programme of the Authority. In addition to consideration of the budget placed at the disposal of the Authority, the Management Board must ensure that the Work Programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

7. This document is provides the basis for the work of the Authority during the 2004 period and in many cases work initiated in 2004 will continue to grow in subsequent years. The Work Programme should be considered as predictive and as with all predictive tools subject to changes It should be considered to be based on the framework document MB 19/20.03.2003 – 8 Draft Budget Information Note adopted by the Board at its meeting of March 2003.

5 MB 18.06.2003 – 3 The Setting Of Work Priorities

## II. THE AUTHORITY'S MISSION AND TASKS

8. Regulation (EC) No. 178/2002 of the European Parliament and of the Council No 178/2002 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 amended by Regulation (EC) No. 1642/2003 of 22 July 2003[6] forms the legal basis of the Authority. It sets out the mission, tasks and responsibilities of the European Food Safety Authority that provides the basis for the key objectives of this Management Plan.

9. The Authority's mission are as follows:

- Improve consumer confidence by acting as an independent scientific source of advice, information and risk communication
- Contribute to the smooth functioning of the internal market by acting as an independent scientific point of reference in risk assessment
- Contribute to a high level of protection of human life and health by providing a comprehensive scientific view of the safety and other aspects of the whole food and feed supply chain and in this respect take account of animal health and welfare, plant health and the environment.

**The Authority's founding Regulation sets the following:**

10. Support to EU legislation and policies

- Provision of scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. This includes the provision of independent information on all matters within these fields and communication on risks.

- Provision of scientific opinions which will serve as the scientific basis for the drafting and adoption of Community measures in the fields falling within its mission

- Provision of scientific advice and scientific and technical support on human nutrition in relation to Community legislation and, at the request of the Commission, assistance concerning communication on nutritional issues within the framework of the Community health programmes;

Other scientific aspects

- Provision of scientific opinions on other matters relating to animal health and welfare and plant health;

- Provision of scientific opinions on products other than food and feed relating to genetically modified organisms as defined by Directive 2001/18/EC and without prejudice to the procedures established therein.

[6] OJEU No L 245 of 29.9.2003

11. Emerging risks

Collection and analysis of data to allow the characterisation and monitoring of risks which have a direct or indirect impact on food and feed safety.

12. A centre of excellence

The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it.

13. Openness and Transparency

One of the core principles underpinning all the work of the Authority is to operate as a model of transparency and openness. Early work on this was initiated in 2003, but significant efforts will be made during 2004 to ensure that these principles are translated into concrete policies and procedures. In addition the Authority will build closer working relationships with stakeholders through the implementation of recommendations put forward from the 2003 Stakeholder Colloque and as agreed by the Management Board.

14. International dimension

The Authority should also contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety standards and trade agreements.

15. Enlargement

The European Union will be enlarged during 2004 with the accession of 10 new Member States and the Authority is preparing to integrate these States into the work of the Authority at this time. The Authority's work with the Accession countries started in 2003 will be consolidated in 2004 to integrate the new entrant states into the work of the Authority. Not only will they become full members of the Advisory Forum but additional efforts will be made in 2004 to ensure recruitment from these states.

**Tasks of the Authority**

16. The tasks of the Authority shall be the following:

- to provide the Community institutions and the Member States with the best possible scientific opinions in all cases provided for by Community legislation and on any question within its mission;

- to promote and co-ordinate the development of uniform risk assessment methodologies in the fields falling within its mission;

- to provide scientific and technical support to the Commission in the areas within its mission and, when so requested, in the interpretation and consideration of risk assessment opinions;
- to commission scientific studies necessary for the accomplishment of its mission;

- to search for, collect, collate, analyse and summarise scientific and technical data in the fields within its mission;

- to undertake action to identify and characterise emerging risks, in the fields within its mission;

- to establish a system of networks of organisations operating in the fields within its mission and be responsible for their operation;

- to provide scientific and technical assistance, when requested to do so by the Commission, in the crisis management procedures implemented by the Commission with regard to the safety of food and feed;

- to provide scientific and technical assistance, when requested to do so by the Commission, with a view to improving co-operation between the Community, applicant countries, international organisations and third countries, in the fields within its mission;

- to ensure that the public and interested parties receive rapid, reliable, objective and comprehensible information in the fields within its mission;

- to express independently its own conclusions and orientations on matters within its mission;

- to undertake any other task assigned to it by the Commission within its mission.

17. In addition, there are several legal requirements set out under European Union legislation that provide competence to EU Scientific Committees. By virtue of Article 62 paragraph 1 of the Authority's founding Regulation, tasks conferred upon Committees or Panels in areas now falling within the Authority's tasks and responsibilities are part of its Work Programmes and indeed form a large part thereof. The work of the Authority in relation to all its areas of competence will be continually reviewed during 2004 to ensure that activities are progressing in line with the agreed objectives of the Authority. This relates not only to the scientific programmes but also to other areas within its tasks and mission. During 2004 the Authority will be reviewing with the Commission its role in relation to nutrition to ensure that all areas for which it should be responsible are indeed being addressed.

18. Since the establishment of the Authority, the Commission has issued a number of legislative proposals that will have a direct and significant Impact on the future workload of the Authority. These are listed in Annex II.

**Two areas remain unclear:**

**Examination of Existing Networks and Information collection systems**

19. The Authority, Commission and Member States co-operate to promote the effective coherence between risk assessment, risk management and risk communication functions. Central to this is the close co-operation with the competent bodies in the Member States carrying out similar tasks to these of the Authority.

20. One of the key objectives for the Authority during 2003 was to promote networking in the fields within its mission and to facilitate scientific co-operation through the Advisory

Forum which works to ensure that the national agencies and administrations expertise can be harnessed to enhance the overall available knowledge on the scientific aspects of food safety. The Management Plan includes a proposal for the establishment of a formal scientific network of national food safety agencies and expert centres. It also proposes ways for efficient expert and expertise exchange between the Member States and the Authority between the Member States themselves. The proposed scientific networks will be channelled through the work of the Advisory Forum.

**Data Collection**

21. At the time of presenting this Management Plan the Authority is not able to anticipate when the work on this task can commence. The founding Regulation which provides the basis for this work requires the Commission to draw up a proposal on which the Authority may act. [7] In anticipation of this proposal, the Authority in 2004 will build on the initiatives it has already started in 2003 jointly with the Member States the Commission to collect data and other scientific information. During 2004 it is proposed that within the Scientific Expert Service Department one of the proposed science units will be charged with a data collection function including the maintenance and improvement of existing databases (e.g. those on acrylamide / dioxins / furans / PCB's)

[7] By February 2003 the Regulation required the Commission to publish an inventory of existing data collection systems in the fields of the mission of the Authority. The report should have been accompanied by a proposal concerning each system and the role that the Authority should have assigned to it, and which modifications and improvements may be appropriate. The report should also identify any shortcomings and remedies to enable the Authority to collect and summarise relevant scientific and technical data.

## III. The Main areas of Resource Growth and Consolidation during 2004

**Scientific Work**

22. The Scientific Panels and Committee established during the latter part of 2003 have now established extensive work programmes to address the questions posed to them. In the main their work programmes in 2004 are derived from requests from the European Commission and from those 'self-tasked' by the Executive Director on matters of concern brought to his attention as warranting serious consideration by them. It can be anticipated that questions may also arise from the Member States or the European Parliament during this period.

23. In the main the Panels and the Committees have formed specific working groups which are addressing scientific questions for adoption at the plenary meetings of their respective parent Committee or Panel. One objective during 2004 is for the Authority to start to be in a position to offer further in-house support to the work of the Committee and Panels so that they may make more efficient use of their time in addressing questions than has been possible during 2003.

24. The scientific work programme comprises two main areas:

-the work of the Scientific Panels and Committee, that is, the questions and resultant opinions (details are in Annex III and IV)
-and other scientific work including, for example, the development of Authority's in-house scientific expertise, the identification of emerging risk, networking and scientific data / information gathering.

25. Both areas should be considered within the framework of the Authority's overall policy driven by the pursuit of excellence to ensure that the Authority maintains the highest standards of scientific rigour in all its scientific work and in particular in its risk assessment and safety evaluation procedures.

26. In order to compile a comprehensive estimate of the likely questions and opinions of the scientific committee and panels it is necessary to consider both the annual and multi-annual nature of the work. Annex II of the Updated 2003 Management Plan[8] contained a list of questions, many of which will be considered through into the 2004 period. Although some components of the Work Programmes may be considered to be short term and completed within a short period, more complex questions and those involving several steps may continue over a considerable period of time. In addition the consideration of some questions may not start until well into the period covered by an annual programme and therefore the Panel or Committee may be considering these into the next programme period. This document therefore should be considered to consider both the annual and multi-annual elements referred to in the Authority's founding Regulation.

**Communication Activities**

27. A key area of growth for the Authority during 2004 will be in the field of communication. Successful communications is seen as essential in the Authority's overall mission to make a significant contribution towards improving food safety in Europe. Through the dissemination of appropriate, consistent and accurate communications on food safety

8 MB 16.09.2003 – 7 Updated 2003 Management Plan of the European Food Safety Authority with Annexes I and II

issues, based on the risk assessments and scientific expertise of its Scientific Committee and Panels, the Authority will play an important part in rebuilding consumer confidence in food safety. Work will focus on establishing the Authority as an expert and trusted source of information on food safety issues among its stakeholders and the public at large. The strategy will work towards building and promoting the Authority's reputation as an organisation dedicated to scientific excellence, openness and transparency whilst ensuring that messages are relevant, understandable and address food safety concerns. In particular attention will be given to enhancing and improving the co-ordination and coherence of communication on food safety matters across the Community.

28. Not only will the Authority engage in active communications on matters within its mission but it will also seek the views of stakeholders, media and the public at large. This will ensure that communications programmes address public concerns and expectations and will also allow evaluation of their effectiveness over time. A critical success factor for 2004 will be the establishment and implementation of an appropriate organisational structure and the recruitment of highly qualified communications professionals in order to develop and implement successfully the Authority's communications strategy. Significant resources will be required to support the launch of new initiatives, and more generally, to ensure that the Authority is able to build and develop fully its communications capacity during 2004.

**General Staffing matters for the above and other activities**

29. During 2004 the Authority will need to put in place a significant recruitment drive so that it can continue to grow and function in the areas assigned to it under the founding Regulation. At the beginning of 2004 the staff will be approximately one fifth of the numbers envisaged for it to function at full capacity but in fact the Authority has already a full, comprehensive work programme and legal responsibilities to carry this out. Therefore it is imperative that during 2004 the Authority is able to recruit both senior and junior staff to put in place the appropriate structures to manage and carry out these tasks. As a young agency it is important to recruit the best staff possible at all levels.

30. The management capabilities and infrastructure, the administrative and other support mechanisms needed to run a complex organisation will continue to be built during 2004 to ensure that the core activities of the Authority can flourish. The objective is to ensure that the Authority develops into an efficient, effective organisation with well qualified and motivated staff drawn from the whole of the EU. This is true for both the scientific and other staff.

31. The staff of the Authority have been and will continue to be selected for their excellence and competence. Consideration is also being given to the appointment of staff from all parts of the EU area including the Accession states. In the main, staff are engaged with the status of temporary agents and are subject to the Rules and Regulations applicable to officials and other servants of the European Communities. Other support solutions to the work of the Authority are also being utilised through the input of Detached National Experts, Auxiliary and Interim staff.

## IV. ACTIVITIES

### A THE AUTHORITY DURING 2004 - AN OVERVIEW OF OBJECTIVES

32. During the 2003 the Authority through the appointment of its Executive Director became fully operational, independent of the Commission and a separate legal entity. All four components of the Authority were therefore in place: the Management Board, the Executive Director and staff, the Advisory Forum, the Scientific Committee and 8 Panels. During 2004 the objectives are to build capacity in all of its areas of competence in order to meet the requirements of the founding Regulation and in particular in the areas of its scientific activities and communications.

33. In general, objectives of the Authority over the medium term are as outlined in "The Authority's Road Map" considered by the Management Board at its meeting in September 2003.[9] The Management Plan for 2004 develops these objectives.

34. The main objectives established in this paper are:

i) to establish the Authority as a source of high quality advice within and outside the EU.
ii) to establish strong and mutually valuable relationships with the Member States.
iii) to operate as a model of transparency and openness.
iv) to provide a high level of service to the Authority's stakeholders.
v) to provide a high level of service to those tasking the Authority (the Commission, the European Parliament and Member States).
vi) to play its role effectively in times of EU-wide food crises and scares.
vii) to be able to identify and characterise emergency risks.
viii) to integrate the new entrant States into the Authority's work.
ix) to collect relevant data.
x) to operate as an effective, efficient organisation with a well-qualified and motivated staff drawn from the whole of the EU.

35. The Authority's Management Plan and in particular its Work Programmes Work Programme establishes the main direction that the Authority should take during a particular year in relation to the missions and tasks assigned to it under the provisions of the founding Regulation. The Management Plan therefore provides a tool for building the annual framework for resource planning, budget allocation and its subsequent usage. It does not of itself create the overall strategic direction for the Authority. The above objectives establish the Authority's overall aspirational objectives provide the platform for the medium term direction and guide the Authority's Annual and Multi-Annual Work Programmes.

### B. Management activities

36. The overall objectives for the activities in this chapter are to ensure that the Authority is appropriately managed and can ensure the smooth build up of the main components and tasks of the Authority. As a young agency it is important that the Authority is able to recruit some senior managerial staff as well as senior scientists and junior staff. So far during 2003 the recruitment patterns have followed the normal balance of staff needed in an organisation

[9] MB 16.09.2003 – 11 – The Authority's Road Map

with an appropriate balance of senior and junior staff grades. In 2004, while maintaining this balance, emphasis will be on expanding the scientific staff. As the headquarters of the Authority are now known it is anticipated that this may aid recruitment at least in relation to aspects concerning the certainty about employment location. The Authority will focus on putting in place good administrative procedures and quality management systems to facilitate the application of good managerial practices.

37. ***Management Board***

| | |
|---|---|
| Chair of the Management Board | Stuart Slorach |
| Vice-Chairs of the Management Board | Deirdre Hutton<br>Catherine Geslain-Lanéelle |

The Management Board's function and role have evolved and changed during the period since the Authority became operational in late 2002. Initially, much of its work focused on the need to adopt a raft of rules and procedures which were necessary from a legal point of view, to enable the other components of the Authority to be established and function. Its role during 2004 will be to focus more on providing the strategic overview and direction for the growth of the Authority on horizontal managerial matters, for example on matters relating to transparency and openness. The Authority will also ensure that all legal and budgetary matters for which it is responsible are handled correctly and in a timely manner, thus guaranteeing that the Authority has the necessary tools to develop the plans laid down in this document.

**Work Programme**

**Purpose:** In line with the requirements of the Regulation the Management Board will meet to oversee the work of the Authority.

**Objectives:**

- to establish the Authority as an expert and trusted source of information on food and food safety issues amongst its stakeholders and the public at large.
- to continue to oversee the growth of the Authority and to guide it to build into the organisation foreseen in the founding Regulation.
- to adopt and approve key business documents including work programmes, activity reports, budget related documents, and accounts
- to ensure that the correct operational procedures are in place so that the Authority can function as a correctly managed publicly accountable organisation
- to oversee during 2004 the planning and preparation for the move to Parma

**Indicators:**

- Adopted budget and other management documents with the time lines established in the founding Regulation
- Efficiency of organisation and execution of meetings

**Initiatives**

During 2004, the "openness strategy" for the Management Board will be developed including holding meetings which are open to members of the public. This will be in addition to the webstreaming which enable people from across Europe and beyond to follow its work. The support to the Management Board will ensure improved quality and timeliness of Board documents. The Board will also hold a Team Building Day during 2004.

38. ***Executive Director***

Executive Director: Geoffrey Podger

Deputy Executive Director: Herman Koëter

**Work Programme**
**Purpose:** Following the initial work of establishing the Authority during 2003, the Executive Direction will lead and manage the activities of the Authority. He will also ensure the progressive build up of all components of the Authority to deliver the work programme of the Authority within its budget.

**Objectives:**

- To establish the Authority as an expert and trusted source of information on food and food safety issues amongst its stakeholders and the public at large.
- to manage during 2004 the planning and preparation for the move to Parma
- To manage the further development of the European Food Safety Authority.
- To ensure financial and human resources are used in the most efficient, balanced and effective manner.
- To provide detailed information to the Management Board concerning the creation of the Authority, including ensuring that the work programme and decisions of the Board are implemented.
- To ensure that the timetable established for key tasks in the founding regulation are met.
- To consolidate the organisational structure.

**Indicators:**

- A clear managerial structure capable of delivering the 2004 Work Programmes
- Work programme delivered at the end of 2004 within budget

39 ***Managerial and Administrative co-ordination***

**Work Programme**

**Purpose:** The Authority must be able to develop as an excellent organisation with all elements of its administrative work co-ordinated and reviewed.

**Objectives:**

- To provide overall management of all activities in terms of finance, human resources, IT, communication, legal advice, amongst others.
- To ensure a coherent and co-ordinated approach to the administrative activities of the Authority.
- To ensure that human and financial resources are spent in the most efficient and effective manner.

**Indicators:**

- All activities functioning efficiently
- Comparing achievements with activities in the work programme

**2004 Initiatives**
The management team put in place during 2003 will continue to provide the overall managerial impetus of the Authority under the direction of the Executive Director.

40. ***Quality Management***

**Work Programme**

**Purpose:** Promote a culture of continuous improvement by implementing a quality management system, in order to ensure consistency through the Authority's internal procedures and a common methodology.

**Objectives:**

- To implement the principle of continuous improvement in a structured and systematic way
- To identify and document the appropriate processes and procedures for the Authority's scientific and horizontal activities, in cooperation with the owner of those processes and procedures

**Indicators:**

- Participating in benchmarking networks and networking with other Community agencies and similar organisations
- Number of procedures, guidelines and work instructions
- Feedback from stakeholders on efficiency, effectiveness, timeliness, quality of opinions

**Initiatives in 2004**
In 2004 work will be initiated on improving work and other procedures as identified through staff consultation. Benchmarking activities will be initiated through networking with other European Union institutions and agencies. A general framework for quality initiatives will also be put in place during 2004.

41. ***Legal affairs***

**Work Programme**

**Purpose:**
Providing legal analysis and advice in support of all the Authority's development and operations.

**Objectives:**

- To ensure fulfilment of all legislative, regulatory and contractual obligations and facilitate implementation of these, in the light of the Authority's policy and business objectives.
- To complete all the Authority's basic operating instruments internal rules and other measures necessary to the effective functioning of the Authority

**Indicators:**

- Number of internal rules and decisions adopted and guidance developed
- Number of requests for legal advice dealt with

**Initiatives in 2004**
In 2004 particular attention will be given in completing all the Authority's basic operating instruments such as internal rules and other measures necessary to the effective functioning of the Authority as an independent legal entity, and to providing all necessary input to the development of regulatory guidance in order for the Authority to optimise the fulfilment of its obligations

**External Relations**

42. There are three areas that will be given particular attention during 2004. These are institutional, International and Stakeholders relations.

43 The Authority will also build during 2004 its relationships with the new entrant states as well as forge links with countries and organisations beyond the European borders. The new Member States have been members of the Advisory Forum from its inception and Switzerland, Norway and Iceland also participate. During 2004 links will be further developed with similar agencies in the USA, Japan and Canada to bring scientists together at an early stage in considering risk assessment issues. In parallel links with international organisations such as WHO, OECD and FAO will be developed.

44. The Authority will forge greater involvement of stakeholders and over 2004 will need to be better resourced to ensure this occurs. In this respect stakeholders are identified as the food science (and animal health) academic community, the related consumer organisations, environmental NGOs and the relevant worker and food sector business groupings. The Authority will develop relationship with its stakeholders together, not just to develop a better understanding between them and the Authority but also so that they develop a better understanding of each other. In this respect, during 2004, consideration will be given to finding ways of opening up even further the risk assessment process, and looking at how the Authority can involve stakeholders with risk communication activities. In particular consideration will be given as to how the Authority can develop a mechanism for stakeholders to continue to contribute to the Authority's development.

45. Institutional links will also be strengthened with the Parliament, the Commission and the National Authorities.

**Work Programme**

**Purpose:**

- To ensure that the work of the Authority is well known internationally and that its methods of work are transparent and known throughout the scientific community, at national and international level for the excellence of the work done by the Authority
- To ensure that the Commission, European Parliament and other Community institutions understand the importance of the Authority's work and play their part in its on-going development
- To ensure that stakeholders are able to have appropriate input to the work of the Authority so that trust and understanding can build in the scientific basis for food law in the Community.

**Objectives:**

**Institutional**

- To continue to develop and maintain working relationships with the Commission, European Parliament and other Community institutions
- To ensure that the Authority is kept informed of developments in the community institutions

**International**

- To continue to develop links with those countries which have concluded agreements with the European Community by virtue of which they have adopted and apply Community legislation in the field covered by Regulation 178/2002/EC.
- To develop close links with third country national and international bodies involved in scientific work relating to the safety of the food chain.

**Stakeholders**

- To build and maintain relationships with key stakeholders in an interactive manner
- To build an active dialogue with concerned stakeholder groups

**Initiatives in 2004**

46. During 2004, it is proposed that the Authority convenes Stakeholder meetings in order to build on the dialogue started in 2003. Stakeholder involvement will be built into several areas of the Authority's activities. Communications activities will be geared so as to ensure that stakeholders' views are understood and that they are able to input into the communications and other activities of the Authority. Consideration will be given during 2004 on how to open up the scientific work of the Authority to stakeholders on key scientific matters and to the greater use of public consultation on draft scientific opinions.

The Authority will develop stronger international contacts during 2004 building on those already established during 2003 especially in relation to scientific and risk assessment activities. A particular task in 2004 will be to develop an overall strategy on international relations for the Authority.

In line with the founding Regulation the Authority will continue to foster the close cooperation necessary to promote effective coherence between risk assessment, risk management and risk communication functions through building effective working relations with the Community institutions, Member States and key stakeholders.

## C. SCIENTIFIC ACTIVITIES

### GENERAL INTRODUCTION

47. As stipulated in the Regulation No. 178/2002 of the European Parliament and the Council on the establishment of the European Food Safety Authority, the Authority should be an independent scientific source of advice, information and risk communication related to food and feed safety. It should provide technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety and ensure that the national authorities, the public and interested parties receive rapid, reliable, objective and comprehensive information in these fields. In order to fulfil this mission, a number of tasks are identified in Article 23 of the Regulation which relate to: (i) providing scientific opinions and advice in response to questions formally addressed to the Authority; (ii) the monitoring of defined risk factors, including zoonoses, zoonotic agents and BSE/TSE-related monitoring; (iii) assessing the risks and maximum residue levels (MRLs) of existing and new pesticides and (iv) maintaining a pro-active approach with respect to the application and the promotion of new and harmonized scientific approaches for hazard and risk assessment methodologies. In order to achieve substantial progress in each of these four areas, measures will be taken to avoid that as a result of heavy workload in one area other work areas would receive less than desirable attention. Such measures could include the outsourcing of defined activities and making the most efficient use of expertise and information available in Member States. Furthermore, criteria will be developed to set priorities for the development of opinions within and between Panels. These criteria will take into account, among other aspects, anticipated public health impact, possible legal obligations, the level of urgency as indicted by the submitting entity, possible connections between the question and other questions or work items, and the social-economic relevance of the question.

### PROVIDING SCIENTIFIC OPINIONS AND ADVICE TO QUESTIONS FORMALLY ADDRESSED TO THE AUTHORITY

#### General

48. In order to address questions and issues formally submitted to the Authority, a number of Scientific Panels and one Scientific Committee have been established in May/June 2003. The Scientific Expert Panels were composed of independent scientific experts selected following an open call for expressions of interest. The Scientific Committee was composed of the chairpersons of the Scientific Panels and six independent experts who do not belong to any of the panels. Panel members and the 6 additional experts of the Scientific Committee were appointed by the Management Board at its meeting in April 2003 for a three year period of office acting upon a proposal from the Executive Director.

49. The responsibility of the Scientific Committee and Scientific Expert Panels is to address scientific questions and to provide independent opinions of scientific excellence on matters within the remit of the Committee or Panels. Scientific excellence was understood by the Management Board as the expression of awareness and knowledge of the newest scientific developments and the consideration of this fore-front science in the development of risk assessments. Scientific excellence was also considered to mean the active contribution of the Authority's scientists to the advancement of generic quantitative risk assessment methodologies in order to reduce uncertainty levels and the understanding of the concept of risk.

50. Risk management and risk communication will benefit from clear understandable opinions, which are comprehensive in their characterisation of hazards, assessment of

exposures, and, where possible quantitative, assessment of risks. Therefore, one objective of the Authority is to ensure that both the highest standards of science and communications are met by the Authority so that scientific opinions can be appropriately communicated to the European Commission, the European Parliament, the Member States and all other stakeholders.

51. The Work Programme for 2004 for each of the four work areas mentioned in the general introduction to this chapter is addressed below preceded by a brief synopsis of the progress made in 2003. Additional information on the purpose, objectives and milestones for the various (sub-areas of) subjects is presented in more detail in Annex III. An abbreviated overview of the questions received (or expected) by the Authority, together with the date of receipt and expected date of completion of the work is included in Annex IV.

**Work of the Scientific Committee and Panels**

**Scientific Committee**

52. The Scientific Committee is responsible for the provision of scientific advice on multi-sectorial issues falling within the competence of more than one Panel, and on issues which do not fall within the competence of any of the Panels. The Scientific Committee is also responsible for the general co-ordination necessary to ensure the consistency in the scientific opinions of the different panels.

***Progress Report***

53. The Scientific Committee met four times in plenary session at the following dates:

- 30 June – 1 July: inaugural meeting; minutes adopted on 27 August
- 27 - 28 August; minutes adopted on 17 September
- 17 - 18 September; minutes adopted by written procedure on 17 October
- 19 and 20 November, minutes adopted by written procedure on 10 December

54. The Committee devoted a great part of its meetings to the identification of issues to be considered for inclusion in the Work Programme of the Committee for 2003. These issues included:

- Introduction of harmonised approaches in the risk assessment process:
  - General format for scientific opinions
  - Guidelines for preparation of requests
  - Advice on the Authority's crisis management plan
  - Development and implementation of the Authority's strategies and general guidance in the area of exposure assessment
- Scientific Co-ordination:
  - Strategies for building the Authority's capability for identifying and evaluating emerging risks
- Challenges in the area of risk assessment:
  - Uniform approach for the risk assessment of genotoxic and carcinogenic substances
- Specific subjects:
  - Qualified presumption of safety
  - 'Non-nutritional components' in the EU diet

The Committee established Working Groups (i) on guidelines for the preparation of requests for scientific opinions, (ii) on crisis management, (iii) on exposure assessment, (iv) on genotoxic and carcinogenic substances and (v) on emerging risks. First meetings of these Working Groups were held in the second half of 2003 with the main objective to prepare advice from the Committee to the EFSA on a work plan for each of the respective areas. The Committee's advice on EFSA's crisis management plan was discussed at the Advisory Forum meeting of the 10th of December 2003. Details of the progress made with the various issues included in the Work Programme are provided in Annex III.

***Work Programme 2004***

54. The proposed Scientific Committee's Work Programme for 2004 comprises the subjects that were already initiated in 2003, together with objectives and expected milestone achievements that would contribute to the advancement of the science of risk assessment.

The Work Programme of the Scientific Committee includes a number of "horizontal subjects" of interest for more than one Panel which were considered relevant for the scientific activities of the Authority. For 2004, the Committee proposed to give priority to the development and implementation of harmonised approaches in the area of exposure assessment, risk assessment, and in the area of the quantitative risk assessment with particular reference to genotoxic and carcinogenic substances. The newly established Working Groups have been charged with the preparation of guidance documents and scientific opinions for each of these areas. Relevant documents and developments in the framework of other international harmonisation projects shall be taken into consideration.

The Scientific Committee will also proceed with the development and implementation of appropriate strategies for the identification and evaluation of emerging risks. The objective will be to establish monitoring procedures for systematically searching for, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission. In this context, a project consultant will assist the Scientific Committee in establishing and maintaining an expert network of university groups, research institutes, national food authorities, consumer organisations and industry associations to support the Authority in the identification and evaluation of emerging risks. The work shall be carried out in close collaboration with the Committee's Working Group on Emerging Risks and with other relevant parties working in this area.

In the course of 2004, it is foreseen that EFSA will be in the position to provide more assistance to the Scientific Committee and its working groups through its Scientific Expert Services Department. This may lead to a reduction of the workload and a further prioritisation of the work to be carried out by the members of the Scientific Committee and its Working Groups.

55. In order to proceed with the work of the Scientific Committee in the most efficient way the Committee planned to meet approximately every two months (approximately 6-7 plenary meetings of 2 days each). In addition, approximately 30-90 meeting days are foreseen for the various Working Groups.

**Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)**

56 The Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC) is responsible for delivering opinions on scientific questions relating to the safety in use of food additives, flavourings, processing aids and materials in contact with

food; associated subjects concern the safety of other deliberately added substances to food and questions related to the safety of processes (including irradiation, but excluding heating).

***Progress Report***

57. The Panel consists of 17 Members and met four times in plenary session in 2003 at the following dates:

- 22 May inaugural meeting; minutes adopted on 9 July
- 9 July; minutes adopted on 30 September
- 30 September-1 October; minutes adopted by written procedure on 31 October
- 9-10 December, minutes in preparation

58. The Panel established 3 permanent working groups on food additives (met 4 times in 2003), on flavourings (met twice) and on food contact materials (met 3 times). In addition, one ad hoc working group meeting on nutrient sources was held in June and 2 ad hoc expert group meetings on semicarbazide in various foods, including baby food, were held in July and October. Besides members of the Panel and the working group on food contact materials, members of other panels and outside experts also participated in these meetings to meet the multidisciplinary challenges created by this emerging crisis. At each of the meetings an advice was published at the Authority's website and a press release was issued and a press conference on this subject was held mid October.

59. In addition to a statement on semicarbazide, adopted at its third meeting, the Panel adopted six opinions on the request of the European Commission: four on nutrient sources and two on in all nine substances intended for use in food contact materials. A special task has been assigned under contract to continue the work performed in SCOOP Task 1.1 to build up and maintain the FLAVIS database which compiles information for the scientific evaluation of chemically defined flavouring substances according to Commission Regulation (EC) No. 1565/2000. The FLAVIS group has also prepared data sheets which summarises this information including a pre-evaluation and presented them to the AFC Panel, which is presently considering them.

***Work Programme 2004***

60. The proposed AFC Panel Work Programme for 2004 comprises the subjects that were already initiated in 2003 in the 3 main areas of the Panel (processing aids have still not been a major issue).

61. Besides the additives carried over from the work of the Scientific Committee on Food (SCF) and part of the 2003 Work Programme further requests have been received through the European Commission on certain food additives including nutritional sources, and the Commission has beyond that requested a re-evaluation of all permitted food additives with highest priority on colours followed by the group with miscellaneous functions and lowest priority for the sweeteners which have been evaluated comparatively recently by the SCF. Although no defined timeframe has been defined by the Commission, this task is expected to claim considerable resources and it is therefore the intention to outsource main parts of the preparatory work. It is not foreseen that the Panel would have started the actual re-evaluation by 2004, but still considerable initial work must be foreseen in this area throughout the year.

62. In case the draft Regulation on food additives is adopted in 2004 this would create considerable extra work for the Authority and the Panel, especially as it is foreseen that several tasks beyond the food safety aspect (e.g. question of efficacy) will be imposed on the Authority.

63. In case the draft Regulation on enzymes is adopted in 2004 this will impose considerable extra work on the Panel and administrative work on the secretariat. It is likely that it would be necessary to create a new working group for this area.

64. The Work on the flavouring substances under various programmes will continue in 2004 according to the plan. With the adoption of the Regulation on smoke flavourings adopted on 10 October 2003 considerable additional work of the Panel can be foreseen in 2004 and beyond. Besides the actual risk assessment of the smoke flavours in question, the Regulation also imposes considerable administrative work on the Authority. It may be necessary to create a specific working group to deal with these matters as well as employing additional staff.

65. The Panel has not received any indication of coming requests on processing aids (except the enzymes). Should any question arise during 2004 they would be dealt with by the food additive working group. The work in the FLAVIS group will be continued as planned.

66. The Panel will continue evaluating the long list of substances intended for food contact materials, which has grown with the addition of a series of new substances and other requests of a more general nature. The administration of incoming requests, which was previously outsourced by the Commission, is now managed by the Authority. However the review of dossiers and preparation of working papers for the Panel is presently being outsourced.

67. The main task concerning the migration of semicarbazide from lids on glass jars and bottles is likely to have culminated and for the Panel will mainly remain to follow whether the recommended change in procedures will cause the expected reduction in the migration of this substance. The European Commission has beyond this question requested a full risk assessment of semicarbazide in all foods from all sources. This question will be dealt with in cooperation with the Panel on Contaminants.

**Scientific Panel on additives and products or substances used in animal feed (FEEDAP)**

68. The Scientific Panel on additives and products or substances used in animal feed (FEEDAP) is responsible for scientific and technical questions concerning safety for the animal, the user/worker, the consumer of the products of animal origin, the environment and to the efficacy of biological and chemical products / substances intended for deliberate addition/use in animal feed.

***Progress Report***

69. The FEEDAP Panel is composed of 20 experts. The FEEDAP Panel met six times in plenary session at the following dates:

- 21 May inaugural meeting; minutes adopted on 8 July
- 8-9 July; minutes adopted on 9 September
- 9-10 September; minutes adopted on 22 October
- 22-23 October; minutes adopted on 12 November
- 12-13 November; minutes adopted on 2 December
- 2-4 December, minutes in preparation

70. The work of the FEEDAP Panel is largely related to the scientific assessment of the products under authorisation process at the Community level. The working program consists of questions from the Commission addressed previously to the Scientific Committee on Animal Nutrition (SCAN) and new questions from the Commission, mainly in connection with the Council Directive 70/524/EEC.

71. Two permanent working groups have been established: one on micro-organisms, another one on enzymes to deal with the continuous number of assessments requested on products within the scope of those categories. Additional ad hoc working groups have been created to deal with the re-evaluation of certain additives in accordance with the article 9G of Directive 70/524/EEC (coccidiostats), other provisional or permanent authorisations, or the more general questions (such as iodine and carotenoids). A considerable number of working group meetings related to these questions have been organised (24 working group meetings took place until the end of December).

72. The various Working Groups met on the following dates:

- WG on Coccidiostats (met as sub groups of the Working Group): 16 June, 17 June, 24 June, 3 September, 19 September, 13-14 October, 28 October, 29 October, 14 November, 21 November, 25 November, 26 November
- WG on Micro-Organisms: 24 August, 17 October, 16 December
- WG on Enzymes: 2 September, 11 December
- WG on Iodine: 21 October, 10 December

73. Most of 2003's meetings were dedicated to the assessment of coccidiostats under brand specific approval, either as re-evaluation or evaluation of safety and efficacy of these products, the assessments being based on data submitted by the notifiers. The first opinion of the Panel was issued in September about the safety of enzyme preparation Avizyme 1300. In November, the first opinion on re-evaluation of coccidiostats was issued (Stenorol/ halofuginone) and two opinions on feed additives of the category of micro-organisms were adopted. In December two more opinions on coccidiostats (Deccox/decoquinate and Koffogran/nicarbazin) were issued.

***Work Programme 2004***

74. The proposed FEEDAP panel Work Program for 2004 comprises the subjects initiated in 2003 in the main subject areas are expected to be: coccidiostats and other medicinal products as feed additives, micro-organisms, enzymes, trace elements, preservatives, other feed additives, direct or indirect sources of protein, and products for particular nutritional purposes. The tasks will include safety assessment for the animals, user, consumer and the environment but includes also tasks beyond safety aspects (efficacy).

75. It is foreseen that the frequency of submission of dossiers and corresponding questions will be similar to 2003. An indication about new questions from the Commission includes 6 new questions within 3-4 months, and 20 supplementary questions related to previous requests. In addition to questions related to product authorisations some general issues might be addressed to the Panel. Some self-tasking activities will be addressed as well.

76. New Regulation (EC) No. 1381/2003 on Additives for use in Animal Nutrition was published in October 2003. Most likely it will create considerable extra work for the Panel and administrative work of the secretariat beyond the regular flow of new applications for authorisations of feed additives. The new regulation will require adoption of a series of new or amended guidelines, new guidance for the applicants and consultation of the Authority on scientific progress in certain fields.

77. These tasks are likely to lead to the creation of new working groups. It is also foreseen that a number of tasks currently carried out by Member States will be referred to the Authority in 2004. The new Regulation will also result in the submission of notifications of all existing feed additives to the Authority within a year and consequently, verification and confirmation of the completeness of, or deficiencies in that information will need to be submitted by the

Authority to the Commission. Some parts of the work in the dossier evaluation and preparation of working papers will be considered for outsourcing.

**Scientific Panel on plant health, plant protection products and their residues (PPR)**

***Progress Report***

78. The Scientific Panel on plant health, plant protection products and their residues (PPR) is responsible for delivering opinions on scientific questions relating to the safety of plant protection products for the user/worker, the consumer of treated products and the environment and plant health. The PPR Panel was established in May 2003 and is composed of 18 experts.

79. The Panel met three times in plenary session at the following dates:

- 22nd May: inaugural Meeting; minutes adopted on 8 July
- 7th October: minutes adopted on 29 October
- 2nd December: minutes adopted on 19 December

80. The Panel established two Working Groups, one in toxicology and one in ecotoxicology. These Working Groups met both on 25th June and 11th September in parallel.

81. Two opinions were developed and issued in response to a request from the Directorate-General for Health and Consumer Protection of the European Commission. The subjects of these opinion were on:

- the toxicological effect of the new fungicide mepanipyrim (liver tumours);
- the effects of existing insecticide azinphos-methyl on non target arthropods and birds.

82. These opinions were published on 23rd October and 3rd November respectively and are available on the Authority's website.

***Work Programme 2004***

83. For 2004, the PPR Panel has planned to have approximately 7 plenary meetings to consider and respond to an increasing number of requests. The majority of these requests will be forwarded by the Commission and are arranged into the following main areas (see also Annex III and IV for details):

- Existing active substances (already on the EU market) of the first and the second stages of the re-evaluation procedure under Directive 91/414/EEC and also new active substances. A certain number of requests are expected on the remaining active substances of the 1st stage (maximum of 15, Commission in charge): dinocap, daminozide, alachlor, methamidophos) and on the 2nd stage (maximum of 36, the Authority in charge[10]) and a few on new active substances.
- Technical Guidance Documents produced by Expert Working Groups of DG Health and Consumer Protection of the Commission (maximum of 6).

[10] See section "Pesticide Risk Assessment Peer Review (PRAPeR)".

- Revision of Annexes II and III of Directive 91/414/EEC in the five sections of the dossiers (toxicology, ecotoxicology, residues, fate and behaviour and physico-chemical properties).
- Some requests in the area of plant health.

84. Some requests will have a higher priority than others (because of regulatory deadlines) which had some major impacts on the organisation and prioritisation of the work program.

**Scientific Panel on genetically modified organisms (GMO)**

85. The mandate of the Scientific Panel on genetically modified organisms (GMO Panel) is to deliver opinions on scientific questions relating to genetically modified micro-organisms, plants and animals. These questions relate to the deliberate release of GMOs into the environment and to genetically modified food and feed including the derived products. Thus, questions may range from environmental issues to human and animal health.

86. The GMO Panel is composed of 21 experts, whose experience provides a balanced representation of the necessary expertise. The Panel may seek additional expertise from other panels and external experts on specific issues as needed.

***Progress report***

87. The current and anticipated work program of the GMO Panel consists mainly of delivering opinions on requests received from the Commission that can be divided into:

- questions on generic, horizontal issues such as drafting or assessing guidance documents for the risk assessment of GMOs;
- questions related to applications for the placing on the market of GMOs and/or derived products introduced under Community legislation (on *the deliberate release into the environment of GMOs*, on *novel foods and novel food ingredients* and on *genetically modified food and feed*, comprising also additives for use in animal nutrition, food additives and enzymes used in food when produced from a GMO);
- and specific questions, such as the notification by the Provincial Government of Upper Austria.

88. In addition, the Panel will undertake self tasking initiatives in areas where there could be an immediate or future need to address scientific questions.

89. The Panel met five times in plenary session at the following dates:

- 26 May (inaugural meeting); minutes adopted on 4 July
- 4 July: minutes adopted on 2 October
- 2 October: minutes adopted on 7 November,
- 25 November: minutes adopted on 11 December
- 11 December, minutes in preparation

90. Three Working Groups were created for the evaluation of authorisation dossiers. These Working Groups focus on the following subjects: (i) molecular characterisation, (ii) food and feed safety, and (iii) environmental risk assessment. In addition, the following four *ad hoc* Working Groups were established to deal with a specific question: (i) WG Austria case, (ii) WG Markers, (iii) WG Microbiology, and (iv) WG GM food & feed guidance. The Working Groups meetings were scheduled on the following dates:

- WG Molecular Characterisation: 17 September, 26 November, 10 December
- WG Food and Feed Safety: 17 September, 26 November, 10 December
- WG Environmental Risk Assessment: 17 September, 10 December
- WG 'Austria case': 4 July
- WG Markers: 28 August, 1 October, 26 November
- WG Microbiology: 1 October
- WG Food and Feed Guidance: 4 November, 16 December.

91. The Panel issued its first opinion on a specific topic (Austria case) in July 2003. In November, the Panel released two more opinions relating to applications for the marketing of GMOs (GM maize NK603) and an opinion on a guidance note (on the contained use of GM micro-organisms under Directive 90/219/EEC) was adopted in December.

***Work Programme 2004***

92. The proposed GMO Panel's Work Programme for 2004 comprises an expected large (but yet unknown) number of marketing applications (including existing applications that are currently with the national authorities but for which no initial risk assessment was finalised) and a number of generic issues and self tasking activities. With regard to GMO marketing applications, the Panel is requested to deliver opinions on 3 applications in early 2004 (for details see Annex III).

93. As an immediate priority for 2004, it has been proposed that the Panel proceeds with the drafting of guidance documents for applications under the new GM food and feed Regulation (EC) 1829/2003. Priority will be given to the food and feed derived from GM plants. In parallel, the Panel is expected to start with the development of guidance for food and feed produced from genetically modified micro-organisms. The GMO panel will organise a Stakeholder Consultation before final adoption of the guidance documents.

94. The new Regulation (EC) 1829/2003 on GM food and feed, that will be of application from 18 April 2004 onwards, imposes new management tasks on EFSA, as EFSA will in future play a central role, not only in the risk assessment, but also in the administrative management of notifications, a task which is currently carried out by Member States and /or the Commission. Notifications will have to be made available to the Commission and the Members States; moreover, Member States will be actively involved in the risk assessment process and (part of) the risk assessment can or has to be delegated to national bodies. For this purpose, EFSA will set up collaborative networking with national agencies and competent authorities involved in the risk assessment of GMOs.

EFSA will inform the public of the introduction of new GMO applications (under 1829/2003) through its website. EFSA will investigate how to get feedback from stakeholders within the restricted timeframes in the most efficient manner.

This new Regulation will create considerable extra work for the Panel and administrative work of the secretariat beyond the current flow of new applications for authorisations of GMOs as the scope has been considerably enlarged and new types of products such as additives or enzymes derived from GMOs will have to be assessed under this Regulation. A close collaboration will be set up with other panels (such as FEEDAP, AFC). These tasks are likely to lead to the creation of new working groups. Some parts of the work relating to dossier evaluation and the preparation of working papers may be considered for outsourcing.

95. It has also been proposed that the Panel initiates self tasking in areas where the need for a scientific opinion has already been identified (i.e., the safety of use of viral promoters, post-market human/animal health monitoring of GM food/feed, post-market environmental

monitoring of GM crops, new approaches for the allergenicity assessment of GMOs, guidelines for GM micro-organisms in the environment and impact of GMOs on microbial biodiversity and function in the soil environment).

**Scientific Panel on dietetic products, nutrition and allergies (NDA)**

96. The Scientific Panel on Dietetic products, Nutrition and Allergies (NDA) is responsible for providing scientific opinions on questions relating to dietetic products (i.e. foodstuffs intended to satisfy particular nutritional requirements of specific groups of the population, as defined in Community legislation), human nutrition and food allergy, and other associated subjects such as non-GM novel foods.

***Progress Report***

97. The NDA Panel is composed of 13 members and met two times in plenary session at the following dates:

- 21 May: Inaugural meeting; minutes adopted on 16 September
- 24 and 25 November: minutes adopted on 19 December

98. The Panel established 4 Working Groups on the following subjects: (1) food allergy; (2) infant formulae; (3) novel foods; and (4) upper levels for vitamins and minerals. These Working Groups met on the following dates:

- Working Group on Food Allergy: 8 July, 29 September, 30 and 31 October, 11 and 12 December
- Working Group on Infant Formulae: 17 July, 7 October, 12 November
- Working Group on Novel Foods: 5 September, 29 October
- Working group on Upper Levels for Vitamins and Minerals: 8 and 9 October

***Work Programme 2004***

99. For 2004, the NDA Panel has planned to have approximately 5 plenary meetings. The majority of the requests will come from the European Commission and are arranged into the following main areas (see also Annex III for details):

- Evaluation of a number of dossiers following a notification procedure related to a temporary negative list of allergenic ingredients for labelling purposes under the new Labelling Directive approved by the Council on 22 September 2003. This task will have a very tight legal deadline and, therefore, a major impact on the organisation and prioritisation of the work program of the Panel.
- Safety assessment of a number of novel food ingredients under the current Novel Food Regulation 258/97/EC.
- Safety assessment and suitability of ingredients for infant formulae.
- Presence of *trans* fatty acids in foods and effect on human health of the consumption of *trans* fatty acids.
- Setting tolerable upper levels of intake for a number of vitamins and minerals.
- Health claims: preparatory work in relation to a number of issues specified in the Commission's proposal, such as guidelines for the preparation and presentation of information necessary to support applications for authorisation of health claims, establishment of nutrient profiles, etc.

**Scientific Panel on biological hazards (BIOHAZ)**

100. The Scientific Panel on biological hazards (BIOHAZ) is responsible for delivering opinions on scientific questions on biological hazards relating to food safety and food-borne diseases, including food-borne zoonoses and transmissible spongiform encephalopathies, microbiology, food hygiene and associated waste management.

***Progress Report***

101. The BIOHAZ Panel is composed of 21 experts and met three times in plenary session at the following dates:

- 22 May: Inaugural Meeting; minutes adopted on 24 September
- 24 September: minutes adopted on 24 October
- 26 – 27 November: minutes will be adopted in January 2004

102. The Panel established 15 Working Groups on the following subjects: (no. of meetings in 2003 are presented in brackets)

- On BSE / TSE issues: Steering Group on BSE / TSE (2), BSE-related culling in cattle (1), TSE in sheep (2), Over thirty months rule-Data based export scheme (1), High pressure-hydrolysis biogas (1) Chronic wasting disease (1), Quantitative risk assessment for residual BSE risk in products derived from animal by products (1).
- On food hygiene: Tuberculosis in bovine animals (2), the effects of nitrates and nitrites on the microbiological safety of meat products (2), Revision of meat inspection procedures for lambs and goats (2), Antimicrobials to control *Salmonella* in poultry flocks (1), *Campylobacter* in animals and in foodstuffs (1).
- On Animal-by-products: Safety of the application on pastureland of organic fertilisers and soil improvers (0), Safety of biogas and compost treatment standards of animal-by-products (0) and Combustion of tallow in a thermal boiler process for safe disposal of animal-by-products (0).

103. In 2003, the BIOHAZ Panel adopted four opinions at its plenary meeting in November. These opinions were prepared and issued in response to a request from the Directorate-General for Health and Consumer Protection of the European Commission. The subject of these opinions were: 1) Tuberculosis in bovine animals, 2) the interpretation of results of EU surveillance of transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals, culling strategies for TSEs in small ruminants and the TSE-related safety of certain small ruminant products, 3) effects of nitrites/nitrates on the microbiological safety of meat products and 4) the process of High Pressure Hydrolysis Biogas (HPHB) as method for safe disposal of category 1 Animal by-Products (ABP) not intended for human consumption.

***Work Programme 2004***

104. For 2004, the BIOHAZ Panel has planned approximately 8 plenary meetings to consider and respond to an increasing number of requests in addition to the requests already received. The majority of these requests is expected to be forwarded by the Commission and are arranged into the following main areas:

- BSE / TSE issues (12 new questions)
- Food hygiene (15 new questions)
- Animal by-products (5 new questions)

105. Some requests will have a higher priority than others and this will be taken into account in the organisation and prioritisation of the work programme.

**Scientific Panel on contaminants in the food chain (CONTAM)**

106. The Scientific Panel on Contaminants in the food chain (CONTAM) is responsible for contaminants in food and feed, associated areas and undesirable substances such as natural toxicants, mycotoxins and residues of non-authorised substances not covered by another Panel.

***Progress Report***

107. The CONTAM panel is composed of 21 experts and met four times in plenary session at the following dates:

- 21 May; minutes adopted on 7 July
- 7-8 July; minutes adopted on 15 September
- 15-16 September; minutes adopted by written procedure on 17 November
- 25-26 November, minutes adopted by written procedure on 15 December

108. The CONTAM Panel established four Working Groups (WG) on the following subjects: (i) undesirable substances in animal feed - section heavy metals (WG USAF–HM); (ii) undesirable substances in animal feed - section mycotoxins (WG USAF-MT); (iii) organotin compounds (WG ORGTs) and (iv) non-dioxin-like polychlorinated biphenyls (WG NDL-PCBs). These Working Groups met on the following dates:

- WG USAF-HM: 3 October and 15 December
- WG USAF-MT: 13 October and 19 December
- WG ORGTs: 28 October and 17 December
- WG NDL-PCBs: 7 November and 18 December

109. The Panel and its Working Groups devoted a great part of their meetings on the organisation of the work programme, identification of experts for the Working Groups and distribution of tasks. The Panel received twenty-one requests from the Commission in the period August to November 2003, twelve of which were allocated an urgent deadline. In addition, two requests on NDL-PCBs in food and organotin compounds were transferred from the Commission to the Authority. In most cases, the requested work requires an extensive evaluation of available information on exposure and potential health effects and are expected to be completed in 2004/2005 (see Annex III).

***Work Programme 2004***

110. For 2004, the CONTAM Panel has planned to have five plenary meetings to consider and respond to the various requests from the Commission (see Annex III for details). These requests fall within the following sub areas:

- Feed:
  Detailed risk assessments are necessary to enable a review of the provision on the Annex of the new feed Directive 2002/32/EC which came in force on 1 August 2003. Besides 18 requests (received in 2003) at least four more requests related to undesirable substances in animal feed are expected.
- Food:

EU legislation setting maximum levels for mercury (fish and fishery products), lead, and cadmium are in place, but some have been set without a detailed scientific risk assessment. Therefore, requests to these substances are expected (one request for mercury was already received in 2003).
It is likely that the CONTAM panel will be also asked to issue scientific opinions on following topics: brominated flame retards, ochratoxin A, acrylamide and semicarbazide in food.

- Other subjects:
  The CONTAM panel will start its work related to the request on fluorine and boron in mineral water.

Some requests will have a higher priority than others which will have some major impact on the organisation and prioritisation of the work programme.

**Scientific Panel on Animal Health and Animal Welfare (AHAW)**

111. The Scientific Panel on Animal Health and Animal Welfare (AHAW) is responsible to provide scientific opinions on scientific questions related to animal health and animal welfare, with a focus on food producing animals including fish.

***Progress Report***

112. The AHAW Panel is composed of 20 experts and met two times in plenary session at the following dates:

- 21 May 2003: Inaugural Meeting; minutes adopted on 1 October
- 31 September-1 October: minutes adopted on 24 October
- 9 December; minutes in preparation

113. The Panel established 4 Working Groups on the following subjects: transport of animals, stunning methods, castration methods for piglets and microclimate conditions for transport. These Working Groups met on the following dates:

- Working Group on Transport of Animals: 8 September and 7 November
- Working Group on Stunning Methods: 8 October
- Working Group on Microclimate Conditions for Transport: 23 October and 10 November
- Working group on Castration Methods for Pigs: 12 November and 15 December

114. Most of the current tasks are developed and issued in response to requests from the Directorate-General for Health and Consumer Protection of the European Commission. Two requests were transferred from the previous Scientific Committee on Animal Health and Animal Welfare (SCAHAW) of the Commission. Three requests for scientific opinions in the area of animal welfare were received in September and one request related to animal health was received in December. In considering the respective questions, the Panel agreed that it was necessary to take into account an integrated approach of the food chain. Consequently, for some of the questions a modification was proposed in order to cover all aspects of the question: animal health, animal welfare and food safety (if any).

115. Two draft opinions will be submitted for possible adoption at the plenary meeting on 9$^{th}$ December. The subject of these opinions is transport of animals and stunning methods.

***Work Programme 2004***

116. For 2004, the AHAW Panel has planned to have 7 plenary meetings of two consecutive days each to consider and respond to an increasing number of requests. The majority of these requests will be forwarded by the Commission and are arranged into the following main areas (see also Annex III for details):

- Effects on the welfare of the various species during transport. This request was transferred from the previous Scientific Committee on Animal Health and Animal Welfare (SCAHAW).
- Welfare aspects of the main systems of stunning and killing the main commercial species of animals. This request was transferred from the previous Scientific Committee on Animal Health and Animal Welfare (SCAHAW).
- Welfare aspects of the castration of piglets.
- Welfare aspects of various systems of rearing laying hens.
- Standards for the microclimate inside animal transport road vehicles.
- Scientific review of new tools for eradication for 11 diseases on the OIE list A and some B diseases. Diseases considered to be reviewed were Classical Swine Fever, Foot and mouth Disease, Avian Influenza, Blue Tongue, Infectious Salmon Anaemia, Rabies, Rift Valley fever, African Horse sickness and from the B list Tuberculosis and Brucellosis.

117. Some requests will have a higher priority than others (because of regulatory deadlines) which had some major impacts on the organisation and prioritisation of the work programme.

**ASSESSING THE RISKS AND MAXIMUM RESIDUE LEVELS OF EXISTING AND NEW PESTICIDES AND THE MONITORING OF SPECIFIC RISK FACTORS AND DISEASES**

### Pesticide Risk Assessment Peer Review (PRAPeR)

118. With Commission Regulation (EC) No 1490/2002, amending Commission Regulation (EC) No 451/2000, the Authority was assigned the task of organising the peer review of the initial assessment by the rapporteur Member States for active substances of the second and third stages of the work programme.

119. Additionally, the Authority has the responsibility of assessing the reports on completeness of dossiers for 79 active substances of the third stage provided by the respective rapporteur Member States and to report to the European Commission as required by Art. 9 (1) of Regulation (EC) No 1490/2002. Furthermore, based on a bilateral agreement between the Authority and the European Commission, the Authority is responsible for peer reviewing the draft assessment reports for 16 new active substances, for which the completion of dossiers has been concluded after 1 July 2002. This bilateral agreement was reached to transfer responsibilities of risk assessment to the Authority.

120. To fulfil the legal requirements and deadlines for peer reviewing draft assessment reports given in Community legislation, the Authority's PRAPeR section is planning to organize a public and Member States consultation of draft assessment reports for about 50 active substances and is holding 4 rounds of each of the 5 expert meetings in 2004. Besides the involvement of the 15 EU-MS, participation and incorporation of experts of the 10 acceding countries in the peer review has to be accomplished. Based on the submission dates of the reports, the Authority's conclusion on the risk assessment has to be finalized for 36 active substances in 2004 and for 16 active substances in 2005.

### Maximum Residues Levels of pesticides (MRL)

121. A new regulation of the EU Parliament and of the Council regarding the harmonisation of legislation on Maximum Residues Levels (MRLs) and the definition of the Authority's role in setting MRLs is foreseen to be adopted in 2004 and to enter into force on 1 January 2005. As already indicated from the proposal presented to Council and Parliament, a tremendous amount of work will be transferred to the Authority. The Authority will become responsible for the provision of an opinion on the safety of each MRL within extremely short deadlines as well as for reporting of monitoring data and for maintaining databases.

The Commission could request in 2004 a technical assistance in that area.

### Geographical BSE Risk and BSE/TSE testing

122. The Commission has requested the Authority for advice on the risk assessment for the appearance of BSE in a number of countries specified below and in the following order of priority:

- Canada (review of he current GBR II classification after its first BSE case)
- GBR I countries with major export to the EU: Botswana, Namibia, Swaziland, Australia and Norway;
- Other GBR I countries: El Salvador, Nicaragua and Panama which export to the European Union to a more limited extent;
- Sweden;

- Major trading partners in GBR II: USA and Mexico
- TSE Testing – validation of diagnostic tests including Live Animal tests

***Progress Report***

123. Following the publication (in the O.J. 15 of 22 January 2003) of an open call for the expression of an interest to participate in a program for the evaluation of tests for the diagnosis of TSEs in ruminants, around 20 proposals for new tests have been received. These include new post mortem and live animal tests. The Commission has requested the Authority to organise the evaluation and validation process of these submitted test for TSE diagnosis in ruminants, including Live Animal tests.

In May, a group of experts and a work plan was established. In the period June-October, the expert group met three times. Since then, the following milestones were achieved: 1) a first selection of tests was forwarded to the Institute for Reference Methods and Measurements (IRMM) of the Commission's Joint Research Centre for further organisation of the laboratory and field trial evaluations (BSE PM tests and scrapie tests); 2) the design of a Live Animal Test field evaluation Protocol was initiated, discussed and adopted by the expert group; and 3) a Scientific Support Unit was created within EFSA; 4) a Temporary Agent was recruited to coordinate the work of this unit, and 5) a laboratory evaluation was started under the supervision of the IRMM.

**Monitoring of zoonoses and zoonotic agents and new regulation on the control of salmonella and other specific food-borne zoonotic agents**

124. In May 2004 the New Directive on the monitoring of zoonoses and zoonotic agents amending Council Decision 90/424/EEC repealing the Council Directive 92/117/EEC (adopted 29.9.2003) and the new Regulation of the European Parliament and of the Council on the control of salmonella and other specific food-borne zoonotic agents (adopted 29.9.2003) will be in place. The Commission is expected to deal with incurring activities until the end of 2004.

125. In March 2004 a call for tenders will be launched to outsource the compilation and publication of the annual European report on Trends and sources of zoonoses in Europe for 2004 to be carried out in 2005 including the new Member States.

126. In 2004 a Task Force will be organised to produce reports on the following objectives:

- To set up priorities for harmonisation of monitoring schemes
- To develop harmonised monitoring schemes for the most important zoonotic agents
- To define the minimum data set to be collected on human disease

To decide on the procedures to prepare a zoonoses report

**APPLICATION AND PROMOTION OF NEW AND HARMONISED SCIENTIFIC APPROACHES FOR HAZARD AND RISK ASSESSMENT METHODOLOGIES**

**Scientific Expert Services**

***Progress Report***

127. In 2003 the scientific activities of the Authority were focused fully on the development of opinions in response to formal questions and other scientific issues as included in the work

plans of the eight Expert Panels and the Scientific Committee. In addition, initial scoping discussions were initiated at the Authority on the development and details of a structure for additional scientific expert services.

***Work Programme Proposal for 2004***

128. In addition to the proposal for staff enforcement necessary to maintain an adequate level of administrative and management support for the steadily increasing number of Working Groups and for the scientific co-ordination of the eight Expert Panels and the Scientific Committee, a substantial expansion is proposed of scientific staff not assigned to any of the Expert Panels or the Scientific Committee.

129. This additional expansion is considered essential in order to provide scientific assistance to the members of the Expert Panels and Scientific Committee so that they may be able to cope with the increasing number of technical and fundamental questions and provide responses and opinions in a timely manner.

130. Furthermore, the additional scientific resources are essential for the Authority to establish itself in a leading position on the forefront of scientific development and application of new hazard and risk assessment methodologies and techniques in food and feed safety evaluations and to ensure an adequate pro-active regulatory approach. .

131. It is proposed to establish in 2004 a Scientific Expert Service Department comprising a number of Science Units with recognised expertise in scientific areas such as:

- Data collection, including the maintenance and improvement of existing databases (e.g. acrylamide / dioxins / furans / PCB's)
- Environmental effects assessment, including chemical fate and behaviour in the environment and ecotoxicity and covering the aquatic, terrestrial and aerial environment;
- Toxicology, including endocrine disruption, (non-genotoxic) carcinogenesis, developmental neurotoxicity and functional/behavioural effect assessments;
- Replacement, refinement and reduction of experimental animals in hazard characterisation studies, including the development of conceptual frame works and testing strategies in which animal and non-animal methods are optimally used;
- Emerging new tools and techniques in hazard characterisation and risk assessment, including genomics, proteomics and toxicogenomics once emerged and developed as practicably applicable tools for biological model building, nanotechnologies would be considered as well;
- Risk assessment models, including probabilistic approaches, (quantitative) structure analysis relationships and integrated risk assessment approaches;
- Epidemiology and exposure assessment models including pollutant release and transfer models and models for identifying emerging risks
- Analytical chemistry, and other advanced methodology for the detection of substances;
- Statistical analysis and data interpretation procedures.

132. These Science Units will:

i. assist, and closely co-operate with, the Scientific Committee on new emerging issues, not necessarily related to questions addressed by any of the Panels;
ii. assist the Scientific Panels with the interpretation and assessment of contentious and technically complicated issues, related to the development of opinions on formal questions ;

iii. upon request, provide background review documents, literature surveys, initial assessments and other support documents that would allow the National Expert members of the Panels and Scientific Committee to proceed more quickly and efficiently with the development of opinions on formal questions;

iv. closely monitoring relevant activities in other (inter)national bodies and organisations such as national food safety authorities in the EU and elsewhere; the Commission's Scientific Committees on Non-Food Products; European sister Authorities/Agencies including the European Environment Agency (EEA), the European Chemicals Bureau (ECB) and the European Agency for the Assessment of Medicinal Products (EMEA); and international organisations including FAO, OECD and WHO; and

v. invest in fore-front science through expert networking, active participation in scientific projects, conferences and project meetings in Member States, and organising scientific workshops on emerging issues. Projects and issues that are high on the priority list include: (i) the search for links between human toxicity and exposure to food and food-borne substances, (ii) the effect of simultaneous exposure to a variety of substances via food, (iii) obesity, and (iv) identification of major microbiological risks and harmonisation of their detection methods.

**Scientific Expert and Knowledge Exchange and Networking**

***Progress Report***

133. The establishment of informal expert networks has begun in 2003 but time did not allow the development of a harmonised data base of national experts, searchable by scientific discipline and affiliation.

***Work Programme 2004***

134. It is proposed to establish a formal network of national food safety authorities and national expert centres affiliated with national food safety authorities. This network would include contact details of both managers and technical experts, grouped according to categories of scientific disciplines. The latter would be subject to agreement by all national authorities. Network details would be fully transparent and shared with all individuals included in the network. This expert network would form a 'European food science pool' available and accessible to all national food authorities and the Authority. Third country national authorities and agencies and the relevant international organisation would be linked into the networks as appropriate.

135. The network would be a most efficient tool for the identification of the most relevant national experts in the case of an emerging food crisis. In addition, the network would facilitate bridging national or regional differences of opinion or approach. It would further provide a source of information on national activities, priorities and concerns.

136. In addition to the establishment of the network as an information source and easy personal contact tool, it is proposed to start a programme of expert exchange and secondment. The co-ordinated exchange of national experts amongst national authorities and the secondment of national experts to the Authority would be a very efficient way of improving the cross-boundary, cross-cultural and cross-social understanding of food safety issues.

137. It is therefore proposed that the Authority should co-ordinate the rotational exchange of national experts in such a way that for all participating national institutes and authorities each outgoing secondment is compensated by an incoming secondment and thus be cost-neutral.

The co-ordination should also include the effort to involve the national authorities in all member states in a balanced way.

138. In addition to the exchange of experts among Member States, the co-ordination should also include the secondment of national experts to the Authority. This would not only guarantee a close contact of the respective national authority with the Authority but also provide an insight in the process of consensus building by Expert Panels and the Scientific Committee and in the management and co-ordination of food safety issues.

## D. Communication Activities

139. Along with the scientific programme of the Authority, Communications will be a key area of growth for the Authority during 2004. The overall mission of the Authority is to make a significant contribution towards improving food safety in Europe. The Authority will play a major part in rebuilding consumer confidence in food safety both through the quality of its scientific opinions as well as through effective, consistent and accurate communications. The 2004 communications plan will therefore concentrate on building the Authority's reputation as an expert and trusted source of information on food safety issues among its stakeholders and the public at large.

140. This will require a fully staffed communications function with an appropriate organisational structure. There will therefore be a need to recruit highly qualified communications professionals in order to develop and implement the Authority's communications strategy. Significant resources will be required in this area in 2004.

141. **Work Programme -** ***Overall communication strategy***

**Purpose:** Rebuild consumer confidence in food safety evaluation through appropriate, consistent and accurate communications on food safety issues based on the Authority's risk assessments and scientific expertise.

**Overall objectives:**

- Establish the Authority as an expert and trusted source of information on food and food safety issues amongst its stakeholders and the public at large.
- Build and promote the Authority's reputation as an organisation dedicated to scientific excellence, openness and transparency.
- Ensure that messages are relevant, understandable and address food safety concerns.
- Enhance/improve the coherence of information on food safety matters across the Community.

**Strategies:**

- Translate scientific evidence into accessible and meaningful communications addressing the specific needs of key audiences.
- Develop and implement communications processes that illustrate and exemplify a culture of openness including:
  - involvement of stakeholders in the risk communications process
  - collaboration with contact points in Member States.
- Ensure effective organisational structure and resources to deliver agreed goals.
- Implement objective measurement tools in order to evaluate public perception and inform programme development.

**2004 Initiatives**

142. 2004 will be a critical year as the Authority, having established itself as an independent organisation, builds capacity in its areas of competence. The Authority's

success will depend not only on its scientific excellence but importantly, on its ability to communicate effectively to the public on food safety matters. The 2004 communications programme must therefore establish the Authority as a predominant and authoritative voice on food safety issues in the EU while demonstrating principles of openness and transparency. The establishment of the Advisory Forum's Communications Working Group will also enhance collaboration with Member States with regards to risk communications in order to ensure the coherence of food safety messages across the European Community.

143. In order to establish the Authority as a true flagship for food safety in Europe, it will be important to further develop and agree its mission, identity and desired image. The purpose of this work will be to ensure that as the Authority expands both in size and in the scope of its activities, it remains focused on and aligned with the objectives and identity outlined in the founding Regulation. Considerations should be given to the Authority's operating principles, capabilities, processes and values so that their development remains true to the original intent and identity set out in the Regulation and as agreed with the Management Board. A benchmarking exercise should be undertaken and measurement tools determined in order to monitor and adjust the Authority's performance both internally and externally and progress towards the desired image.

144. Based on the above, a clear communications strategy will be developed and implemented in order to support the Authority's overall goals. The communications strategy will be fully integrated with risk assessment activities and take into account consumer and key stakeholder requirements. The communications strategy will articulate: who says what; via which channels; to which targets; in order to meet which defined and measurable objectives.

145. As a foundation for this strategy, it is recommended to assess the views of consumers and key target audiences on food safety issues as well as the perception of the Authority's role in addressing such issues. An audit will be conducted among key stakeholders as well as media in order to evaluate both their perception of and expectations for the Authority. An analysis of consumer concerns regarding food safety issues will also be undertaken on the basis of existing research. In this regard, the feasibility of conducting a pan-European consumer survey to identify and track consumer concerns over time will be assessed. If it is decided to go ahead such an initiative would be undertaken in collaboration with Member States. Such an "EU Food Safety Barometer" would provide invaluable input to the Authority's work in the areas of risk assessment and communications. It would also clearly position the Authority as an organisation dedicated to understanding and addressing public concerns related to food and food safety.

146. Further development of the Authority's logo will be undertaken to ensure that it effectively conveys the Authority's corporate identity, core values and desired image. In doing so, consideration should be given as to how the logo and corporate identity could be further developed in order to make the Authority more real and accessible to the people of Europe. The logo will be applied across all of the Authority's communications materials, both on- and off-line, as well as on all internal communications.

147. Fundamental to achieving the Authority's communications goals in 2004 will be the establishment and implementation of an appropriate organisational structure and the need to meet staffing requirements of the Authority's Communications Department. Following on from the recruitment of the Communications Director, a team of highly qualified communications professionals will need to be constituted in order to effectively meet the specific areas of expertise required. In doing so, care will be taken to ensure an appropriate linguistic balance key to building relations with media and stakeholders across the EU. Consideration will also be given to the externalisation of certain competencies and/or

services where appropriate. The services of outside contractors will be secured as and where required.

148. The Communications team will develop appropriate tools, processes and systems to meet the Authority's desired goals, including such initiatives as:

- An up-to-date network/database of media contacts (EU, national), off- and on-line. This database should also include key stakeholders and multipliers involved in the dissemination of scientific information produced by the Authority.
- Media monitoring on key themes of interest to the Authority's work programme as well as on the role of the Authority itself.
- A media tool kit including basic information and visuals to support press communications such as: fact sheets, and background documents on the Authority (mission, organisation, key subject areas…); biographies and photos for the Authority's staff and scientific panels; and a photo library including stock shots and film footage on the Authority, food, and food safety issues that could be utilised by the media in describing the aim and mission of the Authority as well as illustrating the Authority's communications.
- Press releases and briefing documents for the media.
- Communications of risk assessment: in collaboration with the Authority's Scientific Staff, further develop and agree the objectives, role and format for communications of risk assessments (e.g. scientific opinions, scientific advice, opinion summaries…).
- Internal position statements and 'Question and Answers' to be utilised by the Authority's staff and spokespeople.
- Publications, including such initiatives as: a "Corporate" brochure outlining the Authority's mission, organisation and work programme will be developed; the Authority's 2003 Annual Report; a monthly newsletter issued to media and multipliers, including national stakeholders.

149. The Authority's web site will be further developed in 2004 in order to ensure that it is authoritative and user friendly, containing all of the necessary and relevant information appropriate for each target audience.

150. Early in 2004, the Authority will have a new web site that will transform the current structure into a real communications tool, supporting the Authority's strategies and plans, and addressing the needs of its stakeholders and public at large. The web site will evolve significantly both in terms of content and technical capacity. The architecture is based on an exhaustive categorisation of needs (carried out within the Authority) including interactive regions to meet consultation requirements. It also addresses the need for a register of documents and a register of the requests for scientific advice submitted to the Authority.

151. The new website will be housed on the new web server giving the Authority true independence. As part of the overall restructure of the information technology used by the Authority, other elements have been developed to synchronise with and add depth to the new website. For example, the web site's search engine will be capable of accessing documents which have been authorised for publication from the Authority's IT systems.

152. A comprehensive testing programme will be carried out on all key elements of the new web site and server before release. In addition, all current elements of the old web site will be transferred to the new, updating where necessary.

**Work Programme - Web in 2004**

153. Work will begin immediately in 2004 to update and further refine all of the new elements of the web including:

- The search engine
- The register of documents
- The register of scientific questions
- Notifications and submissions
- Consultation in general
- Archiving
- Synchronisation between the web site and other IT systems

154. The Authority's web site will also be further developed in order to address the need for interactivity with stakeholder groups. Together with IT, the Communications team will evaluate the feasibility of establishing a closed extranet to facilitate consultation and communications with stakeholders.

155. The new web site will also allow the development of new communications tools to update the public and key stakeholders on the Authority's activities. These include:

- Email notification of "What's new at the Authority"
- Publication of a monthly newsletter on the Authority's activities through online publishing.

156. In 2004, the Authority will continue to strengthen its communications with key stakeholders and media through such events as seminars and briefing meetings for journalists to present the Authority, the Authority's staff, and work programme and the active communications on key matters with stakeholders.

157. A media training programme will be pursued in order to provide a team of receptive and expert spokespeople to respond to any queries relating to the Authority. This will include the training of the Chairs of the Authority's Scientific Panels as well as additional training for the Authority's own Communications and Science Departments, as required.

158. The Communications Department will contribute to the development of a crisis preparedness plan in order to ensure appropriate systems are in place for effective communications in time of crisis. While it is the European Commission that co-ordinates crisis communications, the Authority must ensure that its own systems allow quick and accurate communications, with the greatest efficiency possible, in order to reassure the public and regain public confidence as soon as possible.

159 **Overall Communications Indicators:**

- Development of a communications strategy and plan
- Development of measurement tools to benchmark and evaluate the Authority's communications activities. These will include tools such as:
  - Stakeholder and media perception audits (e.g. media focus groups)
  - Media monitoring and analysis of coverage regarding the Authority's public relations initiatives
  - Analysis/surveys of consumer views regarding food safety issues and the Authority/national food authorities
  - Evaluation of web site traffic and consultation (number of contacts, pages consulted etc…)

- Interaction with media: number of contacts; proportion of targeted media covered; geographical spread; analysis of media coverage generated (quality and quantity); implementation of media guidelines and training of spokespeople etc…

- Implementation of new communications tools: web site and publications
- Establishment of effective organisational structure for Communications
- Stakeholder feedback

## E Advisory Forum

160. During 2004 the work of the Advisory Forum will continue to play an important part in the development of close links between the Authority and the Member States including the 10 new Accession countries. This vital component of the Authority is essential to the building of collaboration and co-operation with the national food agencies and authorities working on risk assessment and communication activities.

161. The Forum will continue through a series of meetings to encourage information exchanges and discussion on key food safety matters within the remit of the Authority.
The Forum work started in 2003 on the risk communication will continue through a working group established under the leadership of the Authority. This will enable the Authority to identify how to develop collaboration and partnership with national and other agencies and facilitate communication during crisis and non-crisis periods.

162. Another objective during 2004 will be to continue to build on the links developed during 2003 to establish strong collaborative networking with national agencies and administrations in the Member States as a mechanism for exchanging information on potential risks and for pooling knowledge. Wider arrangements will be introduced to enable the Forum to link with relevant institutions in the EU. Consideration of the practical aspects of connecting the agencies through information technology links will commence in 2004 so as to provide effective tools for such networking to flourish. In addition to the open publication of the agendas of the Forum and the minutes of its meetings on the web the work of the Forum will be made more widely known during 2004. Towards the end of 2004 the Forum will hold a public meeting at which it will present its work and encourage open discussion.

**Work Programme**
**Purpose**
163. In line with the requirements of the Regulation, the Advisory Forum, convened by the Executive Director, is to build close collaboration between the Authority and the national agencies and administrations in the Member States dealing with the same matters as the Authority.

**Objectives**

- To ensure that the work of the Advisory Forum leads to close collaboration between the Authority and the Member states food agencies and authorities with a similar remit to the Authority
- To ensure that the Forum and its working groups meet and build collaborative networks
- To ensure that information is exchanged concerning food safety matters in a timely and open manner

**Indicators**

- The practical aspects of networking the Member States' national agencies and authorities will have been identified and plans put in place to build this
- Communications and IT working groups will have delivered their initial reports and some actions will already have been initiated in these groups
- The work of the Advisory Forum has been publicised

**2004 Initiatives**
164. During 2004 the Advisory Forum will build on its 2003 programme and seek to develop close collaboration between the Authority and the national agencies through a series of meetings and other initiatives related to the establishment of a network with the Authority. The work of the Advisory Forum will continue to be made publicly accessible by placing the agendas, minutes and relevant papers considered by the Forum on the Authority's website

prior to its meetings. In addition the Forum will hold a seminar at the end of 2004 at which it will publicise its work.

165. Two working Groups have been established under the umbrella of the Advisory Forum and are both due to report back regularly to the Forum during 2004 with a formal interim report at the end of 2004.

166. Communications Working Group

Objective: to build collaboration between communications contacts points in the Member States' national food agencies and administrations in order to enhance the coherence of food safety messages across the Community.

The group will consider among others:

- How communications networks between the Commission, the Authority and the Member States can be improved.
- How the experience of working group members in risk communications can best be utilised and leveraged (e.g. review and evaluation of case studies; sharing of best practices etc)
- How public risk perception on food safety could be evaluated and monitored
- The types of communications activities that can be built as a priority for non-crisis situations. The types of mechanisms that can be foreseen for crisis situations
- Are there any practical, political, cultural or other barriers that can be identified and how could these be overcome in order to build greater coherence

167. Information Technology Working Group

Objective: To identify the feasibility of building Information Technology infrastructure tools to enable members to collaborate actively, share information, cross-reference scientific advice or any other type of documents.

The Group will consider among others:

- The assessment of the development of links between websites of the member organisations of the Advisory Forum including developing an agreed short text describing the Member State entity which will be linked to the Authority's website.

- To develop a collaborative tool for Advisory Forum document sharing

- The construction of technical collaboration between the various technical layers of the Advisory Forum organisations and the Authority in order to build a common repository in which scientific and technical information is organised, potentially in a multilingual way, and accessible to each Forum member and the Authority.

- The technical requirements for such collaboration and the identification of the necessary funding

168. In addition, the Advisory Forum will develop ways to make its work more publicly known. During 2003 the Forum agreed to put together ideas for an 'event' in 2004 and to form a Task Force to plan this.

169. The 'event' will be held during November or December 2004. The flavour of the 'event' will be mainly scientific but will also look at the work of the Forum in a broader context. The exact nature of the 'event' and its programme will be agreed by the Forum's members themselves during 2003. The task force will meet during 2004 to develop the plans for this event. The objective is to ensure that the members of the Forum are actively involved in the event itself.

## F Crisis and Emerging Risk Situations

### The Authority's work in relation to a crisis

170. The Authority will play a major role if a food safety crisis were to arise in Europe. During 2003 the Authority put in place simple procedures in order to be able to identify and react should a crisis situation occur. These will be further developed during 2004. The Authority will put in place the nucleus of a permanent Crisis Team which will be well-prepared to take immediate action should a crisis be identified.

171. The Authority's Advisory Forum, its Scientific Panels and the Scientific Committee as well as its staff will all have a role to play with the authority should a crisis arise and depending on the nature of the crisis. The Authority's in-house plan ensures that their essential input is sought on urgent, new or emerging issues in a co-ordinated and available to the Authority without delay. The Authority will also monitor and, if necessary, contribute to the Rapid Alert system.

172. **Work Programme**

**Purpose:**

- To assist the Commission by the provision of scientific and technical support during a crisis
- To anticipate and advise on the identification of a potential crisis.

**Objectives:**

- To ensure that in the time of a food or feed safety crisis that adequate timely and excellent scientific and technical information is available to the risk managers as well as appropriate public information,
- To put in place sufficient resources and systems to enable the Authority to anticipate and advise on the identification of a potential crisis
- To provide adequate co-ordination of scientific and communications activities in a crisis
- To keep stakeholders, Member States, stakeholders, partner organisations informed of the developing matters during a crisis

**Indicators:**

- The Authority is able to provide the necessary support in a food safety crisis
- The Authority's Crisis team functioning effectively should a crisis be identified or in the management of a potential crisis
- Members States, the Commission and key stakeholders are kept fully informed as the crisis develops

**2004 Initiatives**

173. In this respect the Authority will develop further in 2004 in-house procedures for the practical procedures in times of crisis, including the putting in place of a nucleus of a crisis team with specific crisis co-ordination responsibilities. Standard procedures, for example in relation to out of office hours emergency call out cover for the Authority, emergency budgetary, translation and communications procedures will be enhanced during 2004. In addition through the Advisory Forum links and the formation of scientific networks, the Authority will be able to draw upon experts from across the European Union in order to address scientific aspects of a crisis.

***Identifying and evaluating emerging risks (including the Rapid Alert System for Food and Feed)***

174. The founding Regulation requires the Authority to establish monitoring procedures for systematically searching for, collecting, collating and analysing information and data with a view to the identification of emerging risks in the fields within its mission. Consequently the Authority needs to have access to up-to-date information on not only emerging risks, but also on emerging hazards as a means of providing early warnings on potential risks.

175. **Work Programme**
**Purpose:** Under Regulation 178/2002/EC, and in particular Article 34 thereof, the Authority through its collection of data and other networks shall monitor information with the explicit purpose of identifying emerging risks

**Objectives:**
- To ensure that emerging concerns are tracked and emerging risks to health are identified and brought to the attention of the Authority so that it may act according to the matter at hand,
- To build emerging risk identification capability and capacity during 2004
- To provide scientific and technical support to the Rapid Alert System for Food and Feed

**Indicators:**
- Information sources have been identified
- Provisional emerging risk capability in place with further developmental work planned
- Studies and third party involvement initiated to build this area

**Initiative for 2004**
176. The Scientific Committee will be looking at this matter in detail to identify a network of key persons (e.g. networks, university groups, research institutes, national food authorities, industry associations) to support the Authority in the identification of emerging risks. This will lead to the development and implementation of a strategy for this during 2004. In addition the Authority's Advisory Forum, its Scientific Panels and Committee, will continue to be asked to give their input on emerging issues so as to give the Authority an early warning of matters of concern. The Authority will continue to track emerging problems through its membership of the Rapid Alert system. The building of scientific networks through the Advisory Forum and other mechanisms will also enhance the Authority's capability to identify emerging matters.

## G Support activities

177. The main activities in this chapter are to ensure that the Authority has: adequate administrative planning and support; accurate and appropriate financial planning; is able to recruit the appropriate staff within the time-scales needed to ensure the functioning of the key activities; is able to address legal matters that may arise in the establishment and subsequent running of the Authority, the move to Parma, and is able to provide the complex information technology infrastructure that will be vital to the operation of the Authority. These activities are required to be operational throughout the whole of 2004 although there will be some build up within the different activities.

***Human Resources (planning, job descriptions, selection, recruitment, grading, training and development, administration of staff)***

178. **Work Programme**

**Purpose:**

- Providing HR services to staff within the Authority
- Proposing and delivering effective answers to staff needs in line with HR planning.

**Objectives:**

- to manage from the human resources point of view during 2004 the move to Parma
- to undertake a substantial recruitment drive in 2004.
- To oversee the management and implementation of rights and obligations in accordance with the staff regulations (CEOS/RAA),
- To ensure that the requirement set in the work programmes translate into job descriptions and an establishment plan for 2005.
- To manage the budget for HR activities.
- To identify training needs of all staff members, record, prioritise, organise and evaluate
- To ensure proper and equitable application of the Staff Regulations Commission policies and procedures in the Authority
- To arrange induction for all new staff joining the Authority.
- To inform staff and management on HR issues and particularly on the Reform applied to the Staff Regulations of the Commission.

**Indicators:**

- Development of an establishment plan for 2005
- Recruitment of adequate staff in predetermined phases
- Having an IT tool to support the Personnel administration
- Establishment of reserve lists
- Documented job descriptions

**Initiatives for 2004**

179. The main initiatives in this area in 2004 will be to progress with recruitment process to provide adequate staff to deliver the priorities of the management plan, to develop the basis of a career development plan and a portfolio of training courses adapted to groups of staff members. There will be a need to recruit further into the human resources department itself in order for the move to Parma and any subsequent issues to be handled adequately.

.***Information Technology***

**Work Programme**

**Purpose:**

180. Ensuring a secure, efficient and integrated IT environment to streamline the operational requirements of the Authority and its staff (integrated information systems including content management solutions and electronic workflows supported by a solid and dynamic infrastructure) so that the Authority can work using appropriate Information Technology solutions internally and in connection with its stakeholders and the public.

**Objectives:**

- to ensure from an It point of view that the Authority is prepared to the fullest extent possible for the move to Parma
- Review regularly the IT strategy of the Authority, in the light of the evolution of the needs of the Authority and the evolution of the technology.
- Manage all the IT projects for all aspects of the Authority's work.
- Maintain a sound expertise in IT architecture.
- Ensure cost-effectiveness in the supply and the use of the Information Technology solutions
- Build plans for an effective and efficient interchange of content between the Authority and the national food authorities and agencies
- Develop further the IT infrastructure to cope the growth in number of staff according to the building configuration
- Ensure an appropriate infrastructure for the web

**Indicators:**

- Improvement of the efficiency of the internal and external functioning of the Authority.
- Development and implementation of projects according to project plan and budget
- Development and implementation of the IT infrastructure elements (hardware and software)
- Level of service of the Help Desk and support

**Initiatives in 2004**

181. The main initiatives in this area in 2004 will be to further develop the ability of the Authority to handle and follow complex documents and process, to develop further the IT infrastructure to cope with the growth in numbers. In addition the Information Technology Working Group of the Advisory Forum, chaired by the Authority's Head of Information Technology, will meet during 2004 to identify the practical infrastructure needed to enable information exchange networks to be developed between the Authority and the food agencies in the Member States.

***Finance***

182. **Work Programme**

**Purpose:**

- Ensuring sound financial management in budget planning and implementation

**Objectives:**

- To provide expertise in finance and ensure cost-effectiveness, efficiency and value for money

- To build during 2004 management tools which allow adequate management of the funds and resources employed
- To train staff in financial and related matters

**Indicators:**

- Annual and multi-annual planning
- Setting the appropriate financial control standards throughout the organisation
- Having audited systems to manage a budget and accounts
- Payment delays

**Buildings, logistics and reception**

183. **Work Programme**

**Purpose:**

- Ensuring a systematic and manageable approach in providing and maintaining the necessary services in terms of buildings, logistics and reception.

**Objectives:**

- to provide sufficient support for the move to Parma
- To provide adequate facilities and supplies
- To provide adequate support in relation to buildings, and facilities during 2004 and beyond

**Indicators:**

- Provision of adequate supplies, space and facilities for meetings and offices

**Documentation Management/Archiving/Library**

184. **Work Programme**

**Purpose:**

- Ensuring a systematic and coherent approach in dealing with documents (including information, dossiers for evaluation and data other scientific information), and in archiving the appropriate documents.
- To provide library facilities to support the scientific work and other Authority activities

**Objectives:**

- To collect, archive, secure and make accessible the data, and any other information produced by the Authority or submitted to the Authority and any relevant information produced by key stakeholders.

**Indicators:**

- Efficient document management system
- Library facilities available to all staff with access to relevant data bases and other scientific information

**Annex I**

| Indicative ESTABLISHMENT PLAN FOR 2004 | | | | |
|---|---|---|---|---|
| Category and Grade | Authorised for 2003 | | Authorised for 2004[11] | |
| | Perm | Temp | Perm | Temp |
| A1 | | | | |
| A2 | | 1 | | 1 |
| A3 | | 4 | | 4 |
| A4 | | 6 | | 6 |
| A5 | | 12 | 1 | 22 |
| A6 | | | | 3 |
| A7 | | 13 | 1 | 28 |
| A8 | | | | |
| Total A | | 36 | 2 | 64 |
| B1 | | | | |
| B2 | | | | |
| B3 | | 5 | 1 | 7 |
| B4 | | | | |
| B5 | | 8 | | 14 |
| Total B | | 13 | 1 | 21 |
| C1 | | | | |
| C2 | | | | |
| C3 | | | 1 | 16 |
| C4 | | | | |
| C5 | | | | 30 |
| Total C | | | | 46 |
| D1 | | | | |
| D2 | | | | 3 |
| D3 | | | | |
| D4 | | | | |
| Total D | | | | 33 |
| Total Posts | | 49 | 4 | 134[12] |

[11] The figures for 2004 include those already authorised for 2003

[12] The total figure only includes staff who have permanent status or the status of a Temporary Agent. It does not include Detached National Experts, other seconded visiting experts, auxiliary or interim staff or consultants

**Annex II**

## COMPENDIUM OF PROPOSED OR DRAFT LEGISLATIVE PROPOSALS AND OTHER EU INITIATIVES IMPACTING ON THE AUTHORITY

This compendium presents EU legislation and other initiatives that will directly or indirectly have an impact on the future workload of the Authority. Details about changes that will have an impact in 2004 are spelled out in detail in the relevant sections of this Management Plan.

### 1. Legislation recently adopted

*Legislation recently published*

- Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1)

- Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p.24)

- Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (OJ L 287, 5.11.2003, p.1)

- Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (OJ L 268, 18.10.2003, p. 29)

- Directive (EC) No 2003/74 of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists (OJ L 262, 14.10.2003)

- Directive (EC) 2003/50 of the European Parliament and of the Council of 11 June 2003 amending Directive 91/68/EEC as regards reinforcement of controls on movements of ovine and caprine animals (OJ L 169, 8.7.2003)

- Directive (EC) 2003/52 of the European Parliament and of the Council of 18 June 2003 amending Directive 95/2/EC as regards the conditions of use for a food additive E 425 konjac, (OJ L 178, 17/7/2003)

- Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC (OJ L 146, 13.6.2003)

- Regulation (EC) No 1642/2003 of the European Parliament and of the Council of 22 July 2003 amending Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 245, 29.9.2003). This text deals with the implementation of the reform of the EU Financial Regulation and also with EU requirements for access to documents.

- Directive of the European Parliament and of the Council on monitoring of zoonoses and zoonotic agents (adopted 29.9.2003)

- Regulation of the European Parliament and of the Council on the control of salmonella and other specified food-borne zoonotic agents (adopted 29.9.2003)

- Regulation of the European Parliament and of the Council on the control of salmonella and other specified food-borne zoonotic agents (adopted 29.9.2003)

- Regulation of the European Parliament and of the Council on smoke flavourings used or intended for use in or on foodstuffs (COM 2002 400 final - adopted in Council 10.10.2003. Will be applicable 18 months after publication)

- Directive of the European Parliament and of the Council amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs (EP 2nd reading 2 July 2003, Commission opinion on the 2nd reading COM (2003) 466)

**2. Commission proposals undergoing legislative process**

- Proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods (COM (2003) 424 final, COD 2003/0165, adopted by the Commission on 16 July 2003; legal basis article 251, sent to EP, awaiting 1st reading, PE - Forthcoming adoption by parliamentary committee:16/03/2004, PE - Probable part-session by the DGI:29/03/2004, PE - Probable part-session: DGII coordination:29/03/2004 Rapporteur Mauro Nobilia (ENVI) shadow Piia-Noora Kauppi, Legal Affairs

- Proposal for a Regulation of the European Parliament and of the Council laying down requirements for food hygiene Amended proposal for a Directive of the European Parliament and of the Council repealing certain Directives on the hygiene of foodstuffs and the health conditions for the production and placing on the market of certain products of animal origin intended for human consumption, and amending Directives 89/662/EEC and 91/67/EEC (legal basis article 250(2)/COM/2003/0455 final - COD 2000/0182). This is the only remaining part of the original Food Hygiene proposal which contained 4 proposals for Regulations and 1 proposal for a Directive. Awaiting a common position from Council. Rapporteur Horst Schnellhardt, shadows Pat Gallagher (FISH) Danielle Auroi (AGRI) as well as Caroline Lucas (INDUSTRY)

- Proposal for a Regulation of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption (1st reading vote in EP 5 June 2003, PE - Probable part-session by the DGI: 09/02/2004, Rapporteur Horst Schnellhardt, shadows Danielle Auroi (AGRI) and Ian Stewart Hudghton (FISH).

- Proposal for a directive of the European Parliament and of the Council amending Directive 95/2/EC on food additives other than colours and sweeteners COM/2002/0662 final - COD 2002/0274 - awaiting common position
- Proposal for a Regulation of the European Parliament and of the Council on official feed and food control COM/2003/0052 final - COD 2003/0030, PE - Forthcoming adoption by parliamentary committee:27/11/2003
  PE - Probable part-session: DGII coordination:15/12/2003, PE - Probable part-session by the DGI:12/01/2004 CSL - Council common position

expected:16/12/2003, rapporteur Marit Paulsen (ENVI), shadow Avril Doyle (AGRI)

- Proposal for a Directive of the European Parliament and of the Council amending Directive 94/35/EC on sweeteners for use in foodstuffs, COM/2002/0375 final - COD 2002/0152

- Proposal for a Regulation of the European Parliament and of the Council establishing the European Centre for Disease Prevention and Control (COM (2003) 441), adopted on 8 August 2003.

- Proposal for a Regulation of the European Parliament and of the Council on the setting, monitoring and control of maximum levels of pesticides residues in products of plant and animal origin. COM(2003) 117 final 2003/0052 (COD) PE - Forthcoming adoption by parliamentary committee:27/01/2004, PE - Probable part-session by the DGI:09/02/2004, PE - Probable part-session: DGII coordination:09/02/2004, CSL - Council common position expected:17/11/2003, rapporteur Robert William Sturdy (ENVI), shadow Encarnacion Redondo Jimenez (AGRI)

- Proposal for a European Parliament and Council Regulation on fortified foods, adopted 10.11.2003. This proposal sets out common rules for adding vitamins and minerals to foods.

**3. Other initiatives**

- Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions - Life sciences and biotechnology - A Strategy for Europe/* COM/2002/0027 final */

- Decision No 1513/2002/EC of the European Parliament and of the Council of 27 June 2002 concerning the sixth framework programme of the European Community for research, technological development and demonstration activities, contributing to the creation of the European Research Area and to innovation (2002-2006), OJ L 232, 29.08.2002.

**4. Selection of relevant initiatives presented in the 2004 Commission Work programme**

- Proposal for a Directive amending Directive 90/469/EC on nutrition labelling. Brief description: To amend Directive 90/496/EC with a view to updating it in respect of technical and scientific progress and bring it into line with consumer expectations

- Proposal for a Regulation amending Regulation (EC) No 258/97 on novel foods. Brief description: To update the provisions of the novel food regulation in respect of novel foods other than those derived from GMOs, in the light of the experience gained and as a consequence of the adoption of a new framework for food safety, as laid down in Regulation (EC) No 178/2002.

## Scientific Activities Annex III[13]

[13] An abbreviated overview of the questions received by the Authority is included in Annex IV.

# *Scientific Committee (SC)*

## I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

***Own initiatives***

**Sub-area: Introduction of harmonised approaches in the risk assessment process**

| **EFSA-Q-2003-101** | **Guidelines for preparation of requests** |
|---|---|
| Origin of request | EFSA |
| Date of receipt | July 2003 |
| Date of acceptance | July 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Committee meetings | 1 |
| Expected no. of Working Group meetings | 1 |

*Purpose*
To assist the Authority in the preparation of guidelines for the preparation of requests by the European Parliament and the Member States.

*Objectives/Milestones for 2004*
New guidelines for requests for the Authority scientific opinions to be prepared.

| **EFSA-Q-2003-102** | **Advice on EFSA's crisis management plan** |
|---|---|
| Origin of request | EFSA |
| Date of receipt | July 2003 |
| Date of acceptance | July 2003 |
| Expected date of completion | January 2004 |
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
To provide scientific advice on "what should the Authority do in case of a food or feed crisis".

*Objectives/Milestones for 2004*
Scientific advice to the Authority with views of the Scientific Committee on how the Authority could handle a food or feed crisis.

## II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

***Own initiatives***

**Sub-area: Scientific Co-ordination**

| **EFSA-Q-2003-103** | **Strategies for building EFSA's capability for identifying and evaluating emerging risks** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | March 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Committee meetings | 5 |
| Expected no. of Working Group meetings | 6 |

*Purpose*
To assist the Authority in building the Authority's capability for identification and evaluation of emerging risks

*Objectives/Milestones for 2004*
- Recruitment of a project consultant who will identify a network of key persons (e.g. networks, university groups, research institutes, national food authorities, industry associations) to support the Authority in the identification of emerging risks.
- To develop and implement a strategy for the evaluation of emerging risks.

**Sub-area: Introduction of harmonised approaches in the risk assessment process**

| **EFSA-Q-2003-100** | **General format for scientific opinions** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | January 2004 |
| Potential date of acceptance | January 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
The Scientific Committee advised the Authority on a common format for scientific opinions in August 2003. This general format is currently used by the Scientific Panels and Committee for the preparation of their opinions. At the August plenary, the Committee expressed the wish to reconsider its advise on the general format for opinions in 2004 on the basis of experiences in the Scientific Panels and Committee and to further harmonise the assessment chapter of the Authority's document.

*Objectives/Milestones for 2004*
- To agree on a general format of the assessment chapter of the scientific opinions taking into account the risk assessment procedures commonly used in the various areas covered by the Scientific Panels and Committee.
- To issue an updated version of Authority's document on the general format of opinions.

| **EFSA-Q-2003-107** | **Development and implementation of EFSA strategies and general guidance in the area of exposure assessment** |
|---|---|
| Origin of request | EFSA |

| | |
|---|---|
| Potential date of receipt | January 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 6 |

*Purpose*
To assist the Authority in the development and implementation of strategies and guidelines for the Scientific Panels in the area of exposure assessment.

*Objectives/Milestones for 2004*
- To organise/manage the activities of an EXPOSURE Working Group composed of Panel members and experts from the non-food area for the development and implementation of strategies and guidelines in the area of exposure assessment.
- To create a network of exposure assessment experts (INTAKE Working Group) to assist the Authority in dietary intake assessments in the various areas covered by the Scientific Panels.

**Sub-area: Challenges in the area of risk assessment**

| **EFSA-Q-2003-104** | **Uniform approach for the risk assessment of genotoxic and carcinogenic substances** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | January 2004 |
| Expected date of completion | November 2004 |
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 6 |

*Purpose*
The Scientific Committee created a Working Group to prepare a uniform approach for the risk assessment of genotoxic and carcinogenic substances. This issue was also discussed by an ad-hoc working group of the former SCF, but as there are many potential approaches requiring an in-depth evaluation of their suitability, the SCF concluded that it would need more time to evaluate these approaches and to consult other experts in this field. The Authority accepted the proposal that the Scientific Committee would take this issue on board in the very short term.

*Objectives/Milestones for 2004*
- Opinion of the Scientific Committee on a uniform approach for the risk assessment of genotoxic and carcinogenic substances.

**Sub-area: Specific subjects**

| **EFSA-Q-2003-105** | **Qualified Presumption of Safety** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | January 2004 |
| Expected date of completion | September 2004 |

| | |
|---|---|
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To provide scientific advice on whether or not the Authority should endorse a new approach for the safety assessment of micro-organisms in food/feed and food/feed production (referred to as 'Qualified Presumption of Safety'). A document on this QPS approach was prepared by a joint working group of the former SCAN, SCF and SCP.

*Objectives/Milestones for 2004*
- To reach agreement in the Scientific Committee whether or not this new approach should be further considered by the Scientific Committee.
- If yes, to reach agreement on whether or not the Authority should use this new approach for the safety assessment of micro-organisms in food/feed and food/feed production.

| **EFSA-Q-2003-106** | **'Non-nutritional components' in the EU diet** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | March 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Committee meetings | 3 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
To assess the possible health risks of products, referred to as 'non-nutritional components in the diet, that are consumed by a large portion of the European population and for which there is no legislation established yet.

*Objectives/Milestones for 2004*
- To specify the products concerned.
- To assess the existing legislation in this area.
- To assess the current situation in different Member States.
- To evaluate whether there is a reason for concern, taking into account information provided by national food authorities and information provided by the Commission.

| **EFSA-Q-2003-xx**[14] | **Improving the Interface between Risk Assessment and Risk Management** |
|---|---|
| Origin of request | EFSA |
| Potential date of receipt | March 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Committee meetings | 2 |
| Expected no. of Working Group meetings | 4 |

*Purpose*

[14] Question number not allocated yet

To advise the Authority in the establishment of appropriate procedures for the framing and processing of scientific questions by the Authority.

*Objectives/Milestones for 2004*

- Opinion of the Scientific Committee on options for improvements in the framing and processing of scientific questions by the Authority.

**Other possible issues for future consideration by the Scientific Committee**

Besides the subjects presented above, the Scientific Committee agreed to consider a number of other subjects in the future. The discussion of each of these subjects will be done in agreement with Authority's procedure for 'self-tasking'.

The current list of possible issues for future consideration comprises

- 3 subjects in the sub-area 'introduction of harmonised approaches in the risk assessment process',
- 5 subjects in the sub-area 'scientific co-ordination',
- 5 subjects in the sub-area 'challenges in the area of risk assessment',
- 6 'specific subjects' and
- 4 issues in the sub-area 'risk communication'.

## *Scientific Panel on food additives, flavourings, processing aids and materials in contact with food (AFC)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: Food additives**

| **EFSA-Q-2003-xx**[15] | **Evaluation of food additives requested by industry to be included into the 3 food additives directives. 13 substances** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 1-2 per substance |
| Expected no. of Working Group meetings | 2-4 per substance |

*Purpose*
To evaluate the safety in use of the additives in relation to the requested use conditions for subsequent inclusion into the food additives directives.

*Objectives/Milestones for 2004*
Four of the substances are waiting for supplementary information. Finalisation will depend on when this information is received. For the rest an opinion is expected during 2004

**Sub-area: Food additives, nutrient sources**

| **EFSA-Q-2003-017**<br>**EFSA-Q-2003-164** | **Evaluation of substances added for specific nutritional purposes in foods for particular nutritional uses. 15 substances** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August/September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | First half of 2004 for most of them |
| Expected no. of Panel meetings | 1-2 per substance |
| Expected no. of Working Group meetings | 2-4 per substance |

*Purpose*
To evaluate the safety in use of the specific sources of various nutrients. The safety of the nutrient as such is not part of the task.

*Objectives/Milestones for 2004*

[15] Question number not allocated yet.

For 4 of the substances a dossier has not yet been received and for 2 others supplementary data have been requested. Finalisation will depend on when this is received.
For the remaining substances an opinion is expected in first half of 2004.

**Sub-area: Food additives**

| **EFSA-Q-2003-xx**[16] | **Re-evaluation of all permitted food additives in the 3 directives** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | November 2003 |
| Expected date of completion | Ongoing process |
| Expected no. of Panel meetings | To be assessed on a case by case basis |
| Expected no. of Working Group meetings | To be assessed on a case by case basis |

*Purpose*
To evaluate the safety in use of all the additives presently permitted in food within the European Union in order to ascertain whether some of the earliest evaluated substances will meet the criteria expected for food additives to day.

*Objectives/Milestones for 2004*
As food colours were the first food additives to be evaluated and regulated, and most of them not evaluated since, they have the highest priority followed by the group of miscellaneous food additives and last the sweeteners, which have been evaluated comparatively lately by the SCF.
In 2004 it is envisaged to refine the list of priorities and to lay down strategies for the future work including exploring the possibilities to outsource major parts of the initial work of collecting and collating data. Likely it will also be necessary to issue guidelines to supplement the existing guidelines.

**Sub-area: Food flavourings, revision of annex II of Council Directive 88/388/EEC**[17]

| **EFSA-Q-2003-xx**[16] | **Evaluation of biological active principles: aloe-emodin, hydrocyanic acid, camphor, coumarin, pulegon/-menthofuran** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | 2004 |
| Expected no. of Panel meetings | 1-2 per substance |

[16] Question number not allocated yet.

[17] COUNCIL DIRECTIVE of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (88/388/EEC) (OJ L 184, 15.7.1988, p. 61)

| | |
|---|---|
| Expected no. of Working Group meetings | 2-5 per substance |

*Purpose*
To ascertain whether new data would suggest a revision of the present limits for these substances in the directive.

*Objectives/Milestones for 2004*
The revision has a high priority and it is envisaged that the work could be finalised in the first half of 2004.

**Sub-area: Food flavourings, chemically defined flavouring substances (FLAVIS)**

| **EFSA-Q-2003-xx**[18] | **Chemically defined flavouring substances according to Commission Regulation EC 1565/2000 (~800 substances divided into 34+1 groups)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | June 2005 |
| Expected no. of Panel meetings | 1-2 per group of substances |
| Expected no. of Working Group meetings | 2-3 per group of substances |

*Purpose*
To evaluate the safety in use of a series of defined chemical substances with the purpose to include them into a positive list.

*Objectives/Milestones for 2004*
The legal deadline for the directive is June 2005, which means that the evaluations shall be finished so much before that that the directive can be finalised in time. Thus the main part of the work should be finalised before the end of 2004.

**Sub-area: Smoke flavourings**

| **EFSA-Q-2003-xx**[18] | **Evaluation of smoke flavourings according to the regulation adopted 10 October 2003** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | From November 2003 onwards |
| Date of acceptance | - |
| Expected date of completion | Legal deadline 18 months after coming into force |
| Expected no. of Panel meetings | To be assessed |
| Expected no. of Working Group meetings | To be assessed |

*Purpose*

[18] Question number not allocated yet.

To assess the safety in use of smoke flavourings used in foods within the European Union

*Objectives/Milestones for 2004*
Guidelines for submission and dealing with the incoming data should be issued and strategies for dealing with the task should be defined. The possibility of outsourcing should be investigated. The actual evaluation should be initiated in 2004 to be able to meet the legal deadlines.

**Sub-area: Materials in contact with food**

| **EFSA-Q-2003-069** | **Substances intended for use as monomers or additives in food contact materials according to the plastics directive** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | From May 2003 onwards |
| Expected date of completion | 2004 |
| Expected no. of Panel meetings | 1-2 per substance |
| Expected no. of Working Group meetings | 1-3 per substance |

*Purpose*
To evaluate the safety of use of new monomers and additives in plastics for food contact purposes in order to finalise the positive list and re-evaluate old when found desirable in light of new data.

*Objectives/Milestones for 2004*
To meet the legal deadline of December 2004.

**Sub-area: Materials in contact with food**

| **EFSA-Q-2003-162**<br>**EFSA-Q-2003-163** | **Specific questions:**<br>**Use of mineral oils in jute bags**<br>**ESBO and hydrochloride derivatives** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | First half 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2-3 |

*Purpose*
The European Commission has been made aware of a problem that some jute bags containing various foods have been treated with mineral hydrocarbons, which migrate into the food. The Authority has been asked whether the substances found could cause a health risk to consumers and whether another treatment constitutes a safe alternative.

ESBO is used as a plasticiser in PVC gaskets sealing metallic lids used for glass jars. The

European Commission has been informed that ESBO as such, but also reaction products with hydrochloric acid may migrate into food.

The Authority has been asked whether this migration, to baby food in particular, will constitute a risk for children.

*Objectives/Milestones for 2004*
Special deadline has been defined by the Commission to April 2004.

**Sub-area: Materials in contact with food**

| **EFSA-Q-2003-070**<br>**EFSA-Q-2003-161** | **Consumption factors:**<br>**Examine the possibility to establish the full factor of 5 for DEHA**<br>**Examine the potential risk for children by introducing a fat (consumption) factor** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | First half 2004 |
| Expected no. of Panel meetings | 1-2 per question |
| Expected no. of Working Group meetings | 2-3 per question |

*Purpose*
Special fat (consumption) factors have been introduced in order to create a system for lipophilic substances more realistic to actual exposure that the usual default exposure assumption model applied when allocating maximum migration limits. Requests have been received to investigate the possibility of allocating a full factor for DEHA without the restrictions used for other substances. Likewise the Authority has been asked to investigate whether the introduction of the special fat (consumption) factor in general could be of special risk to children taking their special eating habits into account.

*Objectives/Milestones for 2004*
Special deadline has been defined by the Commission to April 2004.

## II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

New regulations on food enzymes and on food additives are expected in the future. They will create considerable extra work also in areas other than mere safety aspects if adopted as drafted. It is not known when an adoption is likely, but when the official draft has been published the possible consequences for the workload should be assessed and possible strategies developed.

## *Scientific Panel on additives and products or substances used in animal feed (FEEDAP)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: Re-evaluation (Directive 70/524/EEC) of coccidiostats**

| | |
|---|---|
| **EFSA-Q-2003-042**<br>**EFSA-Q-2003-043**<br>**EFSA-Q-2003-045**<br>**EFSA-Q-2003-046**<br>**EFSA-Q-2003-047** | **Lasalocid sodium (Avatec 15%®)**<br>**Robenidine hydrochloride (Cycostat 66G®) Monensin sodium (Elancoban®)**<br>**Narasin (Monteban®)**<br>**Salinomycin sodium (Sacox 120 micro-Granulate®)** |
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
According to article 9g of Directive 70/524/EEC as amended by Directive 96/51/EC, additives subject to authorisation linked to a person responsible for putting them into circulation before 1st January 1988 should be re-evaluated.
Seven dossiers for products of the category "Coccidiostats and other medicinal substances" have been retained by Member States for re-evaluation.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel before May 2004

**Sub-area: Evaluation of the efficacy and safety of additives of the category "Coccidiostats and other medicinal substances" for use in chickens for fattening**

| | |
|---|---|
| **EFSA-Q-2003-050**<br>**EFSA-Q-2003-009** | **Salinomycine sodium (Kokcisan 120G)**<br>**Salinomycine sodium (Biocox 120G)** |
| Origin of request | European Commission |
| Date of receipt | May 2003 / July 2003 |
| Date of acceptance | May 2003 / August 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
The Commission requests the Authority to advise it on the efficacy and the safety of these additives.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by spring 2004

**Sub-area: Micro-organisms**

**Evaluation of the safety of the product Turval for the weaning piglets**

| **EFSA-Q-2003-051** | ***Kluyveromyces marxianus* & *fragilis* (Turval)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

**Evaluation of the safety of the product Biomin for the piglets, the pigs for fattening and the chickens for fattening**

| **EFSA-Q-2003-052** | **Biomin** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

**Evaluation of the request for the extension of use of Biosprint in dairy cattle**

| **EFSA-Q-2003-053** | ***Saccharomyces cerevisiae* (Biosprint)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | January 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2 |

**Evaluation of the safety of the product MLB for dogs**

| **EFSA-Q-2003-055** | ***Lactobacillus acidophilus* (MLB)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 2 |

| | |
|---|---|
| Expected no. of Working Group meetings | 4 |

**Evaluation of the safety of a new additive of the category 'Micro-organisms' for use in piglets**

| **EFSA-Q-2003-010** | ***Lactobacillus reuteri*** **(Reuteri Pig Powder)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | July 2003 |
| Date of acceptance | 2003 |
| Expected date of completion | Mid-end 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

**Evaluation of the efficacy of Toyocerin for pigs for fattening**

| **EFSA-Q-2003-086** | ***Bacillus cereus*** **(Toyocerin)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 1 |
| Expected no. of Working Group meetings | 2 |

**Evaluation of the request for the extension of use of Lactiferm in chickens for fattening**

| **EFSA-Q-2003-087** | ***Enterococus faecium*** **(Lactiferm)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

**Evaluation of the request use of MLB for cats**

| **EFSA-Q-2003-115** | ***L. acidophilus (MLB*****)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | November 2003 |
| Date of acceptance | Under consideration |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

**Evaluation of the request for use of Oralin for dogs**

| **EFSA-Q-2004-001** | ***Enterococus faecium*** **(Oralin)** |
|---|---|

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | January 2004 |
| Date of acceptance | Under consideration |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

**Evaluation of the request for use of Cyclatin for dogs and cats**

| **EFSA-Q-2004-006** | ***Enterococus faecium* (Cyclatin)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | January 2004 |
| Date of acceptance | Under consideration |
| Expected date of completion | Mid-end 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
The Commission requests the Authority to advise it on the safety and/or the efficacy of these additives.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Enzymes**

| **EFSA-Q-2003-057**<br>**EFSA-Q-2003-012**<br>**EFSA-Q-2003-011** | **3-phytase (Natuphos)**<br>**6-phytase 3.1.3.26 (Bio-feed phytase)**<br>**3-phytase (Finase)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 / August 2003 / July 2003 |
| Date of acceptance | May 2003 / August 2003 / July 2003 |
| Expected date of completion | Early-mid 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 4 |

| **EFSA-Q-2004-003**<br>**EFSA-Q-2004-004** | **Endo-1,4,-beta-Xylanase (Belfeed 1100)**<br>**Efficacy of Endofeed** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | January 2004 / January 2004 |
| Date of acceptance | Under consideration |
| Expected date of completion | Early-mid 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 2 |

*Purpose*

The Commission requests the Authority to advise it on the safety and/or the efficacy of these additives.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Safety assessment of iodine**

| **EFSA-Q-2003-058** | **Iodine** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Mid-end 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
The Commission has the intention to review the maximum content of trace elements authorised in feedingstuffs in order to adapt these levels to the physiological requirements and to minimise negative effects on human health, animal health and the environment. In regard with these objectives, particular attention should be paid to the use of Iodine which is authorised under Directive 70/524/EEC concerning additives in feedingstuffs under the category “trace elements”.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion for these requests

**Sub-area: Use of synthetic sodium aluminium silicate (zeolite) for the reduction of milk fever in dairy cows**

| **EFSA-Q-2003-059** | **Zeolite** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*

To assess if zeolite when used at very high levels have detrimental effect on human or animal health or on the environment.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level

- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Carotenoids**

| **EFSA-Q-2003-060** | **Caroteinoids** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 5 |

*Purpose*
To assess the safety of use of capsanthin (E160c), beta-apo-8'-carotenal (E160e), ethyl ester of beta-apo-8'carotenic acid (E160f), lutein (E161b), cryptoxanthin (E161c), zeaxanthin (E161h), citranaxanthin (E161i), astaxanthin (E161j) in feedingstuffs for laying hens, other poultry, salmon, trout, on the basis of currently available scientific literature. In making its assessment, the panel on feed additives is requested to prioritise the substances which may be used as alternatives to canthaxanthin.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Evaluation of the efficacy and safety of the product Nutrigrow as source of protein in pigs for fattening**

| **EFSA-Q-2003-082** | **Nutrigrow** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 3-4 |

*Purpose*
The Commission requests the Authority to advise it on the efficacy and the safety of this product for the target species, the worker, the user, the consumer and the environment.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Evaluation of the environmental impact of Phaffia rhodozyma (Ecotone)**

| **EFSA-Q-2003-112** | **Ecotone** |
|---|---|

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | December 2003 |
| Date of acceptance | December 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 1-2 |

*Purpose*
The Commission requests the Authority to advise it on the environmental impact of astaxantin-rich Phaffia rodhozyma as feed additive for salmon and trout

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

**Sub-area: Proposal for the establishment of Maximum Residue Limits for canthaxantin in foodstuffs coming from animals fed with canthaxantin as feed additive**

| **EFSA-Q-2003-113** | **MRLs for canthaxantin** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 4-5 |

*Purpose*
The Commission requests the Authority to make a proposal for the establishment of MRLs for canthaxantin in eggs, poultry meat, trout and salmon resulting from the addition of canthaxantin to feed.

*Objectives/Milestones for 2004*
- To gather data and complete the evaluation at the working group level
- To have an opinion adopted by the Panel by the expected date of completion

## II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

An indication about new questions from the Commission includes six new questions within 3-4 months, and 20 supplementary questions related to previous requests. In addition to questions related to product authorisations some general issues might be addressed to the Panel. Some self-tasking activities will be addressed as soon as they have been accepted to the work program.

New Regulation (EC) No 1381/2003 on Additives for use in Animal Nutrition will create considerable amount of extra work on the Panel beyond the regular flow of new applications for authorisations of feed additives. The new regulation will require adoption of a series of

new or amended guidelines, new guidance for the applicants and consultation on the Authority on scientific progress in certain fields such as development of alternative substances and alternative methods of management, feeding, hygiene, etc. A proposal for the establishment of Maximum Residue Limits (MRLs) for some additives will be regulated from the Authority (the FEEDAP Panel), which has not been the case until now.

## *Scientific Panel on plant health, plant protection products and their residues (PPR)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: Evaluation of specific active substances of the first stage of the re-evaluation procedure under Council Directive 91/414/EEC[19]**

| **EFSA-Q-2003-120** | **Evaluation of daminozide** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | December 2003 |
| Date of acceptance | December 2003 |
| Expected date of completion | July 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

*Request for the WG toxicology on daminozide:*
The PPR Panel is asked to comment on the possible risks for operators and workers after re-entry from exposure to the metabolite UDMH.

### II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

**Sub-area: Evaluation of specific active substances of the first stage of the re-evaluation procedure under Council Directive 91/414/EEC[20]**

*Purpose*
The Authority is expecting a maximum of 15 requests from the Commission on existing active substances (substances which are already on the EU market) of the first stage of the re-evaluation procedure under Directive 91/414/EEC for evaluation by the PPR Panel[21].

*Objectives/Milestones for 2004*
The first three requests expected are described below. A more complete list is expected to become available in 2004.
The time constrain on the PPR Panel is due to the Commission legal timeframe: the decision on inclusion/non inclusion on Annex I of the Directive 91/414/EEC has to be taken by the Standing Committee on Food Chain and Animal Health of the Commission by the end of 2005.

**Evaluation of dinocap**

| | |
|---|---|
| Origin of request | European Commission |

[19] ECOJ L230 of 15/07/1991, pp 1-32.

[20] ECOJ L230 of 15/07/1991, pp 1-32.

[21] The European Commission is in charge of the coordination of the peer review of the risk assessment performed by a rapporteur Member State.

| | |
|---|---|
| Potential date of receipt | February 2004 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2-4 |

*Requests for the WG toxicology on dinocap:*
The PPR Panel is asked to comment:
- on the relevance of the eye effects observed in dogs for the human risk assessment and
- on the value of the dermal absorption to be used in the exposure assessment.

**Evaluation of methamidophos**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | February 2004 |
| Expected date of completion | August 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2-5 |

*Requests for the WG toxicology and the WG ecotoxicology on methamidophos:*
The PPR Panel is asked one question in toxicology on the dermal absorption and one question in ecotoxicology on the risk assessment for birds and mammals.

**Evaluation of alachlor**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | February 2004 |
| Expected date of completion | August 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2-5 |

*Requests for the WG toxicology on alachlor*
The PPR Panel is asked two questions:
- on the relevance for human of nasal turbinate tumours in the rat carcinogenicity,
- on the appropriate studies to be used to set an ADI and AOEL.

**Sub-area: Evaluation of new active substances**

| | |
|---|---|
| Origin of request | European Commission and<br>EFSA (self-tasking from PRA peer review) |
| Expected date of completion | 2004/2005 |
| Expected no. of Panel meetings | 1 to 2 per active substance |
| Expected no. of Working Group meetings | 2 to 4 per active substance |

*Purpose*
The Commission will also send some requests on new active substances produced by the plant protection product industry, under evaluation that are the most problematic; provisional authorisations exist in certain EU countries only on the contrary to existing active substances. As the Authority is now in charge of the peer review of the draft assessment report (as explained in the paragraph 3 of the PRAPeR sector) a maximum of 13 requests

could be also expected as “self-tasking”.

*Objectives/Milestones for 2004*
A maximum of 15 requests could be expected on new active substances, first from Commission and later in 2004 from the Authority. The deadlines are slightly less strict (paragraph 3 of the PRAPeR sector) than for existing active substances.

**Sub-area Evaluation of specific active substances of the second stage of the re-evaluation procedure under Commission regulation n° 1490/2002**

| | |
|---|---|
| Origin of request | EFSA (self-tasking from PRA peer review sector) |
| Date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 1 to 2 per active substance |
| Expected no. of Working Group meetings | 2 to 5 per active substance |

*Purpose*
A maximum of 36 existing active substances of the second stage of the review programme (listed in paragraph 1 of the PRAPeR sector) will be peered reviewed with the coordination of the Authority in 2004. Among them, the ones with unsolved scientific problems will provide requests to the PPR Panel.

*Objectives/Milestones for 2004*
The legal time constrain of 12 months for the Authority together with the decision on inclusion/non inclusion on Annex I of the Directive 91/414/EEC to be taken by the Standing Committee on Food Chain and Animal Health of the Commission by end of 2005, should give this group of existing active substances a higher priority in the work plan 2004.

**Sub-area: Comments on the draft guidance documents prepared by the Commission**

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | 2004 |
| Expected date of completion | End 2004-2005 |
| Expected no. of Panel meetings | 1 to 2 per guidance document |
| Expected no. of Working Group meetings | 3 to 5 per guidance document |

*Purpose*
At least three technical Guidance Documents are under preparation by expert Working Groups and Steering Groups in the Commission. An opinion on each of them will be requested to the PPR Panel before adoption by the Standing Committee on Food Chain and Animal Health.
The titles of the Guidance Documents are:

1. FOCUS on degradation kinetics (Kinetic analyses of degradation and transformation of active substances and their metabolites in soil and water in EU regulation), expected around May 2004.

2. FOCUS landscape and mitigation, expected around September 2004.
3. FOCUS air (establishment of a tiered risk assessment scheme for short-range aerial transport), expected end 2004.

Other Guidance Documents could also be expected from other Commission Working Groups in 2004 such as "Probabilistic methods in operator exposure" (EUROPOEM project) or "The use of probabilistic risk assessment in environment" (EUFRAM project funded by DG RTD). The addendum from the Working Group MED-RICE (Guidance Document on MED-RICE II: environmental risk assessments of active substances used on rice in Mediterranean countries) could possibly be send to the Authority.

*Objectives/Milestones for 2004*
The aim is to give member states and industry updated guidance on how to adapt to the development of scientific knowledge in those areas. The timing of the requests from Commission on FOCUS Guidance Documents was given above. The work on the Guidance Document on the use of probabilistic risk assessment in environment should start at end of 2004/early 2005.

**Sub-area: Technical support on the revision of the Annex II and III to Council Directive 91/414/EEC[22]**

**Revision of Annex II and III in 5 sectors: toxicology, ecotoxicology, residues, fate and behaviour and physico-chemical properties**

| | |
|---|---|
| Origin of request | European Commission |
| Date of acceptance | 2004 |
| Expected date of completion | End 2004 |
| Expected no. of Panel meetings | 1 to 2 for each sector |
| Expected no. of Working Group meetings | 2 to 5 for each sector |

*Purpose*
The Commission contracted with member states for the revision of the five sectors of the Annexe II and III to Council Directive 91/414/EEC: toxicology, ecotoxicology, residues, fate and behaviour and physico-chemical properties. The EU member states and the OECD countries were consulted on an early draft during autumn 2003. Three of the five Working Groups integrated their comments in the text and updated their draft end of 2003.

*Objectives/Milestones for 2004*
Commission should send early 2004 the 3 requests to the PPR Panel for: toxicology, ecotoxicology and physico-chemical properties; the two others could be expected later in 2004. Those new Annexes II and III should be used at the earliest for the assessment of the 4th stage of the review programme and thus should not have the higher priority.

**Sub-area: Plant Health**

| | |
|---|---|
| Origin of request | European Commission |

[22] ECOJ L230 of 15/07/1991, pp 1-32.

| | |
|---|---|
| Date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 1 per active substance |
| Expected no. of Working Group meetings | 2 to 4 per active substance. |

*Purpose*
Depending on the outcome of ongoing discussions with Member States and decision in the Council, a small number of questions could be send to the PPR Panel in 2004.

*Objectives/Milestones for 2004*
No estimation from Commission available so far, possible decision in 2004.

## *Scientific Panel on genetically modified organisms (GMO)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: General questions**

| **EFSA-Q-2003-005** | **Guidance for new GM food and feed applications** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | April 2004 |
| Expected no. of Panel meetings | 5 |
| Expected no. of Working Group meetings | 5 |

*Purpose*
The GMO Panel is requested to publish detailed guidance material to assist the applicant in the preparation and presentation of applications for authorisation of GM food and/or feed introduced within the framework of the new Regulation (EC) 1829/2003 on genetically modified food and feed. According to the Regulation it is necessary to establish harmonised procedures for risk assessment and criteria for evaluation of the potential risks arising from genetically modified food and feed.

*Objectives/Milestones for 2004*
The Panel intends to produce two guidance documents on (1) food and feed derived from GM crops and on (2) food and feed derived from GM micro-organisms. The objective of the Panel is to adopt the first document before the date of application of the new Regulation in April 2004 and to make substantial progress with the drafting of the second document that was initiated in parallel. In future, also guidance notes on other kinds of GMOs (e.g. GM food/feed with altered composition, food/feed derived from GM animals) should be established.

**Sub-area: Environmental risk assessment of GMOs in the framework of Directive 2001/18[23] on the deliberate release into the environment of GMOs**

**Applications received under Directive 2001/18/EC:**

| **EFSA-Q-2003-078** | **GM oilseed rape GT73 (C/NL/98/11)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | January 2004 |
| Expected no. of Panel meetings | 2 |

[23] 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

| | |
|---|---|
| Expected no. of Working Group meetings | 3 |

| **EFSA-Q-2003-089** | **GM maize MON 863 and MON863xMON810 (C/DE/02/9)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | November 2003 |
| Date of acceptance | November 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
In accordance with Article 28 of Directive 2001/18/EEC the GMO Panel can be consulted on questions related to applications for the placing on the market of GMOs '*in cases where an objection as regards the risks of GMOs to human health or to the environment is raised by a competent authority or the Commission and maintained, or where the assessment report by the lead Competent Authority indicates that the GMO should not be placed on the market*'. Article 18 of this Directive prescribes that '*the period of time during which the Commission is awaiting the opinion of the Scientific Committee shall not exceed 90 days'*.

Since the entry into force of the Directive, 23 applications have been introduced within the framework of 2001/18 (2 were withdrawn since). Most concern products introduced under former Directive 90/220/EEC and blocked by the *de facto* moratorium. It is expected that EFSA will be requested to deliver an opinion on all products for which there was no opinion from the former Scientific Committee on Plants. Currently, the Authority has received questions relating to 3 applications.

*Objectives/Milestones for 2004*
The GMO Panel has established 3 permanent working groups for the evaluation of authorisation dossiers: WG Molecular Characterisation, WG Food & Feed Safety and WG Environmental Risk Assessment. Where possible, the Panel will work towards delivering an opinion within the legally determined 3 months upon appropriate receipt of all documents.

**Sub-area: Food safety assessments of GMOs and/or derived food products in the framework of Regulation 258/97[24] on novel foods and novel food ingredients**

**Applications received under Regulation (EC) 258/97:**

| **EFSA-Q-2003-108** | **GM maize MON 863 and MON863xMON810** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | November 2003 |
| Date of acceptance | November 2003 |

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

| | |
|---|---|
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
In accordance with Article 11 of Regulation 258/97, the GMO Panel '*shall be consulted on any matter falling within the scope of this Regulation likely to have an effect on public health'.* In practical terms the GMO Panel is consulted on questions related to applications for the placing on the market of GM foods, in cases of an objection with regards to the risks of consumption of GMOs and/or derived products to human health as raised by a competent authority or the Commission, or where the initial assessment report by the lead Competent Authority indicates that the GMO should not be placed on the market.

Since the entry into force of the Regulation 258/97, 13 GMO applications have been introduced (5 were since withdrawn). The Scientific Committee on Food delivered an opinion on 3 dossiers. It is expected that the Authority will be requested to deliver an opinion on all products for which there was no opinion from the former Scientific Committee on Food and for which the initial assessment report was submitted before the date of application of the new GM food and feed Regulation 1829/2003. Currently, the Authority has received questions relating to two 258/97 food applications.

*Objectives/Milestones for 2004*
Two of the permanent working groups established by the GMO Panel for the evaluation of authorisation dossiers will assess the GM food applications: WG Molecular Characterisation and WG Food & Feed Safety. Where possible, the Commission has agreed to synchronise questions on marketing applications that relate to the same GMO in order to optimise the work of the Panel and to allow parallel assessment of the information by the GMO Panel. In such cases, the Panel will work towards delivering an opinion within the same time frame for both requests.

**Sub-area: Own initiatives**

| **EFSA-Q-2003-109** | **Biosafety of antibiotic resistant marker genes** |
|---|---|
| Origin of request | EFSA |
| Date of receipt | July 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
The GMO Panel decided to deliver a scientific opinion on the use of antibiotic resistance marker genes in GMOs, in line with the provisions of art 4 (2) of Directive 2001/18/EC: '*Member States and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse*

*effects on human health and the environment. This phasing out shall take place by the 31 December 2004 in the case of GMOs placed on the market according to part C and by 31 December 2008 in the case of GMOs authorised under part B.'*
Several GMOs, for which a marketing application was submitted under Community legislation, contain an antibiotic resistance marker gene. As the presence of such genes has been the subject of a lot of discussion and no final decision has been made on what are the *antibiotic resistance markers which may have adverse effects* the GMO Panel considered it useful to draft a scientific opinion on this topic.

*Objectives/Milestones for 2004*
The Panel aims to finalise its opinion by early 2004.

## II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

**Sub-area: Food and feed safety assessments of GMOs and/or derived food products in the framework of Regulation (EC) 1829/2003[25] on GM food and feed.**

*Purpose*
In accordance with the new Regulation 1829/2003 on GM food and feed, the Authority will be responsible for *the scientific evaluation of GM food and feed with regards to any risks which they present for human and animal health and, as the case may be, for the environment*. In giving its opinion, the Authority shall endeavour to comply with a time limit of six months as from the receipt of a valid application. Such time limit shall be extended whenever the Authority seeks supplementary information from the applicant.
EFSA may ask the appropriate food assessment body of a Member State to carry out (part of) an initial safety assessment of the food. Where the application concerns products containing or consisting of a GMO, the applicant could apply for the environmental risk assessment (in compliance with the requirements referred to in Directive 2001/18/EC) to be carried out at the same time as the safety assessment under this Regulation. In that case, the Authority can delegate the environmental risk assessment to one of these national competent authorities designated by Member States, for this purpose and all national competent authorities are to be consulted by the Authority before it finalises the environmental risk assessment. In the case of GMOs to be used as seeds or other plant-propagating materials falling within the scope of this Regulation, the Authority has to delegate the environmental risk assessment to a national competent authority.

*Objectives/Milestones for 2004*
The new regulation shall apply from 18 April 2004. It is currently very difficult to make an estimate of the number of applications that will be submitted under this new Regulation. A number of existing applications (under Regulation 258/97) that are currently with the national authorities but for which no initial risk assessment was finalised will be transformed into applications under the new GM food and feed Regulation 1829/2003 after 18 April 2003. Moreover, EFSA has been informed by plant biotechnology companies about marketing applications for new GM crops under the Regulation. It is entirely unclear what the workload

[25] Regulation No 1829/2003 (EC) of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed

will be in the area of products used in animal feed that are derived from GMOs and for which there was no specific Community legislation up to now. In the case of applications of additives for use in animal nutrition for which an additional authorisation is requested if those feed additives are consisting of, containing or produced from GMOs, EFSA intends to organise a close collaboration between the GMO and the FEEDAP Panel.
The GMO Panel will involve its 3 permanent working groups for the evaluation of the GM food and feed applications. In addition, EFSA will explore ways of delegating (part of) the initial risk assessment to an assessment body of a Member State.

**Sub-area: Environmental risk assessment of GMOs in the framework of Directive 2001/18[26] on the deliberate release into the environment of GMOs**

**GM maize Bt11 (C/F/96/05.10)**
**GM maize 1507 (C/ES/01/01)**
**GM maize 1507 (C/NL/00/10)**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | January 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
See above

*Objectives/Milestones for 2004*
See above. Three requests for a scientific opinion are expected to be forwarded to the Authority in January 2004. For 14 other applications, it is expected that requests will be sent to the Authority in 2004, but the Commission is not in a position for the moment to indicate more precise timing.

**Sub-area: Food safety assessments of GMOs and/or derived food products in the framework of Regulation 258/97[27] on novel foods and novel food ingredients**

*Purpose*
See above

*Objectives/Milestones for 2004*

[26] 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

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

See above. Applications submitted under Regulation 258/97 may be forwarded to the Authority if the national authority finalises its initial risk assessment before the date of application of the new GM food and feed Regulation 1829/2003 (18 April 2004).

**Sub-area: Own initiatives**

**Safety of use of viral promoters**

*Purpose*
The GMO Panel proposes to deliver a scientific opinion on the safety of use of viral promoters. As such promoters are used in several of the GMOs for which a market authorisation is sought, and there appears to be a discussion among scientists on the safety of using such promoters, this is considered as an urgent activity for the Panel.

*Objectives/Milestones for 2004*
The GMO Panel will draft a terms of reference early 2004. If adopted, the Panel will proceed with this self tasking activity and deliver an opinion by mid 2004.

**Post-market environmental monitoring of GM crops**

*Purpose*
The GMO Panel proposes to deliver a scientific opinion on the post-market environmental monitoring of GM crops. Many of the comments made by Members States in relation to applications under 2001/18 relate to the monitoring plan that has to be submitted by the applicant. The Panel therefore has identified the need to provide additional guidance on such monitoring.

*Objectives/Milestones for 2004*
The GMO Panel will draft the terms of reference early 2004. As a clear distinction between risk management and risk assessment of post-market monitoring of GM crops is difficult to make, the Commission will be invited to comment on the terms of reference. If adopted, the Panel will proceed with this self tasking activity and deliver an opinion by end 2004.

**Post-market human/animal health monitoring of GM crops**

*Purpose*
The GMO Panel proposes to deliver a scientific opinion or draft a report on the post-market human/animal health monitoring of GM crops. The new Regulation 1829/2003 states that *where appropriate*, a proposal for post-market monitoring regarding the use of GM food for human consumption or the use of the GM feed for animal consumption has to be provided. However, no guidance is given as to in which cases such post-market monitoring could be appropriate. The Panel recognises that this is a very complex issue for which additional guidance might be needed.

*Objectives/Milestones for 2004*
The GMO Panel will set up a working group to identify the right questions first. At a later stage the Panel will decide whether it is appropriate to draft the terms of reference and to proceed with the drafting of a scientific opinion or report.

**Improve the approaches for allergenicity assessment of GMOs**

*Purpose*
The GMO Panel proposes to investigate new ways of assessing (non-)allergenicity. Although there is an agreement within the scientific community on the way and how the assessment of allergenicity of GMOs is currently carried out, the Panel has indicated that it wishes to take pro-active action in this area.

*Objectives/Milestones for 2004*
The GMO Panel will draft a terms of reference and reflect on the best way to address this issue. The Panel may wish to organise a scientific workshop or other activity to share information on the latest developments on this subject in addition to the work of the GMO panel.

**Guidelines for GM micro-organisms in the environment (e.g. bio-fertilisers)**

*Purpose*
The GMO Panel has identified the need for guidance for the release of GM micro-organisms such as bio-fertilisers in the environment.

*Objectives/Milestones for 2004*
The GMO Panel will draft a terms of reference and reflect on the best way to address this issue. The Panel may wish to organise a scientific workshop or other activity to be kept up to date with the latest developments on this subject in addition to the work of the GMO panel.

**Impact of GMOs on microbial biodiversity and function in the soil environment**

*Purpose*
The GMO Panel has identified the need to study the impact of GMOs on microbial biodiversity and function in the soil environment. This is an area for which scarce scientific data is available and the Panel has indicated that it wishes to take pro-active action in this area.

*Objectives/Milestones for 2004*
The GMO Panel will draft a terms of reference and reflect on the best way to address this issue. The Panel may wish to organise a scientific workshop or other activity to share information on the latest developments on this subject in addition to the work of the GMO panel.

## *Scientific Panel on Dietetic products, Nutrition and Allergies (NDA)*

### I ON-GOING REQUESTS FOR SCIENTIFIC OPINION

**Sub-area: Dietetic products and nutrition**

| **EFSA-Q-2003-019** | **Goat's milk protein as a protein source for infant formulae and follow-on formulae** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 1 |
| Expected no. of Working Group meetings | 1 |

*Purpose*
The current legislation on infant formulae and follow-on formulae (Directive 91/321/EEC) provides that infant formulae can only be manufactured from the following protein sources: cow's milk protein, soya protein isolates and partially hydrolysed protein. A request for goat's milk to be considered as a source of protein in infant formula has been submitted to the Commission.

As the Authority should be consulted prior to any modification to the existing legislation on dietetic foods which is liable to affect public health, the Panel is asked to evaluate the above-mentioned submission in order to give an opinion on the suitability of goat's milk protein as a source of protein in infant formulae and in follow-on formulae.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level.
- To have an opinion adopted by the Panel by the expected date of completion for this request.

| **EFSA-Q-2003-020** | **Fructo-oligosaccharides for infant formulae and follow-on formulae** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 1 |
| Expected no. of Working Group meetings | 1 |

*Purpose*
Directive 91/321/EEC provides that infant formulae must comply with the compositional criteria laid down in its Annexes. A submission for the review of fructo-oligosaccharides for use under conditions different from those specified by the Scientific Committee on Food (SCF) in December 2001 and in April 2003 has been sent to the Commission.

As the Authority should be consulted prior to any modification to the existing legislation on dietetic foods which is liable to affect public health, the Panel is asked to issue an opinion on the safety and the suitability for particular nutritional use by infants of fructo-oligosaccharides (FOS) at the conditions specified by the manufacturer in infant formulae and follow-on formulae.

*Objectives/Milestones for 2004*
- To complete the evaluation at the working group level.
- To have an opinion adopted by the Panel by the expected date of completion for this request.

| **EFSA-Q-2003-022** | ***Trans* fatty acids in foodstuffs** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | June 2004 |
| Expected no. of Panel meetings | 1-2 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
Following the notification by the Danish Authorities for a legislative measure limiting the level of *trans* fatty acids in foodstuffs containing fats, some Member States made comments on the proposal. In view of the divergent opinions in this matter the Commission has decided to seek the opinion of the Authority.

The Panel is asked to issue an opinion on the presence of *trans* fatty acids in foods and on the effect on human health of the consumption of *trans* fatty acids. In this context the Panel is asked:

- to advise - whether the evidence indicates any specific effects on health of *trans* fatty acids - whether the effects, if any, differ according to the food source, and - how the effects, if any, compare to effects on health of other types of fatty acids;
- to advise, if there are effects on health, whether the effects are associated with a specific level of intake of *trans* fatty acids in the context of the overall diet.
- In addition, the Panel is asked to advise if there are any methods of analysis that can distinguish between *trans* fatty acids which are naturally present in fats and those formed during the processing of fats, oils or foods. The Panel is asked to report the analytical sensitivity of any such methods.

*Objectives/Milestones for 2004*
To complete the preparatory work needed for this task in order to have an opinion adopted by the Panel by the expected date of completion for this request.

**Sub-area: Food allergy**

| **EFSA-Q-2003-016** | **Allergenic foods for labelling purposes** |
|---|---|

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 1 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
A Commission's proposal for amending the food labelling Directive 2000/13/EC includes a list of allergenic food ingredients which should be indicated on the label whenever they are used in production of a foodstuff. In this framework, the NDA Panel is asked to give an opinion on the scientific basis supporting the identification of foods or food components which induce food allergies and food intolerance for labelling purposes.

The Panel is also asked to consider the possibility of determining thresholds or other elements, including food processing, in order to establish that a food component is no longer susceptible to induce adverse reactions.

*Objectives/Milestones for 2004*
- To complete the evaluation of the individual allergenic ingredients included in Annex IIIa of the forthcoming legislation on food labelling.
- To have an opinion adopted by the Panel by the expected date of completion for this request, which will also form the scientific basis to further work of the Panel in this area.

**Sub-area: Upper levels for vitamins and minerals**

| **EFSA-Q-2003-016** | **Upper levels of daily intakes of 12 vitamins and minerals** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | March 2005 |
| Expected no. of Panel meetings | 5 |
| Expected no. of Working Group meetings | 5-6 |

*Purpose*
The establishment of upper safety limits for vitamins and minerals is essential for the Commission to amend community legislation in the field of food supplements and addition of nutrients to foods. With a view to provide scientific support to the Commission, the former Scientific Committee on Food (SCF) issued from October 2000 to April 2003 a series of opinions on tolerable upper intake levels of individual vitamins and minerals in relation to their use in fortified foods and food supplements.

The SCF covered 22 out of the 29 nutrients included in the SCF mandate for this task. Furthermore, during the decision making process for the adoption of the food supplements Directive 2000/46/EC, the Commission rejected to include 5 additional nutrients (boron, vanadium, nickel, silicon, tin) due to the absence of a positive safety evaluation.

The NDA Panel is now asked to complete the evaluations of the SCF (7 nutrients: iron, vitamin C, fluoride, phosphorus, sodium, potassium, and chloride) as well as to evaluate the 5 additional nutrients (boron, vanadium, nickel, silicon, tin), and in particular the Panel is asked to review the upper levels of daily intakes that are unlikely to pose a risk of adverse health effects, and to provide the basis for the establishment of safety factors, which would ensure the safety of fortified foods and food supplements containing the aforementioned nutrients.

*Objectives/Milestones for 2004*

- To have a first evaluation and preliminary discussion on each of the 12 nutrients at the working group level by July 2004.
- To have opinions on a number of nutrients adopted by the Panel by July 2004.
- To progress with the evaluation of the remaining nutrients at the working group level from July to December 2004 in order to have opinions on some of the remaining nutrients adopted by the Panel by the end of 2004.

**Sub-area: Novel Foods (non-GM)**

| **EFSA-Q-2003-024** | **Cereal brans for use as fat replacers and sources of fibre** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | August 2003 |
| Expected date of completion | See text |
| Expected no. of Panel meetings | - |
| Expected no. of Working Group meetings | - |

*Purpose*

Within the framework of the Novel Food Regulation 258/97/EC a request by a petitioner for authorisation to place “soluble and insoluble fractions of cereal brans for use as fat replacers and sources of fibre” on the market in the Community has been received.

This application was submitted to the former Scientific Committee on Food (SCF) for evaluation, which requested additional information to the petitioner. In the meantime, the property rights of the product were sold. As the new owner of the product has indicated continuing interest in the application the request was transferred to EFSA. The Panel was asked to provide an opinion on this request within 3 months of the date of receipt of the required information from the petitioner.

In October 2003, the petitioner informed the Commission on its decision to withdraw the current application. As the request to the Panel has been accordingly withdrawn it should not be considered under its work program for 2004.

## II POTENTIAL UPCOMING REQUESTS FOR SCIENTIFIC OPINION IN 2004

**Sub-area: Food allergy - evaluation of dossiers related to a temporary “negative list” of allergenic ingredients for labelling purposes**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | January 2004 |
| Expected date of completion | November 2004 (legal deadline) |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 5-6 |

*Purpose*
The new legislation[28] on food labelling recently adopted specifies a list of ingredients (Annex IIIa) which should be mandatory included in the label of a foodstuff whenever they are used in the production of the foodstuff. Moreover, the new Directive establishes a procedure to remove ingredients from Annex IIIa. This is a notification procedure to inform the Commission on studies which are currently being carried out by third parties to determine which ingredients derived from allergenic ingredients are no longer likely to trigger allergic reactions. On the basis of these data, a temporary "negative list" containing those ingredients that should be removed from Annex IIIa will be adopted by the Commission after consulting the Authority.

From this background, it is foreseen that the Panel will be asked to evaluate and to give an opinion on dossiers submitted by third parties in the framework of the aforementioned notification procedure.

The time frame specified in the new legislation is 9 months after the entry into force of the Directive for the notification procedure to the Commission (i.e. by 24 August 2004) and, subsequently, 3 months for the Commission to adopt the temporary negative list (i.e. by 24 November 2004). At the present moment, it is not possible to have a forecast of the workload to be expected from this request. Nevertheless, in view of the short time limit and the uncertainty on the workload this request will have a considerable impact on the estimated workload of the Panel for 2004.

**Sub-area: Novel Foods - Vegetable oils (rapeseed and maize germ oils) high in unsaponifiable matter**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | January 2004 |
| Expected date of completion | 6 months after the date of receipt |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
In implementing the Novel Food Regulation 258/97/EC, the competent authorities of France have carried out an initial assessment for an application concerning the aforementioned novel food ingredient. In the light of the initial assessment report and later complemented by the comments/questions and objections raised by Member States, it is foreseen that the

[28] Directive 2003/89/EC of the European Parliament and of the Council amending Directive 2000/13/EC as regards indication of the ingredients present in foodstuffs. Official Journal of the European Union L 308, 25.11.2003, p. 15.

Panel will be asked to assess the safety, from the point of view of consumer health, of these two novel foods.

**Sub-area: Health claims**

A proposal for a Regulation of the European Parliament and of the Council on nutrition and health claims made on foods was adopted last 16 June 2003 by the Commission. According to that proposal, and bearing in mind that it could be substantially modified during the decision making process for its adoption, the Authority will be consulted and requested by the Commission to give an opinion on the following subjects:

- Nutrient profiles for foods bearing claims
- Guidelines for the implementation of Article 11 of the proposal on implied health claims that shall not be allowed
- Guidelines for the implementation of Article 14 of the proposal on preparation and presentation of information necessary to support applications for authorisation of health claims
- A list of permitted health claims describing the role of a nutrient or other substance in growth, development and normal physiological functions of the body
- Evaluation of individual applications for pre-market authorisation of health claims

Although some of these tasks will be considered for a longer term within the work programme, there is a considerable preparatory work in relation to, for example, criteria to establish nutrient profiles or developing guidelines for the implementation of a number of issues, an extremely time-consuming task, that should be, at least, initiated in 2004 rather than in 2005. However, at this moment, it is not possible to anticipate the amount and kind of activities that would be considered needed for this task.

## *Scientific Panel on Biological Hazards (BIOHAZ)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

| **EFSA-Q-2003-098** | **BSE-related culling in cattle** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 1 |
| Expected no. of Working Group meetings | 1 |

*Purpose*
To update its opinion of 14-15 September 2000 on BSE-related culling in cattle in the light of submitted information by AFSSA (French Food Safety Agency), AFSCA (Belgian Food Safety Agency), the Authorities of Denmark, the latest surveillance in the EC and information submitted by Switzerland. More specifically: does the Panel see any reason to revise either its definition of birth cohort or its recommendation on the application of birth cohort culling?

| **EFSA-Q-2003-013** | **Over Thirty Months Rule – Date Based Export Scheme – Moderate risk request (UK)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | July 2003 |
| Date of acceptance | July 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
To provide an opinion on (1) the scientific justification or proposed amendments to the United Kingdom Date Based Export Scheme and (2) the application of the United Kingdom for moderate risk BSE status. In particular to estimate the extra BSE risk to human health which would occur if the United Kingdom Date Based Export Scheme were amended to (a) remove the upper (30 month) age limit for eligible cattle and (b) remove the dam survival rule and lower (6 month) age limit for eligible cattle and to base the answers on the statistical modelling carried out as part of the review of the Over Thirty Months Rule in the United Kingdom, and based on the most up-to-date scientific evidence regarding the possibility of maternal transmission of BSE. In addition the Authority is requested in particular to examine how this risk compares with the BSE risk to which EU consumers (outside the UK and Portugal) are currently exposed by consumption of bovine meat, meat products and preparations.

| **EFSA-Q-2003-095** | **Tongue infectivity** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To consider the Spongiform Encephalopathy Advisory Committee (SEAC) report in view of a possible update of the Scientific Steering Committee opinion of 22–23 November 2002 on tissue infectivity distribution. The SEAC report was published on 10 July 2003, and makes a statement on the BSE risk from bovine tonsil and the consumption of ox tongue. Its opinion was based on two reports *i.e.* a Veterinary Laboratories Agency (VLA) report on the presence of tonsil tissue on ox tongue and an assessment of BSE risk from bovine tonsils carried out by DNV Consulting.

| **EFSA-Q-2003-088** | **Chronic Wasting disease** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To provide advice on different aspects of surveillance for Chronic Wasting Disease (CWD) in cervids in the EU. These include the diagnostic methods suitable for the screening and confirmation of CWD, discriminative power (CWD in relation to other TSE's) and to consider if the results of evaluations of screening tests on cervids carried out by administrations outside the EU would be sufficient to allow the approval of these tests for use in the EU on its varieties of cervid more commonly found in the EU (e.g. farmed red deer, fallow deer and reindeer; wild red deer, roe deer, moose and fallow deer)?

| **EFSA-Q-2003-099** | **Quantitative Risk Assessment for residual BSE risk in products derived from animal by products** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
Clarifications of the results of the SSC opinion on quantitative assessment of the residual BSE risk in a number of bovine-derived products such as gelatine, tallow, milk replacers,

tallow derivatives, dicalcium phosphate and animal feeds cross-contaminated with bovine meat-and-bone-meal.

In June 2002, the SSC agreed upon a methodological approach to quantify the residual BSE risk in a number of bovine-derived products. Following the adoption of this working method, the application of this method required specific expertise, substantial computing capabilities, as well as specialised software. It was therefore decided to contract this work outside. The first results from the contract were received in October 2003. They will need to be analysed, and a decision will need to be taken whether they should become the object of independent scientific advice or whether they can be accepted as such, given the fact that the basic methodology had been accepted by the SSC. Although this was a file which was handed over, the Authority is awaiting an updated mandate which is expected to come in October 2003.

| **EFSA-Q-2003-027** | **Revision of meat inspection procedures for lambs and goats** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 2-3 |

*Purpose*
The opinion on revision of meat inspection of lambs and goats will form part of a series of opinions on the revision of meat inspection procedures for different animal species. The SCVPH already adopted three opinions of the series: “revision of meat inspection procedures for fattening pigs” (SCVPH, 2000a). A second opinion was issued in June 2001 on “identification of species and categories of meat-producing animals in integrated production systems where meat inspection may be revised”. This was considered to be a first step approach for the revision of meat inspection procedures. A third opinion was issued in May 2003 on “Revision of meat inspection in veal calves” as a second step in revising the inspection procedures for the identified species/categories of animals.

Considering the above and in view of the future process of redrafting the legislation the Scientific Panel of Biological Hazards (BIOHAZ) is asked to review the currently mandatory post-mortem inspection procedures for lambs raised in integrated production systems, concentrating on the palpation and the incisions.

| **EFSA-Q-2003-079** | **Antimicrobials for the control of *Salmonella* in poultry** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 5 |
| Expected no. of Working Group meetings | 4-5 |

*Purpose*
The Scientific Panel of Biological Hazards is requested to evaluate the advantages and disadvantages of the use of antimicrobials in the framework of salmonella control programmes taking into account the different types of flocks, to assess the risk that could result from the use of such antimicrobials for the (i) prevention of salmonella infection in animals, (ii) treatment of flocks infected with salmonella without clinical signs and (iii) treatment of clinically affected flocks. The Panel was asked to highlight any aspects related to the use of antimicrobials that may jeopardise a successful implementation of a programme to control salmonella.

| **EFSA-Q-2003-080** | **Vaccines for the control of *Salmonella* in poultry flocks** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Panel meetings | 5 |
| Expected no. of Working Group meetings | 4-5 |

*Purpose*
The Scientific Panel of Biological Hazards is requested to identify the different types of vaccines available against salmonella in poultry and to indicate their practical advantages and disadvantages against their possible use in the framework of control programmes taking into account the different types of flocks.

| **EFSA-Q-2003-081** | ***Campylobacter* in animals and foodstuffs** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | End 2004 – Early 2005 |
| Expected no. of Panel meetings | 5 |
| Expected no. of Working Group meetings | 5-6 |

*Purpose*
The Scientific Panel of Biological Hazards is requested to deliver a scientific opinion on *Campylobacter* in animals and foodstuffs in particular to: (i) identify categories of foodstuffs where *Campylobacter* represents a significant risk to public health, (ii) identify possible control options to reduce the risk along the food chain and (iii) identify gaps in available data as well as best means of collecting this information.

| **EFSA-Q-2003-090** | **Animal By-products:** Request for opinion on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil |
|---|---|

| | |
|---|---|
| | improvers |
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To review the opinion of the Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) of 24 April 2001, in the light of the opinion of the SSC of 10-11 May 2001 from TSE risk perspectives and to advise on the levels of biological clearance to allow establishing the appropriate minimum waiting period after which grazing may be allowed following application of organic fertiliser or soil improvers (e.g. meat and bone meal, digestion residues or compost from animal tissues) on pastureland.

| **EFSA-Q-2003-097** | **Animal By-products:** Request for opinion on the safety vis-à-vis biological risk including TSEs of biogas and compost treatment standards of animal by-products |
|---|---|
| Origin of request | European Commission |
| Date of receipt | October 2003 |
| Date of acceptance | October 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To evaluate, from biological (including TSE) risk perspectives, the data presented by interests (different Member states) in the light of the CSTEE opinion of 24 April 2001, and to advise on: (i) Possible alternative temperature, time and particle size combinations other than those already defined in the legislation ensuring equivalent safety for the transformation of animal by-products in biogas and composting plants; and
(ii) Whether and what other microbial agents and criteria than those already defined in the legislation could be used as an indicator of safety of hygienisation for biogas and composting plants.

## *Scientific Panel on contaminants in the food chain (CONTAM)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: Risk assessment of Contaminants in Animal Feed**

| | |
|---|---|
| **EFSA-Q-2003-031**<br>**EFSA-Q-2003-032**<br>**EFSA-Q-2003-033**<br>**EFSA-Q-2003-034**<br>**EFSA-Q-2003-035** | **Arsenic**<br>**Lead**<br>**Cadmium**<br>**Fluorine**<br>**Aflatoxin B1** |
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

| | |
|---|---|
| **EFSA-Q-2003-036**<br>**EFSA-Q-2003-037**<br>**EFSA-Q-2003-038**<br>**EFSA-Q-2003-039**<br>**EFSA-Q-2003-066**<br>**EFSA-Q-2003-067**<br>**EFSA-Q-2003-068** | **Deoxynivalenol**<br>**Zeralenone**<br>**Ergot**<br>**Ochratoxin A**<br>**Endosulfan**<br>**Gamma-HCH**<br>**Toxaphene** |
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | June 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

| | |
|---|---|
| **EFSA-Q-2003-040**<br>**EFSA-Q-2003-061**<br>**EFSA-Q-2003-062**<br>**EFSA-Q-2003-063**<br>**EFSA-Q-2003-064**<br>**EFSA-Q-2003-065** | **Fumonisin**<br>**Glucosinolates**<br>**Ricin**<br>**Tropane alkaloids**<br>**Hydrocyanic acid**<br>**Pyrrolizidine alkoloids** |
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

*Purpose*

The requests in the area of undesirable substances in animal feed are related to the Directive 2002/32/EC which came into force 1st of August 2003 where the possibility to dilute contaminated feed is not allowed anymore. Therefore, detailed risks assessments are necessary to enable a complete review of the provisions in the Annex of the Directive, including the establishment of maximum levels for undesirable substances currently not listed. The detailed scientific opinions should comprise the

- determination of the toxic exposure levels (daily exposure) for the different animal species of relevance (difference in sensitivity between animal species) above which
  - signs of toxicity can be observed (animal health / impact on animal health) or
  - the level of transfer/carry over from the feed to the products of animal origin results in unacceptable levels in the products of animal origin in view of providing a high level of public health protection.
- identification of feed materials which could be considered as sources of contamination and the characterisation, insofar as possible, of the distribution of levels of contamination
- assessment of the contribution of the different identified feed materials as sources of contamination
  - to the overall exposure of the different relevant animal species to,
  - to the impact on animal health
  - to the contamination of food of animal origin (the impact on public health), taking into account dietary variations and carry over rates.
- identification of eventual gaps in the available data which need to be filled in order to complete the evaluation.

*Objectives/Milestones for 2004*

- To establish the section persistent organic pollutants (USAF-POPs) and potentially the section botanical impurities (USAF-BIM) of the working group (WG) on undesirable substances in animal feed (USAF) by identifying experts, distributing tasks and setting meeting dates. To complete the preparatory work in the WG on USAF sections mycotoxins and heavy metals in order to have the different opinions adopted by the Panel by the expected date of completion for these requests.

**Sub-area: Risk assessment of Contaminants in Food**

| **EFSA-Q-2003-110** | **Organotin compounds** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | February 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 3 |

*Purpose*

The Commission is considering the possible need to establish maximum levels for organotin compounds in food at Community level, based on the legal framework of Council Regulation EEC 315/93 of 8 February 1993. It therefore seeks scientific advice on the risks to human health from exposure to these compounds. On the basis of current knowledge it should be

assessed which organotins are of most concern for public health and for which there may be an urgent need for measures to reduce their presence in foodstuffs.

*Objectives/Milestones for 2004*
To complete the preparatory work from the WG in order to have the opinion adopted by the Panel by the expected date of completion for this request.

| **EFSA-Q-2003-021** | **Boron and fluorine in mineral water** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | February 2005 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 4-6 |

*Purpose*
Constituents may be present in the natural state in certain natural mineral waters because of their hydrogeological origin and may present a risk to public health above a certain concentration. The scientific opinion will be used to support the scientific basis to establish concentration limits for these constituents in natural mineral waters.

*Objectives/Milestones for 2004*
To review the scientific opinions on similar issues from the NDA panel (upper limits for boron and fluorine) as well as the AFC panel (sources of boron) and to establish a WG dealing with this matter in order to have the opinion adopted by the Panel by the expected date of completion for this request.

| **EFSA-Q-2003-030** | **Mercury** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 3-4 |
| Expected no. of Working Group meetings | 6 |

*Purpose*
At present there is no EU scientific opinion on mercury in food, except for fishery products. The scientific opinion will be used to support the scientific basis for reviewing the legislative measures on mercury in food, aimed to help reduce possible risks to EU consumers. The scientific opinion should assessment of the risks to EU consumers from mercury, in particular methyl mercury, in food. The assessment of the contribution of different foods towards the overall human exposure should be included. Considerations on the respective risks to vulnerable groups should be made, in particular regarding pregnant women, the unborn child and children.

*Objectives/Milestones for 2004*
To establish a working group (WG) on mercury by identifying experts, distributing tasks and

setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

| **EFSA-Q-2003-xx**[29] | **NDL-PCBs** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | November 2003 |
| Date of acceptance | November 2003 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 3-4 |
| Expected no. of Working Group meetings | 6-10 |

*Purpose*
The Commission adopted a Community strategy for dioxins, furans and PCBs addressing measures to limit or to eliminate the emission of dioxins into the environment through source-directed measures and addressing the way to actively decrease the presence of dioxins in feedingstuffs and in foodstuffs. However, for the *non-dioxin-like ("classical" or "non-coplanar")* PCBs*,* which have another toxicological profile and which could be several orders of magnitude more concentrated than dioxins in some feed and food matrices, a risk assessment needs still to be carried out. Also the Committee on Environment, Public Health and Consumer policy of the European Parliament called on 22 April 2002 upon the Commission to propose measures to limit the presence of the non-dioxin-like PCBs in food and feed.

*Objectives/Milestones for 2004*
To establish a working group (WG) on NDL-PCBs looking into the feed and food aspects by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

## II POTENTIALLY UPCOMING REQUESTS FOR SCIENTIFIC OPINIONS IN 2004

**Sub-area: Risk assessment of Contaminants in Animal Feed**

**Mercury**

| Origin of request | European Commission |
|---|---|
| Potential date of receipt | 2004 |
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

**NDL-PCBs**

| Origin of request | European Commission |
|---|---|
| Potential date of receipt | 2004 |

[29] Question number not allocated yet.

| | |
|---|---|
| Expected date of completion | December 2004 |
| Expected no. of Panel meetings | 3-4 |
| Expected no. of Working Group meetings | 6-10 |

**Gossypol**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

**Camelina sativa**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 3-4 |

*Purpose*
The requests in the area of undesirable substances in animal feed are related to the Directive 2002/32/EC which came into force 1st of August 2003 where the possibility to dilute contaminated feed is not allowed anymore. Therefore, detailed risks assessments are necessary to enable a complete review of the provisions in the Annex of the Directive, including the establishment of maximum levels for undesirable substances currently not listed. The detailed scientific opinions should comprise the

- determination of the toxic exposure levels (daily exposure) for the different animal species of relevance (difference in sensitivity between animal species) above which
  - signs of toxicity can be observed (animal health / impact on animal health) or
  - the level of transfer/carry over from the feed to the products of animal origin results in unacceptable levels in the products of animal origin in view of providing a high level of public health protection.
- identification of feed materials which could be considered as sources of contamination and the characterisation, insofar as possible, of the distribution of levels of contamination
- assessment of the contribution of the different identified feed materials as sources of contamination
  - to the overall exposure of the different relevant animal species to,
  - to the impact on animal health
  - to the contamination of food of animal origin (the impact on public health), taking into account dietary variations and carry over rates.
- identification of eventual gaps in the available data which need to be filled in order to complete the evaluation.

*Objectives/Milestones for 2004*
- To establish the section persistent organic pollutants (USAF-POPs) and potentially the section botanical impurities (USAF-BIM) of the working group (WG) on undesirable

substances in animal feed (USAF) by identifying experts, distributing tasks and setting meeting dates. To complete the preparatory work in the WG on USAF sections mycotoxins and heavy metals in order to have the different opinions adopted by the Panel by the expected date of completion for these requests.

**Sub-area: Risk assessment of Contaminants in Food**

**Lead**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-8 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

**Cadmium**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-8 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

**Brominated flame retards**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-8 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

**Ochratoxin A**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-8 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

**Acrylamide**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-10 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

**Semicarbazide**

| | |
|---|---|
| Origin of request | European Commission |
| Potential date of receipt | 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Panel meetings | 2-3 |
| Expected no. of Working Group meetings | 6-10 |

*Objectives/Milestones for 2004*
To establish a working group (WG) on this issue by identifying experts, distributing tasks and setting meeting dates in order to have the opinion adopted by the Panel by the expected date of completion for this request.

## *Scientific Panel on Animal Health and Animal Welfare (AHAW)*

### I ONGOING REQUESTS FOR SCIENTIFIC OPINIONS

**Sub-area: Animal Welfare**

| **EFSA-Q-2003-094** | **Effects on the welfare of the various species during transport. Part 2** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | January 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 3 |

*Purpose*
The Scientific Panel on Animal Health and Animal Welfare has been asked to report on the welfare of animals during transport with consideration of Directives 91/628/EEC and 95/29/EC and Regulation EC/411/98. In particular, the effects on the welfare of the various species transported of: loading densities, travelling times, resting times, watering and feeding intervals and interactions of each of these with the use of upgraded or other vehicles and with any stress during loading and unloading. Other specific questions concern: the welfare of animals on roll-on roll-off vessels, especially during boarding, and the methods which operators and inspectors can use to monitor the welfare of animals during transport.

*Objectives/Milestones for 2004*
- To identify key experts.
- To organise three meetings, three working group and three panel meetings to finalise the tasks.
- To adopt the scientific opinion on the latest the first quarter 2004.

| **EFSA-Q-2003-093** | **Welfare aspects of the main systems of stunning and killing the main commercial species of animals** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | January 2004 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 2 |

*Purpose*
The Panel of Animal Health and Animal Welfare is asked to elaborate an opinion in relation to the welfare aspects of the main systems of stunning and killing the main commercial species of animals. For each method commonly used that the following three areas should be considered:

- The minimal conditions by which the method is likely to be efficient from the animal welfare point of view in field conditions,
- The criteria or procedures that could ensure that the stunning and the killing method is properly enforced,
- The advantages and disadvantages of the method used, taking into account the commercial/field conditions.

Field conditions, by which stunning and killing methods are used in slaughterhouses, differ in many aspects within the framework of disease control measures. For this reason the two separate contexts should be kept in mind for the purpose of this request.

*Objectives/Milestones for 2004*
- To identify experts in the area of stunning.
- To organise a two working groups and three plenary meetings to discuss the scope of the mandates and the drafting of the document
- To adopt the scientific opinion not later than the first quarter of 2004.

| **EFSA-Q-2003-091** | **Welfare aspects of the castration of piglets** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | September .2003 |
| Expected date of completion | May 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 5 |

*Purpose*
The Commission asks the European Food Safety Authority to issue a scientific opinion on the welfare aspects of the castration of piglets. The mandate does not include some essential aspects, and should take into account an integrated approach of the food chain which could have consequences for the Consumer and the Animal Health. Therefore the Panel AHAW has proposed to amend (in bold) the mandate as follows:

- *Welfare aspects of various methods for the castration of piglets, including methods of analgesia and anaesthesia that may be used*, and consequences for the animal health.
- *The state of art concerning techniques and systems of pig production which would be likely to reduce the need to resort to surgical castration*, and
- The impact of suppression of the castration *on* the organoleptic quality of the meat and the effects on the consumer (refusal/repulsion).
- The state of art concerning in meat processing technology which would be likely to reduce the need to resort to surgical castration,

*Objectives/Milestones for 2004*
- To identify key experts, networks, university groups, research institutes, in that area.
- To organise a 5 working group meetings and 2 Panel meetings to define the best strategy to take into consideration the food chain.
- To adopt the opinion not later than mid 2004.

| **EFSA-Q-2003-092** | **Welfare aspects of various systems of rearing laying hens** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | March 2005 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 8 |

*Purpose*
The Commission requests the European Food Safety Authority to issue an opinion on the welfare aspects of the various systems of rearing laying hens. The mandate does not include some essential aspects, and should take into account an integrated approach of the food chain which could have consequences for the Consumer Animal Health and the Public Health. Therefore the Panel AHAW has proposed to amend (in bold) the mandate as follows:

- *The state of art regarding rearing and housing systems for laying hens, with special reference to those systems described in Council Directive 1999/74/EC and enriched cages in particular, and its impact in the Animal Health.*
- *The ability of these systems to satisfy the physiological and ethological needs of the animals and provide for good animal welfare Animal Health and, zoo technical aspects of these systems.*
- *The implication of these systems towards obtaining safe eggs for the consumers.*

*Objectives/Milestones for 2004*

- To identify key experts, networks, university groups, research institutes, in that area.
- To organise 8 working group meetings and 3 Panel meetings to define the best strategy to take into consideration the food chain, public health and animal health.
- To adopt the opinion not later than the first quarter of 2005.

| **EFSA-Q-2003-085** | **Standards for the microclimate inside animal transport road vehicles** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | March 2004 |
| Expected no. of Panel meetings | 2 |
| Expected no. of Working Group meetings | 4 |

*Purpose*
To assist EFSA in building the Authority's capability for identification and evaluation of emerging risks

*Objectives/Milestones for 2004*

- To identify key players, networks, university groups, research institutes, national food authorities, industry associations etc. active in the area of emerging risks.
- To organise a workshop to define a possible strategy for the Authority to handle emerging

risks
- To develop and implement a strategy for the consideration of emerging risks

## II POTENTIAL UPCOMING REQUESTS FOR SCIENTIFIC OPINION IN 2004

**Sub-area: Animal Health**

**Scientific review of new tools for eradication on the OIE list A and B of diseases**

| | |
|---|---|
| Origin of request | EFSA and European Commission |
| Potential date of receipt | 2004-2005 |
| Expected date of completion | December 2004-2005 |
| Expected no. of Panel meetings | 3 |
| Expected no. of Working Group meetings | 20 |

*Purpose*
Proposal for Scientific reviews. The proposed task should fulfil the Authority's objectives in the framework of the activities of AHAW panel and give support to the managers in their decisions. Strategies may change according to new knowledge, therefore could exist the need to regularly update the latest findings on new tools for eradication. Diseases to be reviewed were Classical swine Fever, Foot and mouth disease, Avian influenza, Blue Tongue, Infectious Salmon anemia, Rabies, Rift Valley fever, African Horse sickness and from the B list Tuberculosis and Brucellosis.

The chairman and the scientific coordinator will check with OIE/WHO in order to avoid any overlapping of possible current tasks. A very close follow up of alerts should be necessary as well as Member states support in data and experts.

*Objectives/Milestones for 2004*
- To identify the most relevant diseases to be reviewed in order to set priorities and a working plan.
- To identify key players, networks, university groups, research institutes, national food authorities, industry associations etc. active in the area for those diseases.
- To organise a groups of experts in a permanent contact with the Authority, to define a possible strategy to handle possible re-emerging risks.
- To develop a periodically review of those diseases by the end of each year.

# Other Scientific Activities

### Pesticide Risk Assessment Peer Review (PRAPeR)

### 1. EXISTING ACTIVE SUBSTANCES (2ND STAGE OF THE REVIEW PROGRAMME)

**Peer Review of the initial evaluation reports for 52 existing active substances of the 2nd stage**

**Substances:** Glufosinate, Tribenuron, Trifluralin, Tolylfluanid, Rimsulfuron, Oxamyl, Diuron, Triticonazole, Dimethenamid, Fosetyl, Captan, Folpet, Dichlorvos, Tolclofos-methyl, Fenitrothion, Pirimicarb, Pirimiphos-methyl, Triazamate, Clodinafop, Trinexapac, Fenamiphos, Cyprodinil, Ethephon, Triclopyr, Metconazole, 1,3-Dichloropropene, Oxydemeton-methyl, Dimethomorph, Dichlorprop-P, Naled, Fipronil, Ethoprophos, Thiodicarb, Haloxyfop-R, Clopyralid, Malathion, Metribuzin, Propamocarb, Methiocarb, Phosalone, Pyrimethanil, Formetanate, Diazinon, Benfuracarb, Cadusafos, Carbofuran, Carbosulfan, Dimethoate, Methomyl, Carbaryl, Trichlorfon, Phosmet

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | January 2003 – April 2004 |
| Expected date of completion | 12 months after the date of receipt |
| Expected no. of Working Group meetings | 40 |

*Purpose*
As provided by Regulation (EC) No 451/2000 as amended by Regulation (EC) No 1490/2002, EFSA has the obligation to peer review the draft assessment reports provided by rapporteur Member States (RMS) for 52 existing active substances of the 2nd stage of the review programme within 12 months after provision each report. Based on the (proposed) submission dates of these draft assessment reports, the Authority's conclusion on the risk assessment is expected to be finalised for approximately 36 substances in 2004 and for 16 active substances in 2005 according to the timing of the following table (expected dates are formatted italic).

*Objectives*
For the peer review of these draft assessment reports representing the initial evaluation by the rapporteur Member State a consultation of the Member States and the public will be organised. The outcome of this consultation will be evaluated by the respective rapporteur Member State taking into consideration possibly requested further data and will be further discussed in expert meetings. Particular contentious issues will be addressed to the Scientific Panel PPR.

*Milestones for 2004*
- Consultation of Member States and the public on draft assessment reports which have not been organised in 2003 (approximately 25 active substances).
- Discussion of active substances as far as necessary in 4 rounds of each 5 expert meetings covering different fields of expertise (physico/chemical properties and analytical methods, toxicology, residues, fate and behaviour, ecotoxicology).
- Discussion of the rapporteur Member State conclusions and the draft conclusions in general expert meetings.

## 2. EXISTING ACTIVE SUBSTANCES (3RD STAGE OF REVIEW PROGRAMME)

**Assessment of rapporteur Member States (RMS) reports on completeness of dossiers for 79 existing active substances of the 3rd stage**

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | November 2003 – May 2004 |
| Expected date of completion | 2 months after submission of RMS report |

*Purpose*
To assess the reports on completeness of dossiers for 79 active substances of the third stage provided by the respective rapporteur Member States as provided by Art. 9 (1) of Regulation (EC) No. 1490/2002.

*Objectives/Milestones for 2004*
As given by the Regulation, the rapporteur Member States have to conduct a check for completeness of the submitted dossiers and report to EFSA on the completeness within 6 months after receipt of the dossier. Deadline for submission of dossiers to the rapporteur Member States as given by the Regulation was 30 November 2003.
Upon receipt of the report by the rapporteur Member State, the Authority has to assess this report and has to report to the Commission at the latest within 2 months.

## 3. NEW ACTIVE SUBSTANCES

**Peer Review of the initial evaluation reports for approximately 13 new active substances**

**Substances:** Dimoxystrobin, 1-methylcyclopropene, Bispyribac-sodium, Fluoxastrobin, Metrafenone, Spirodiclofen, Benalaxyl-M, Benthiavalicarb, Prothioconazole, Spiromesifen, Sulfuryl fluoride, Potassium phosphate, Cyflufenamide

| | |
|---|---|
| Origin of request | European Commission |
| Date of receipt | August 2003 – December 2004 |
| Expected date of completion | 2004-2005 |
| Expected no. of Working Group meetings | No additional meetings foreseen; substances will be discussed in the meetings organised for existing active substances |

*Purpose*
To peer review the draft assessment reports provided by rapporteur Member States for approximately 13 new active substances. The dates of receipt are given as date of submission or estimated on a 12-months period based on the dates of the completeness decision. Although there is no legal deadline, it is the Authority's intension to conclude on the risk assessment without unnecessary delays within 12-18 months. The timing is giving in the following table (expected dates are formatted italic).

*Objectives*

For the peer review of these draft assessment reports representing the initial evaluation by the rapporteur Member State a consultation of the Member States and the public will be organised. The outcome of this consultation will be evaluated by the respective rapporteur Member State taking into consideration possibly requested further data and will be further discussed in expert meetings. Particular contentious issues will be addressed to the Scientific Panel PPR.

*Milestones for 2004*

- Consultation of Member States and the public on those draft assessment reports which have not been organised in 2003 (approximately 8 active substances)
- Discussion of the active substances as far as necessary in 4 rounds of each 5 expert meetings covering different fields of expertise (physico/chemical properties and analytical methods, toxicology, residues, fate and behaviour, ecotoxicology) organised for the evaluation of existing active substances
- Discussion of the rapporteur Member State conclusions and the draft conclusions in general expert meetings

**Biological Hazards related subjects but not under the responsibility of the Scientific Panel on Biological Hazards**

**GBR-UNIT**

| **EFSA-Q-2003-083** | **Geographical BSE Risk Assessment – GBR: risk assessment for the appearance of BSE in a country** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Working Group meetings | 15 |

*Purpose*
To advise on the risk assessment for the appearance of BSE in a country of the countries mentioned hereafter, and in the following order of priority

- Canada ( review of the current GBR II classification after its first BSE case)
- GBR I countries with major export to the EU: Botswana, Namibia, Swaziland, Australia and Norway ;
- Other GBR I countries: El Salvador, Nicaragua and Panama which export to the European Union to a more limited extent ;
- Sweden;
- Major trading partners in GBR II: USA and Mexico

*Milestones for 2004*
January-March 2004
- Canada file completed
- Africa files and south American files (GBR I countries) reviewed and contacts established
- Proposed visits to countries planned and Chief Veterinary Officers contacted
- Norway and Sweden files reviewed and countries visited.
- Australia, USA and Mexico files reviewed

April-June 2004
- All countries on list visited
- All files reviewed and updated with new data.
- All files for discussion in WG presented and advice adopted
- All results communicated to the Commission services.

**TSE TEST EVALUATION UNIT**

| **EFSA-Q-2003-084** | **TSE Testing – validation of diagnostic tests including Live Animal tests** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | May 2003 |
| Date of acceptance | May 2003 |
| Expected date of completion | Mid 2004 |
| Expected no. of Working Group meetings | 7 (3 completed) |

*Purpose*
To organise the evaluation and validation process of submitted test for TSE diagnosis in ruminants, including Live Animal tests.
Following the publication (in the O.J. C 15 of 22 January 2003) of an open call for the expression of an interest to participate in a program for the evaluation of tests for the diagnosis of TSEs in ruminants, around 20 proposals for new tests have been received. These include new post mortem and live animal tests.

A breakdown of the tests received:
- 12 proposals for Post Mortem tests
- 2 proposals for scrapie tests
- 1 proposal for CWD
- 6 proposals for live animal tests

*Milestones for 2004*
January –June 2004
- Tests results of the laboratory evaluation available
- WG meeting(s) to discuss outcome of laboratory evaluation completed
- Companies informed about the outcome
- Tests selected for further field evaluation trial forwarded to the IRMM

June – October 2004
- Tests results of the field evaluation available
- WG meeting(s) to discuss outcome of field evaluation completed
- Advice on validation of tests communicated to the Commission (both on PM tests and Live Animal tests.
- Companies informed about outcome

A scientific support unit has been created and a number of meetings were held during which the first screening of the applications and selection was done. The companies have been informed about the outcome and currently the task is now being handed over to the IRMM for further organisation of the laboratory and field trial evaluation (BSE PM tests and scrapie tests). For the Live animal testing a protocol for the field evaluation is being prepared and when finalised and adopted the evaluation will start. In between the different stages of the evaluation, the expert group will meet and evaluate the results.

| **EFSA-Q-2003-077** | **Evaluation of rapid TSE tests intended for small ruminants (AFSSA report)** |
|---|---|
| Origin of request | European Commission |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | Early 2004 |
| Expected no. of Working Group meetings | 2 |

*Purpose*

To assess the outcome of the evaluation of rapid TSE post mortem tests on tissues from small ruminants, taking also into account the opinion of AFSSA, and to give recommendations on the approval of the tests.

*Milestones for 2004*
January 2004

- Dossier completed and recommendations formulated

**ZOONOSES UNIT**

***Proposed activities:***

**Call for tenders to compile the Annual European Report on zoonoses**

| **EFSA-Q-2003-096** | **Zoonoses and zoonotic agents in the frame of EFSA** |
|---|---|
| Origin of request | New legislation |
| Date of receipt | September 2003 |
| Date of acceptance | September 2003 |
| Expected date of completion | Mid 2004 |

*Purpose*

Under Regulation (CE) No 178/2002, in the Article 33 is stated that the Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission and particularly on the incidence and prevalence of biological risks. This work has been carried out by the CRL in Berlin in the application of the Council Decision 92/117/CEE.

A new Directive has replaced Council Decision 92/117/CEE has been adopted in 29.09.03. The new Directive in its Article 9 foresees that the Authority shall examine the reports Member States transmit to the Commission every year and publish a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the Community.

The Community Reference Laboratory for Zoonoses (CRL) in Berlin has being committed by SANCO to carry out the work from the past 10 years and again in 2004 after agreement by EFSA.

The Authority will need to launch a call for tenders by March 2004 to outsource the compilation of the report for 2005 onwards.

New legislation:
Directive on the monitoring of zoonoses and zoonotic agents amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (adopted 29.9.2003)
Regulation of the European Parliament and of the Council on the control of salmonella and other specific food-borne zoonotic agents (adopted 29.9.2003)

*Milestones for 2004*

March 2004 to launch the call for tenders
May 2004 to close the call for tenders
June - July 2004 Evaluation of the received proposals
August 2004 publication of the outcome

**Task Force on the improvement of the Annual European Report on zoonoses (towards data harmonisation as laid down in the new Directive)**

| **EFSA-Q-2003-096** | **Zoonoses and zoonotic agents in the frame of EFSA** |
|---|---|
| Origin of request | New legislation adopted 29.09.03 |
| Date of receipt | June 2003 |
| Date of acceptance | July 2003 |
| Expected date of completion | End 2004 |
| Expected no. of Working Group meetings | 4 WG to be set up<br>8 participants per WG<br>3-4 meetings per WG |

*Purpose*
The new zoonoses directive is covering: The monitoring of zoonoses and zoonotic agents, the monitoring of related antimicrobial resistance, the epidemiological investigations of food-borne outbreaks and the exchange of information related to zoonoses and zoonotic agents

The Basic principles of the Directive are:

- Data need to be comparable
- Monitoring should in principle cover all stages of the food chain
- The scope of the monitoring of antimicrobial resistance needs to be flexible
- MS's shall assess trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in their territory
- Each MS's shall send to the Commission every year a report on the above topics
- The commission shall send the reports referred to the Authority
- The Authority will examine and publish a summary report on the trends and sources of zoonoses, zoonotic agents and antimicrobial resistance in the community as well as the summarised results of coordinated monitoring programmes.

The new Directive mentions that in the current system:

- ❖ Data collection systems are not harmonised and therefore do not permit comparisons between Member States
- ❖ The SCVPH in its opinion on zoonoses adopted on12/4/2000 considered:
    - The measures in place to control food-borne zoonotic infections were insufficient
    - The epidemiological data Member States were collecting were incomplete and not fully comparable

Other considerations are:
New zoonotic agents to be monitored have been included in the new Directive.
By May 2004, the data collected and compiled will increase from 15 to 25 countries. This will lead to a situation far more complex than before in terms of comparability of data.

Concerning all the above, we would like to have a pro-active approach and settle down a Task Force involving independent experts, NRL's, the CRL in Berlin, Member States through the Advisory forum of the Authority and Commission services to deal with the weakest points of the current zoonoses system. The general idea will be to focus in a few points in order to make an attempt to improve the current report towards the basic principals of the new directive.

*Milestones for 2004*
Early 2004
Meeting with stakeholders (in this case data providers and risk managers from the Public Health side and from the Food Safety side).
To get an agreement on priorities to be set up in the Authority's a Task Force in 2004 to progress towards the objectives laid down in the New Directive on harmonisation and comparability of data.
To establish several WG to develop a report on recommendations and guidelines on the identified priorities for the improvement of the zoonoses annual report.

October 2004
Reports to be finalised and discussed in the framework of the annual workshop meeting in the CRL (with the permission of the Commission, who is funding the workshop) towards a revision and update of the Community Annual Report and National Reports.

End 2004
Reports sent to Commission services.