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Reflection on issues related to the functioning of EFSA's Scientific Committee and Scientific Panels

European Food Safety Authority

TO THE ADVISORY FORUM

The Management Board of EFSA has had an initial discussion on the attached paper regarding issues related to the functioning of the Scientific Committee and Scientific panels, at its meeting on 27 October and will consider the issue further at its meeting on 24 January 2006.

On the latter date it will also have the benefit of the advice of the Chairman of the Scientific Committee and of course would also welcome any observations from the Advisory Forum.
Hence, we would like to discuss the following paper at the meeting on 25th November.

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NOTE TO THE MANAGEMENT BOARD ON ISSUES RELATED TO THE FUNCTIONING OF THE SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS

INTRODUCTION

1. At its meeting of June 2005 the Management Board discussed document MB 20.06.2005-5 and agreed that Article 28.5 of Regulation 178/2002 concerning the appointment of experts to the Scientific Committee and Panels should be interpreted to mean that every three years around the same time all Scientific Panels and the Scientific Committee shall be (re-) established by replacing or re-appointing all expert members. The Management Board further agreed with the establishment of a new Panel on Plant Health and the deletion of the plant health mandate from the current PPR Panel and it urged the Executive Director to request the Commission to arrange for an expeditious procedure aiming at the establishment of the new panel by the end of 2005.

2. At the same meeting in June 2005 the Management Board requested the development of an additional document addressing issues related to the functioning of the various Panels, including the handling of work flow, outsourcing of work and possible overlaps of the Panels' respective mandates.

3. The attached document should be considered a scoping paper introducing various issues for further in-depth discussion. It provides examples of options and background information which may be useful for the Management Board's consideration during its initial discussion in October. The first draft of the document has been shared with the Scientific Committee (SC) in September and the attached version includes its initial comments. The SC has indicated that it needs further discussion before it will be able to make recommendations to the Management Board for changes, as appropriate.

ACTION REQUIRED AND TIMING

4. Following its more extensive discussion of the various issues raised in this document the Scientific Committee may wish to share and discuss its views with the members of the Expert Panels and, subsequently, propose ways for further improvement of work approaches and structures, if deemed necessary or desirable.

5. Suggestions made by the Scientific Committee at their meeting in October will be shared with the Advisory Forum in November before being submitted to the Management Board for its consideration when meeting in December.

6. Suggestions for minor changes which do not need in-depth discussion or modification of Regulation 178/2002 may already be implemented at the time the Scientific Panels and Scientific Committee will be re-established in May 2006. Other modifications to the current work approach, if needed, may require substantial discussions within and between several groups such as the Advisory Forum, Scientific Committee and Scientific Panels and are likely to require modification of Regulation 178/2002. Such discussions will have to be scheduled well ahead together with a detailed time path, a defined end date and objectives.

7. Board Members are therefore not asked to take decisions on any of the issues in the annex: specific recommendations will be made to them in December in the light of the advice of the Scientific Committee. Nevertheless Board Members may like to be aware now of the issues under discussion and have the opportunity to comment on them.

ANNEX

ISSUES RELATED TO THE FUNCTIONING OF THE SCIENTIFIC COMMITTEE AND SCIENTIFIC PANELS

Number of Scientific Panels

1. Currently there are 8 Scientific Panels. The current PPR Panel which is dealing with the risk assessment of active substances (pesticides) does not have the expertise needed for the already received questions on plant health which is a totally different area of work with specific legislation. Therefore appropriate actions have been taken recently to establish an additional, 9th, Scientific Panel on Plant Health. This new Panel will hopefully be established by the end of the year. The current mandates of the respective Scientific Panels, including the new PH Panel, are as follows:

Panel	Mandate
AFC	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).
AHAW	The Scientific Panel on animal health and animal welfare (AHAW) is responsible for providing scientific opinions on scientific questions related to animal health and animal welfare, with a focus on food producing animals including fish.
BIOHAZ	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.
CONTAM	The Scientific Panel on contaminants in the food chain (CONTAM) is responsible for providing scientific opinions on scientific questions on 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.
FEEDAP	The Scientific Panel on additives and products or substances used in animal feed (FEEDAP) is responsible for delivering scientific opinions on scientific and technical questions concerning (i) the safety for the animal, the user and the consumer of the products of animal origin, (ii) the environment and (iii) the efficacy of biological and chemical products/substances intended for deliberate addition/use in animal feed.
GMO	The Scientific Panel on genetically modified organisms (GMO Panel) is responsible for delivering scientific opinions on scientific

	questions related 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 issues.
NDA	The Scientific Panel on dietetic products, nutrition and allergies (NDA) is responsible for providing scientific opinions on scientific 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.
PPR	The Scientific Panel on plant protection products and their residues (PPR) is responsible for delivering scientific opinions on scientific questions relating to the safety of plant protection products for the user/worker, the consumer of treated products and the environment.
PH	The Scientific Panel on plant health (PH) is responsible for providing scientific opinions on scientific questions on phytosanitary aspects of plant health related to organisms harmful to crops or crop products posing a threat to crop production and/or biodiversity.
SC	The Scientific Committee is responsible for the provision of scientific advice and scientific opinions on multi-sectorial issues which do not fall within the competence of any of the Panels or which are of interest or concern to more than one Panel. The Scientific Committee is also responsible for the general co-ordination necessary to ensure the consistency in the scientific opinions of the different panels.

Size of the Scientific Panels

2. At the establishment of EFSA the size of the Panels was set at 21 experts whereas the Scientific Committee would comprise 14 members (8 Panel Chairs and 6 independent experts). These numbers are not part of Regulation 178/2002 but were included in document MB 17.10.2003-3-adopted. As summarized in document MB 20.06.2005-5, at the establishment of the Panels in 2003 only three were filled up to 21 and one Panel (NDA) only managed to select 13 experts with the appropriate profiles. In 2004, following another call for experts most Panels were filled but 3 Panels were still unable to fill all vacancies (AFC: 20; NDA: 16). Various documents have addressed ways to increase the number of applications of high scientific quality experts in future calls and these options have been discussed and agreed by the Management Board (MB 18.01.2005-7 and MB 10.03.2005-6) and the Advisory Forum (AF 03/04.02.2005-7).

3. Issues to be considered in the context of the size of the Scientific Panels and Scientific Committee include: (i) the preference to reach consensus in Panels and the Scientific Committee on all their opinions, (ii) the availability and capacity of meeting rooms, (iii) whether or not the maximum size should be the same for all Panels, and (iv) the costs of SC/Panel meetings (currently approximately €1000/expert/meeting).

Overlap of Scientific Panel work

4. Although the mandates are well-defined for all Panels in the 2004 Management Plan (see document MB 20.01.2004-8-adopted) and apparently seem clearly distinct, there are questions which are broader than the remit of one particular Panel. As examples, the Panels on Biological Hazards (BIOHAZ) and Animal Health and Animal Welfare (AHAW) overlap in issues such as food-borne zoonoses related to the containment and eradication of diseases at farm level and food-borne zoonoses with chances to become a food-borne disease in man (e.g. AI, BSE and vCJD). Other overlaps of work occur between the AFC Panel and the CONTAM Panel (e.g. semicarbazide), the GMO and FEEDAP Panels (e.g. animal feed stuffs involving GMO's), between the CONTAM, NDA, FEEDAP and AHAW Panels on the safety of wild and farmed fish and, most recently, between the FEEDAP and CONTAM Panels (e.g. cross-contamination of non-target feeding stuffs by authorised coccidiostats).

5. Currently the Panels deal with these overlapping work mandates by: (i) co-adopting the opinion, (ii) dividing the mandate and adopting separate opinions, or (iii) by providing input to the other Panel (normally through expert participation in the Working Group dealing with the question) without co-adoption but reference in the opinion to this support.

6. These options may be sufficient or other options may be considered such as: (i) redefining the mandates of all Panels with a view to reducing overlap, (ii) considering additional Panels with more limited mandates or, alternatively, (iii) consider merging Panels to cover the overlap.

Splitting or/and adding Panels

7. Panel mandates are sometimes very broad and require a relatively large number of Working Groups to deal with a diversity of various issues (e.g. AFC and BIOHAZ). However, while mandates of other Panels may be more focused, their workload could be enormous (e.g. FEEDAP). Splitting Panels may have the advantage of reducing workload (twice as many Panel members), but there is the disadvantage of duplication of the expertise with the 'sister' panel which, from a management point of view, is a disadvantage. Adding additional Panels to the current 8 and future 9 Panels would certainly be meaningful if a certain area of the food chain is not covered by any of the current Panels.

Organization of the work and possible outsourcing

8. The Scientific Committee and Scientific Panels have organized most of their work in Working Groups which develop draft opinions or parts of draft opinions for consideration by the Panel. Working Groups normally need a number of meetings and written commenting rounds before they reach agreement by consensus on a draft opinion (or part of a draft opinion). Working Groups often involve external experts in addition to Panel members.

9. So called Standing Working Groups normally have specific expertise and deal with the corresponding part of a given question (e.g. environmental assessment), whereas *Ad Hoc* Working Groups are normally established to deal with all aspects of

a specific question (e.g. in the AHAW Panel the question on pain experience in unborn vertebrate animals). Questions which are cross-cutting through Panels are usually dealt with by Inter-Panel Working Groups (e.g. the SWAFF working group on the safety of wild and farmed fish, dealt with by the CONTAM, NDA, FEEDAP and AHAW Panels). The number of working groups varies considerably between Panels and in time. As an illustration of the level of variability the table below shows the number of working groups of the SC and Panels as it was in June 2005:

SC:	5 standing working groups; 1 *ad hoc* working group;
AFC:	3 standing working groups; 1 *ad hoc* working group;
AHAW:	13 *ad hoc* working groups;
BIOHAZ:	1 standing working group; 20 *ad hoc* working groups;
CONTAM:	5 standing working groups; 1 *ad hoc* working group;
FEEDAP:	2 standing working groups; 11 *ad hoc* working groups;
GMO:	3 standing working groups; 9 *ad hoc* working groups;
NDA:	4 standing working groups; 1 *ad hoc* working group;
PPR:	5 standing working groups.

10. The broad range of scientific activities has resulted in a variety of work approaches. A number of Panels are occupied to a large extent with regulatory risk assessments often with legal deadlines. Some of these Panels and their Working Groups deal with all the work by working groups comprising of Panel members and external experts (e.g. FEEDAP and GMO) whereas others are supported, in addition to their external in working groups, by external expert groups which assist the Panel. This is for instance the case with the AFC Panel where preparation of the underlying work for the risk assessment of food flavourings and chemically defined flavouring substances is outsourced to the FLAVIS Group. Yet other Panels almost exclusively are dealing with generic scientific questions rather than risk assessment of regulated substances (e.g. BIOHAZ, CONTAM and AHAW). The NDA Panel probably is a good mix between generic scientific questions and assessment of regulated substances.

11. Finally, other scientific activities not particularly linked to any of the Panels in particular are organized by EFSA's Scientific Expert Services (SES). These activities include the development of the annual report on zoonoses and the harmonization of methodology for the monitoring of zoonoses in Member States; the SES has set up a Task Force comprising experts from all Member States to assist in this work. In the area of biological hazards some of the work on TSE is carried out by the independent Scientific Expert Group on GBR (Geographical BSE Risk Assessment) and the Expert Group on TSE (Transmissible Spongiform Encephalopathy) test validation. The pesticide risk assessment peer review (PRAPeR) of existing and new substances has been outsourced to an external team (EPCO) that organises the review and evaluation of dossiers by Member States' experts with assistance of EFSA's PRAPeR team.

12. Only in July 2005 EFSA was in the position to invite the Permanent Representatives of all Member States to nominate national competent institutions in the context of Article 36 of Regulation 178/2002 who could assist EFSA in its many scientific tasks. Once the Article 36 network of competent institutions is in place, EFSA will be able to outsource more of its activities; in some cases (environmental assessment of GMO's) outsourcing is even mandatory.

13. The Regulation setting up EFSA states that advice has to come from EFSA, not necessarily from Panels. This opens the door for the possibility to reconsider if some questions might be answered by Panel Secretariats or SES staff, or dealt with solely by Working Groups with the agreement of the Panel chair. There is a precedent for the latter option: the AFC Additives WG gave the Commission advice on industry proposals for future studies on energy drinks. Panels might also consider a less time-consuming way of adopting straightforward written opinions: these may be circulated in advance of plenary meetings and adopted at the Plenary without going through them in detail, unless members had objections or comments. These and other flexible ways of working could be considered appropriate and in line with Regulation 178/2002.

14. Although there is a procedure in place for screening requests for advice or opinions from the Commission before they go on the Register, there have been very few instances of questions being rejected by EFSA. Yet every Panel could probably give examples from the last 2 years experience of questions they felt should never have come to EFSA in the first place. What is clear is that the annual number of questions from the Commission on food and feed issues now far exceeds the number of questions the Commission used to put to the corresponding EC scientific committees when the Commission itself had to service the Committees. Although some increase in the number of questions is understandable the current increase is substantial and EFSA may need to consider more ways of ensuring that questions are appropriate for EFSA.

Inventory of the workload of the Panels

15. The number of questions routed to each Panel since the start of EFSA could be roughly divided into (i) generic questions requiring lengthy considerations and usually long extensive opinions (e.g. risks and benefits of eating fish), (ii) medium length individual substance/issue questions (e.g. question on nitrates and nitrites for the safety of meat production) and (iii) short individual substance/issue questions (e.g. several of the many food contact materials). An inventory could be made on the work load for each Panel using this simplified grouping of question types. A compilation of the currently used progress indicators could provide information on deadlines achieved and not achieved for each Panel and an overview could be provided on person-hours spent by Panel members and members of Working Groups for each Panel separately. These overviews have not yet been made because of other priorities which were considered higher. However, the Scientific Committee may consider such inventories as important for the discussion of the functioning of the Scientific Committee and the Panels.

CHANGES ALREADY FORESEEN

16. Following the establishment of a network of Article 36 national institutions, EFSA will increasingly outsource aspects of the scientific work. Efforts will be made to avoid that Panels no longer would feel ownership of the work and the products produced by outsourcing. Outsourcing should always be considered as assistance to the Panel and the Panel will remain responsible for the opinion resulting from the work.

17. The Scientific Expert Services (SES) will expand substantially and will provide specific scientific support to the Panels, complementing outsourced activities and the core activities of the Panels. In particular, the SES will assist the Scientific Committee with its fundamental scientific projects related to the development of uniform new and harmonised risk assessment methodologies and approaches in line with Article 23(c) of Regulation 178/2002.

18. The SES is responsible for the development and maintenance of databases of (i) national institutions in accordance with Article 36, (ii) national experts, (iii) national consumption patterns and exposure data, and (iv) data on polycyclic aromatic hydrocarbons (PAH) occurrence. The SES will also continue to organise Scientific Colloquia on emerging issues where EFSA would like to receive a broad range of scientific views of the world's leading experts.

19. The Scientific Committee will further expand its role of coordinating inter-Panel projects and will increasingly focus on self-tasks related to the investment in and exploration of new technologies and risk assessment approaches including nanotechnology, genomics and computational quantitative risk assessments.