

### **European Food Safety Authority**

## **EXPLANATORY NOTE TO THE BOARD**

(Not part of the Management Plan)

- a) The following document provides a framework for the provisional Work Programmes with supporting information and Establishment Plan of the European Food Safety Authority for 2006. Together these elements form the Management Plan of the Authority for 2006.
- b) At this early point in 2005, the 2006 provisional Work Programmes should be considered as a continuation of the Work Programmes of 2005 adopted by the Board in January 2005. Much of the work of the Authority does not coincide with the start and end of the calendar year and therefore many activities started in 2005 will continue into 2006 and beyond, or be on-going. Therefore in considering this document, which establishes the direction for the Authority in 2006 and its main activities, **the Board is asked to take into account the Work Programmes for 2005**, particularly those elements which are of a multi-annual nature as the starting basis for the 2006 Work Programmes.
- c) The Board will also be asked at the March 2005 meeting to endorse the draft budget for 2006. Once the budgetary Authority has reached a conclusion on the budget for 2006 (anticipated in December 2005) it will be necessary to revisit this preliminary work programme and seek adoption by the Board during January 2006. The intention would be therefore to introduce in late 2005 a more detailed document to the Board for comment and input. A finalised draft would then be put to the Board in January 2006 for adoption in light of the Budget decision, comments received from the Board, the Advisory Forum and the European Commission.
- d) As with previous EFSA Management Plans it should be noted that this document can only provide predictive planning information and there has to be significant flexibility

for the formation of the detail of the work programme during 2005. Also due to the nature of the work of the Authority, questions may be put to it at any time during 2006 some of which, by their very nature and level of complexity, may have a significant effect on work in other areas.

- e) In order to draw up the more detailed Work Programme for 2006 discussions will be held with the Advisory Forum during 2005 and with Directorate General for Health and Consumer Affairs of the European Commission.
- f) It should also be noted that although 2006 will still be a build-up year for EFSA, it is possible to base predictive estimates of work load more accurately on the experiences gained during 2004 and 2005 for the scientific programmes and also those in other areas.

#### **Adoption of the Management Plan**

The Board is asked to consider this document in its entirety noting in particular that the endorsement of the Work Programme elements is important as this provides the basis for the Authority's budget justification.

It should be noted that the Establishment Plan may be revised by the European Parliament in line with the provisions of the Financial Regulation.

The Board will be asked to reflect on this document once again in 2005 and January 2006 in light of the outcome of the discussion in the Budgetary Authority, the Advisory Forum and following consultation with the European Commission. The final plan will be put forward for adoption in January 2006.

The founding Regulation gives guidance to the Board in relation to its adoption of the Work Programmes of the Authority.

- 1. to consider the budget placed at the disposal of the Authority,
- 2. to ensure that the Work Programmes are consistent with the Community's legislative and policy priorities in the area of food safety.

Clearly the first guidance point can only be relevant following the adoption of the budget by the Budgetary Authority.

The Board is therefore asked to adopt this preliminary document provisionally.

## **DRAFT**

## PRELIMINARY MANAGEMENT PLAN OF THE EUROPEAN FOOD SAFETY AUTHORITY FOR 2006

Document providing the predicted work of the Authority during 2006 both in relation to its annual and multi- annual work programmes

#### **Establishment Plan 2006**

Submitted to the Management Board at its meeting of 9 March 2005

Done at Parma, on

Dr Stuart Slorach

Chair

European Food Safety Authority (EFSA) Palazzo Ducale Parma

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## I. General overview of the Authority during 2006 in relation to its Annual and Multi- annual Work Programme activities

- 1. In 2006 the European Food Safety Authority (EFSA) will be in its 4<sup>th</sup> year of operation although still in its build up phase. All of its activities will have transferred to its Seat in Parma and therefore 2006 should offer the organisation and its staff stability and a firm basis for further development. The competences and capabilities established by the Authority since the adoption of the Founding Regulation will continue to be built and consolidated and new initiatives put into place to ensure that the Authority fulfils its mandate.
- 2. In particular the significant development of both the Authority's scientific and communications functions since 2002 will continue into 2006 enabled by appropriate operational and administrative support. The emphasis will be on strengthening the Authority's reputation as an organisation dedicated to scientific excellence, independence, openness and transparency. The work of the Authority's Scientific Committee and Panels, their meetings and the management of their work will continue to be the major element of the Authority's work during 2006.
- 3. The staffing of EFSA and in particular the scientific staff will be increased in line with the increasing work load of the Authority. In particular further staffing is needed: to support the work of the Authority's Committee and 8 Scientific Panels, and, to manage projects studies and tasks allocated to outside bodies, and to provide an in-house source of scientific expertise in a range of scientific areas.
- 4. The work load of EFSA is particularly affected by a high number of legislative proposals. Therefore in planning terms the Authority has to ensure that it considers priority setting and recruitment as regards new legislation entered into force in 2005 and in anticipation of the new legislation coming into force in 2006. (e.g. Health Claims and fortification of foods, novel foods other than GMOs, new framework regulations on food additives, flavours and enzymes).
- 5. During 2006 the Authority will continue through the work of the Advisory Forum to foster close collaborative relations with the national agencies and authorities in the enlarged Europe. The Forum which brings together the heads or scientific directors of the national agencies provides the Authority with advice on emerging concerns and facilitates the exchange of scientific data and information. This increasing practice of exchanging information on EFSA and national activities, information and data, both at and in-between meetings will be further developed in 2006.
- 6. Information exchanges via the Advisory Forum will continue to be particularly beneficial in co-ordinating at European level, information that existed at national level on specific topical issues. Such specific exchanges via questionnaires, requests for specific data will be used in 2006 particularly where EFSA's Scientific Panels or Committee have identified a need for background data and

information. The assimilated data will then be made available to all those participating, as well as EFSA itself

- 7. The Working Groups of the Advisory Forum have served to provide a practical basis for the exchange of information through an IT infrastructure and platform and are now well established in disseminating scientific and communications information. The EFSA Extranet developed by the IT Working Group will be further developed and will become fully functional in 2006. The infrastructure will be useful not only in periods of normal activity but will be particularly important during emerging crises situations. Networking of scientific bodies and institutes will also be further developed during 2006 for such exchanges
- 8. The Communications Working Group which provides a forum for exchange of communications and a basis for co-ordination of communications activities between the national authorities and EFSA will also continue its activities in 2006. The objective will be to ensure that EFSA and its key partners develop communications activities in a collaborative and co-ordinated manner.
- 9. EFSA will also enhance its collaboration with competent organisations designated by the Member States under Article 36 of EFSA's Founding Regulation and approved by the Management Board based on a proposal from the Executive Director. It is foreseen that where possible and preferable a number of specific projects will be outsourced in 2006 to Article 36 competent organisations. This will further strengthen the collaboration between EFSA and Member States. In addition the Authority will, where necessary, identify and commission preparatory scientific work and studies from external contractors in the context of delivering its overall remit, tasks and obligations, whilst maintaining the overall responsibility for the quality of the work carried out on its behalf.

#### **II. Overall Management Activities**

- 10. The management capabilities and infrastructure, the administrative and other support mechanisms needed to run a complex organisation will continue to be built during 2006 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.
- 11. The Management Board will have an important role to play in guiding the Authority through 2006 ensuring that the necessary resources are available to fulfil and carry out the Authority's missions and tasks within the budget available to it. In line with the Authority's Founding Regulation, during 2006, the Commission will launch a call for expression of interests for 7 places on the Board from across Europe, with the ultimate selection of the successful candidates being undertaken by the Council following consultation with the European Parliament. Therefore new members for some places on the Board can be expected to be selected towards late summer 2006.
- 12. The management of the Authority through this critical period of growth will continue to present significant challenges. The management team of the Authority led by the Executive Director will need to be able to manage a growing organisation while putting in place any recommendations from the Authority's review undertaken in 2005.
- 13. The staff of the Authority have been and will continue in 2006 to be selected for their excellence and competence. Consideration will be given to the appointment of staff from all parts of the EU area including the Accession states. In the main, staff will be engaged with the status of temporary agents. Other support solutions to the work of the Authority will also be utilised through the input of Detached National Experts, Auxiliary and Interim staff. EFSA will develop further its 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.
- 14. During 2006 the tenure of the existing Scientific Panels and Committee will come to an end and therefore the Authority will put in place a call for expression of interests to re-establish these bodies. As with the existing membership scientists will be chosen on the basis of their scientific excellence and experience in carrying out risk assessments. Current members may apply for re-election. In addition EFSA will encourage new Member States to enhance proposals for candidature from scientists from these countries. As with the previous call in 2003, the members of the Advisory Forum will be consulted for their views on the short list drawn up by the Executive Director. The Management Board will in accordance with the Founding Regulation decide upon the final list of members, as proposed by the Executive Director.

- 15. EFSA will continue to foster good relations with the national, regional, provincial and commune authorities in Parma to ensure that the impact on the area remains positive and of mutual interest and benefit. In this respect EFSA will put in place a number of initiatives to engage these authorities and members of civil society in its activities including meetings of the EFSA Liaison Committee established in 2005 and through a series of presentations on EFSA work to those with an interest in EFSA's work.
- 16. In 2006 EFSA will consider its actions in relation to the report of the Article 61 Review carried out by the independent external evaluation of its achievements commissioned by the Authority in 2005. The impact of the report on the Authority in terms of working methods, practices or emphasis will be examined and the impact of any recommendations assessed. The Board shall make recommendations to the Commission regarding changes to the Authority and its working practices so that any legislative changes needed to the remit, missions or tasks of the Authority may be considered by the Commission which can take such recommendation forward. The Authority will participate in any discussions with the Commission concerning changes to the Authority's mandate and remit where these are proposed by the review report.
- 17. EFSA will also make progress during 2006 in establishing a permanent building in Parma which is capable of housing all staff and meetings when EFSA is at full capacity.
- 18. The in-house procedures for the operation of the Authority in a crisis will be kept under review and enhanced as necessary in the light of experience and taking also into account the Joint EFSA/Commission crisis simulation exercise carried out during 2005.
- 19. In 2005 EFSA the work on Progress Indicators will develop initially providing management information in a quantitative manner. Data relating to these Indicators will be assessed by the Board on a quarterly basis and will be publicly available. These will be reviewed in 2005 so that any adjustments can be made to enhance the information provided and during 2006 EFSA will continue to work towards putting in place not only quantitative indicators but also qualitative and where possible impact indicators.

#### **III. Scientific Activities**

- 20. The Scientific Panels and Scientific Committee all have established extensive work programmes to address the questions posed to them. In the main it is expected that their work programmes will be derived from requests from the European Commission, European Parliament, Member States and from those 'self-tasked' by the Executive Director on matters of concern brought to his attention as warranting serious consideration. Such self tasking activities although limited in number will continue to be an important element of EFSA's work in 2006 particularly in areas where harmonising work is required, where important horizontal matters need to be addressed and where public health matters are brought to EFSA's attention. EFSA is also likely to receive an increasing number of questions from Member States and from the European Parliament.
- 21. All requests for opinions will be assessed in terms of their priority and also in terms of ensuring that the best and most appropriate means is applied to addressing the request. In this respect where scientific information is requested which does not warrant full consideration of the Scientific Committee or Panels (e.g. where the science is well established) EFSA will consider in close consultation, as appropriate, with the Chair of the panel responsible for the matter whether such a response can be prepared by EFSA's scientific staff.
- 22. EFSA scientific work has thus far been focussed around four major themes as follows:
  - Providing scientific opinions, guidance and advice in response to questions from the European Commission, the European Parliament, the Member States or by the Authority itself;
  - Assessing the risk of specific groups of regulated substances and developing proposals for risk-related factors, following legally defined notification procedures and time schedules.
  - Monitoring of specific risk factors and animal diseases and providing scientific opinions on test and other tools to control these risk factors and diseases. E.g. geographical BSE risk assessment, validation of BSE/TSE diagnostic tests, the monitoring of zoonoses and other food-borne zoonotic agents, and the scientific review of new tools for the eradication of specific animal diseases;
  - Development, promotion and application of new and harmonised scientific approaches and methodologies for hazard and risk assessment of food and feed.

In addition, as a follow-up to previous Commission initiatives (SCOOP), EFSA's scientific activities will include the development and maintenance of data bases on European food consumption patterns, exposure data of defined population subgroups (including pregnant women, infants and elderly people) and chemical formation and occurrence data.

- 23. During 2006 these themes will continue to provide the driving force for the Authority's scientific work taking into account: i) the growing experience in EFSA dealing with the work of the Scientific committee and Panels since their foundation in 2003, ii) the development of new or revised legislation that may enter into force in 2005 or 2006, and iii) the need to invest in scientific developments in the area of food safety assessment.
- 24. In 2005 the preparatory work for the establishment of a new sub-panel on Plant Health will be completed and the work will start. It is expected that questions for the new Panel will be numerous.
- 25. The NDA Panel will dedicate substantial resources in 2006 on the development of advice concerning dietary intakes, in particular on population reference intakes for macro-and micronutrients.
- 26. The work involved in the risk assessment of regulated substances (second theme), and the monitoring of specific risk factors, zoonoses and animal diseases (third theme) will most likely further expand in 2006 and exceed those already recognised in 2005:
  - Risk assessments of existing active pesticide ingredients, stage 3 (Regulation 1490/2002);
  - Risk assessments of GMO's according to Directive 2001/18/EC on deliberate release into the environment;
  - Risk assessment of GMO's according to Regulation 1829/2003 on genetically modified food and feed;
  - Assessment of the safety and efficacy of new substances and products in animal feed according to Regulation 1831/2003;
  - The verification of approximately 7000 dossiers of existing feed additives for completeness and quality will hopefully be completed in 2005 but may continue in 2006;
  - Re-evaluation of food colourings and other food additives;
  - Risk assessment of substances for use in food supplements according to Directive 2002/46/EC;
  - Risk assessment of smoke flavourings in the context of Regulation 2065/2003;
  - Risk assessments in relation to proposals for internationally harmonised maximum residue levels (MRLs) for pesticides;
  - Reporting of monitoring data on MRL's and the maintenance of the data base for this information;
  - Annual summary report on zoonoses in accordance with Directive 2003/99/EC;
  - Collection, reporting, and analyses of food-borne outbreaks;
  - Harmonisation of national monitoring and reporting approaches of zoonoses:
  - The GBR assessment for different countries;
  - Evaluation of diagnostic tests for TSE: and
  - Review of new tools for the eradication and containment of animal diseases.

- 27. To this list additional assessment activities are likely to be added, most notably in the areas of nutritional profiles/food health claims, fortification and plant health.
- 28. The Scientific Expert Services Division will continue to be built up in 2006. This group of experts from various fields key to EFSA work will expand and consolidate further the in-house support to the work of the Scientific Committee, Panels and other Expert Groups. Their main priorities will be the preparatory work of the highest standard to facilitate the work of all EFSA Expert Groups ensuring that the available time of members of these bodies can be used in the most efficient way by focusing on the fundamental issues and the resulting development of scientific opinions.
- 29. The following activities of horizontal scientific nature which were initiated in the years 2004/2005 will continue in 2006: the development and implementation of appropriate strategies in agreement with the Authority's policy in the field of animal welfare; activities in the area of transparency in risk assessment and the development of an appropriate paradigm for risk/benefit evaluations; the further building up of resources and infrastructure in the field of data mining, data collection and exposure assessments in support of the scientific evaluations to be carried out and a further expansion of in-house support in the area of toxicological and epidemiological support to the work to be conducted by the Scientific Panels, Committee and the Scientific Expert Working Groups. Where appropriate scientific colloquia will be organised for scientific debates on issues of relevance in the area of food and feed safety science with the general aim to provide a suitable fundament for further considerations by the Authority."
- 30. Experts from the Authority will participate in scientific cooperation networks whose aim is the coordination of activities, the exchange of information, the development and implementation of joint projects, and the exchange of expertise and best practices in the fields within the Authority's mission.
- 31. The further enhancement of the Authority's ability to be proactive with regard to the identification of emerging risks and other emerging possible food safety matters will be pursued. The overall competence of EFSA in this respect will require its continued effort to exchange information on food safety matters with the national agencies and authorities and the Commission via the Advisory Forum and the EFSA Extranet
- 32. In 2006, the Authority will again organise 3-4 Science Colloquia, addressing fundamental science issues in the area of food safety. In addition, all Panels will arrange for public consultation meetings and hearings on a variety of subjects.
- 33. Considering the overall workload, the need to maintain an appropriate balance between the 4 themes above, and taking into consideration the logic for priority setting established in the Authority's Management Plan for 2004 and 2005, the criteria for priority setting remain as defined in the 2005 Work Programme:
  - The anticipated public health impact,
  - Legal obligations and deadlines,
  - Level of urgency as indicated by the originator of the question.

Also to be taken into consideration but in no particular order:

- Possible connections between the project and other activities already being addressed,
- The level of public interest taking into account the feedback and input from stakeholders the media,
- Economic importance of the subject/issue,
- The balance of work.

#### IV. Communication Activities

- 34. The Authority will continue to focus on its risk communication strategy providing appropriate communication on food and feed safety risk and the monitoring of the effectiveness of such communication. 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 continue to 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.
- 35. In 2006 EFSA will follow up on its activities related to its work on risk perception to ensure that the messages it relays with the national authorities, for further dissemination to interested parties and the public at large, are appropriately formed, timely and targeted. EFSA will continue to progress its communications activities in 2006, reaching a wider audience with targeted messages on food safety issues, adapted to the needs of key audiences. The communications strategy will be fully integrated with risk assessment activities and take into account consumer and key stakeholder requirements. EFSA will also continue to adapt and update its website in order to facilitate public access to its work and documents, meet information requirements and ensure a more user-friendly interface.
- 36. The establishment of an expert advisory group on risk communications in 2006 is foreseen to continue is activities into 2006. This multi-disciplinary group of experts will assist EFSA in the implementation of its mission with regards to risk communications by providing advice, on an informal basis, regarding the development and implementation of its risk communications strategies and plans. It is expected that this group will provide EFSA with an annual review on key themes addressed in risk communications.
- 37. The Authority's commitment to openness and transparency of its work will be developed further during 2006. This will be undertaken in several guises, notably through the general policy to publish its scientific findings immediately and to publicly share documents used to develop its opinions, where feasible, to ensure that the activities of the scientific Panels and Committee are well publicised, the papers of the Management Board and Advisory Forum are openly available and the meetings of the Management Board are publicly accessible both in terms of webstreaming and to those wishing to attend in person

#### **V External Relations**

- 38. The Authority will continue to involve stakeholders in all appropriate aspects of the work and in line with the Authority's overall objectives to play its part in the development of consumer confidence in the safety of the food supply. The Authority will continue to engage in dialogue and seek feedback from its stakeholders in order to ensure that its goals, priorities and outputs are in line with expectations. This will include in 2006 open consultation on scientific issues either via the web, scientific colloques or public meetings, and the ability for stakeholders to access and review the register of questions and submit information on a scientific topics.
- 39. The Stakeholder Consultative Committee will meet twice in 2006 and will consider in detail the approaches to be taken to enhance stakeholder dialogue with EFSA. In addition EFSA will organise a Stakeholder Colloque which enables a wide participation of interested parties to exchange dialogue with EFSA on the key concerns. EFSA will also continue its practice of close bilateral relations with stakeholder organisations.
- 40. In 2006 EFSA will continue its policy of engaging in early dialogue with its institutional partners to ensure a seamless interface between the risk assessment/risk management and risk communications activities. With the establishment of EFSA in Parma EFSA staff will need to ensure a continuing presence in the various relevant committees within EU institutions which are mainly concerned with risk management matters. As legislation goes through the European Institutions EFSA staff may need to be available to advise on certain aspects of proposals particularly those with resource implications for the Authority. Not only will this enable the Authority to gauge its own workload at an early stage, but amongst other matters, it will help inform those considering proposals of any relevant practical and scientific issues relating to the Authority's work.
- 41. EFSA will increase its activities in relation to the collaboration and co-operation with International bodies operating in the same areas as EFSA through working jointly on projects of mutual relevance and benefit. In particular projects relating to data collection and assessment of global scientific issues in the areas covered by EFSA will be considered. (eg GEMS/SCOOP data assessment). International Organisations (WHO, FAO, OIE, OECD etc) operating in the areas covered by ESFA will be actively nurtured in 2006.
- 42. The Authority will also increase its visibility in the international arena in relation to third countries. It will also pursue developments of the strong links forged with partner organisations in third countries eg. US-FDA, Health Canada, FSANZ, Japanese Food Authority, etc
- 43. EFSA will progress its activities to enhance the further integration of Accession States into the work of the EU and in particular for the development of scientific work related to food safety as part of the Phare multi-beneficiary programmes. The work started in 2005 in relation to Romania and Bulgaria will continue and

the Authority will also consider its participation in other Phare programmes (eg in relation to Croatia and other Balkan States)

## Establishment Plan 2006

Category and grade	2004 Posts actually filled-in		2005 Authorised under the Community budget <sup>1</sup>		2006 Requested	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts	Permanent posts	Temporary posts
A*16	-	-				
A*15	-	1		1		1
A*14	-	1		2		2
A*13	-	-				
A*12	-	7		7		8
A*11	-	18		14		19
A*10	-	-				
A*9	1-	2	1	4	1	14
A*8	-	14		17		29
A*7	-	2	1	20	1	28
A*6	-	5		10		21
A*5	-	-		26		17
Total A	1	50	2	101	2	139
B*11	-	-				
B*10	-	1				
B*9	-	ı				
B*8	_	-				
B*7	_	3		4		4
B*6	-	-				
B*5	-	9		7		16
B*4	-	2	1	3	1	4
B*3	-	3		13		12
Total B	0	17	1	27	1	36
C*7	_	-				
C*6	-	-				
C*5	-	-				
C*4	1	13	1	8	1	20
C*3	-	-				2
C*2	-	10		16		18
C*1		10		38		31
Total C	1	33	1	62	1	71
	_		T	T		T
Total	2	100	4	190	4	246
Grand Total	102		194		250	
Grand Total	1U2		134		250	

Key: Professionals are A Grades with 16 the highest, A\* 5 the lowest, B grades are assistants, C are secretarial staff

 $<sup>^{1}\</sup> A$  BRS has been introduced to re-instate the initial establishment plan requested for 2005

## Overview on basic legal acts relevant to EFSA

Please note that this list serves as an introductory overview and is not exhaustive. In case legislation has been amended, references are made to original act with the addition "as amended".

#### Regulation establishing EFSA

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p.1) as amended

#### Implementing measures of Regulation (EC) No 178/2002

- Commission Regulation (EC) No 1304/2003 of 11 July 2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (OJ L 185, 24.07.2003, p. 6)
- Commission Regulation (EC) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of article 36 of Regulation (EC) No 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety Authority's mission (OJ L 379, 24.12.2004, p. 64)

#### Genetically Modified Organisms

- 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)
- Commission Regulation (EC) 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation.
- 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. OJ L106, 17.04.2001, p.1-39.

#### **Pesticides**

 Commission Regulation (EC) No 451/2000 of 28 February 2000 laying down further detailed rules for the implementation of the second and third stage of the

programme of work referred to in article 8(2) of Council Directive 91/414/EEC (OJ L 55, 29.02.2000, p. 25)

- Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in article 8(2) of Council Directive 91/414/EEC and amending Regulation (EC) No 451/2000 (OJ L 224, 21.08.2002, p. 23)
- Commission Regulation (EC) No 2229/2004 of 3 December 2004 laying down further work further detailed rules for the implementation of the fourth stage of the programme of work referred to in article 8(2) of Council Directive 91/414/EEC (OJ L 379, 24.12.2004, p. 13)
- Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.08.1991, p. 1-32) as amended
- Regulation (EC) No ../2005 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 (to be published).

#### Plant Health

• Council Directive 2000/29/EC of 8 may 2000 on protective measures against introduction into the Community of organisms harmful to plant or plant products and their spread within the Community (OJ L 169, 10.07.2000 p. 1) and further amendments.

#### Animal nutrition

• 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)

#### Animal Health

- Directive 2003/65/EC of the European Parliament and of the Council of 22 July 2003 amending Council Directive 86/609/EEC on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes (OJ L 230, 16/09/2003, p. 32)
- Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (OJ L 306, 22/11/2003, p. 1)
- Council Directive 91/629/EEC of 19 November 1991 laying down minimum standards for the protection of calves (OJ L 340, 11.12, 1991, p. 28). Article 6 requires

not later than by 1 January 2006 a Commission report to the Council drawn up on the basis of an scientific opinion on the intensive farming system (s) which comply with the requirements of the well-being

#### **Flavourings**

- Regulation (EC) No 2065/2003 of the European Parliament and of the Council of 10 November 2003 on smoke flavourings used or intended for use in or on foods (OJ L 309 of 26.11.2003).
- Council Directive 88//388/EEC on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production (OJ L 184, 15.7.1988, p. 61), as amended.

#### **Food Additives**

• <u>Council Directive 89/107/EEC</u> of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption, (OJ L 40 de 11.2.1989, p. 27), as amended .

<u>European Parliament and Council Directive 94/36/EC</u> of 30 June 1994 on colours for use in foodstuffs; (OJ *L 237* , 10/09/1994 P. 0013), as amended

<u>European Parliament and Council Directive 94/35/EC</u> of 30 June 1994 on sweeteners for use in foodstuffs (,OJ L 237, 10.9.1994, p. 3), as amended

<u>European Parliament and Council Directive 95/2/EC</u> of 20 February 1995, on food additives other than colours and sweeteners, (OJ L 61, 18.3.1995, p. 1), as amended

#### Food supplements

• Directive 2002/46/EC of the European Parliament and of the Council of the 10 June 2002 on the approximation of the laws of the Members States relating to food supplements (OJ L 183, 12.7.2003, p. 51)

#### Food contact materials

• Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directive 80/590/EEC and 89/109/EEC (OJ L 338, 13.11. 2004, p. 4)

#### Food labelling

• Directive 2000/13/EC on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs (OJ L 109, 6.5.2000, p.29), as amended

#### Zoonoses

- Directive 2003/99/EC of the European Parliament and of the council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC (OJ L 235, 12.12.2003, p. 31)
- Regulation (EC) no 2160/2003 of the European Parliament and of the Council on the control of salmonella and other specified food-borne zoonotic agents (OJ L 325, 12.12.2003, p. 1)

#### **Novel Foods**

• Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January1997 concerning novel foods and novel food ingredients (Official Journal L 43, 14/02/1997 P.1)

#### EU agencies

- Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European centre for disease prevention and control (OJ L 142, 30.04. 2004, p. 1)
- Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.04.2004 p.1)

#### The sixth framework programme for research

■ Decision No <u>1513/2002/EC</u> 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.

# Overview of Commission legislative proposals undergoing legislative process with European Parliament and Council likely to impact on EFSA in 2006

- 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; awaiting 1<sup>st</sup> reading in the Parliament spring 2005. Rapporteur Adriana Poli Bortone (ENVI))
- Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to foods (COM (2003) 671 final, COD 2003/0262, adopted by the Commission on 10 November 2003; awaiting 1<sup>st</sup> reading in the Parliament in spring 2005. Rapporteur: Karin Scheele (ENVI))
- Proposal for a Directive of the European Parliament and the Council amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (COM (2204) 650 final, COD 2004/0237, adopted by the Commission on 11 October 2004, awaiting 1<sup>st</sup> reading in the Parliament autumn 2005. Rapporteur: Mojca Drcar Murko (ENVI).
- Proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistant Organic Pollutants (COM (2003) 644 final, COD 2003/0256, adopted by the Commission on 29 October 2003, awaiting 1<sup>st</sup> reading in the Parliament autumn 2005. Rapporteur: Guido Sacconi (ENVI))
- Proposal for a Regulation of the European Parliament and of the Council on the application of the provisions of the Århus Convention on Access to Information, Public Participation in the Decision-making and Access to Justice in Environmental Matters to EC institutions and bodies (COM (2003) 622 final, COD 2003/0242)

## Proposals likely to be presented by the Commission during 2005 and with a possible impact on the work in 2006

Regulation of the European parliament and of the Council on food additives

Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods

Regulation of the European Parliament and of the Council on food enzymes