EXECUTIVE DIRECTORATE

Minutes of the
Management Board Meeting
11 September 2007
Hotel Howard Johnson, Bucharest

Members of the Management Board present

Diána Bánáti	Milan Pogačnik
Giorgio Calabrese	Pirkko Raunemaa
Marianne Elvander	Bart Sangster
Peter Gaemelke	Roland Vaxelaire
Matthias Horst	Patrick Wall
Deirdre Hutton	Konstantinos Yazitzoglou
Robert Madelin	

Observers and Invitees of the Executive Director

Professor Vittorio Silano, Chair Scientific Committee	Professor Harry Kuiper, Chair GMO Panel

Staff of the European Food Safety Authority present

Catherine Geslain - Lanéelle	Christine Majewski
Anne-Laure Gassin	Alexandrine Maviel-Sonet
Dirk Detken	Stefano Penati
Herman Koëter	Suzy Renckens
Djien Liem	Ingela Söderlund

Table of Contents

Summary of decisions……3

Preliminary formalities……4

Adoption of Agenda……4

Adoption of draft minutes from the previous meeting and matters arising……4

Progress Report……5

Declarations of Interest……6

Amendment of the Internal Rules of procedure for the Scientific Committee and Panels, Split of the AFC Panel……7

Presentation of the GMO Panel by its Chair, Harry Kuiper……8

Amending budget 2007……10

Concluding remarks……11

SUMMARY OF DECISIONS

The Management Board:

- Adopted the agenda without changes
- Adopted the minutes from the 19 June 2007 meeting without changes
- Agreed that following the incorporation of the comments from the Board, to adopt the documents on Declarations of Interest via written procedure
- Adopted the proposal to split the AFC Panel into 2
- Adopted the updated Rules of procedure for the Scientific Committee and Scientific Panels, subject to editorial comments
- Adopted the document on the Amending Budget for 2007

The Management Board also:

- Announced the nomination of a new Vice Chair, Bart Sangster, replacing Dame Deirdre Hutton
- Welcomed the new Member of the Board, Professor Milan Pogaĉnik
- Asked the Secretariat to circulate a new proposal for 2008 meeting dates
- Deleted the 16 October 2007 extra meeting date
- Asked the Executive Director to provide a presentation of the Advisory Forum
- Took note of the Executive Directors Progress Report and congratulated EFSA on the many activities undertaken since the last meeting
- Asked to be updated on the progress of the opinion on Nanotechnology
- Asked to be informed on the number of requests for opinions EFSA had received during the year
- Suggested that it could be useful to plan a meeting in conjunction with a meeting of the Advisory Forum
- Underlined the importance of EFSA's work on the opinion on food colours
- Noted the progress on the Declarations of Interest and suggested that the new Vice Chair could capture the views of the Board and liaise with EFSA.
- Noted the presentation of Dr Kuiper and offered to support it should there be any need in relation to its workload
- Took note of the update from the Chair of the Audit Committee, Mr Vaxelaire
- Took note of the transfers in the EFSA budget

PUBLIC SESSION

Preliminary Formalities

The Chair opened the meeting by welcoming the Board Members, Professor Silano, Dr Kuiper, the Authority's staff and the viewers on the web. Apologies had been received from Marion Guillou and João Machado. The Chair announced that Bart Sangster had been elected vice Chair for the Management Board. The Chair welcomed the new Member of the Board, Professor Milan Pogaĉnik, and invited him to introduce himself. Professor Pogaĉnik thanked the Board for its warm welcome and told the audience that he is a Professor at the Veterinary Faculty at the University of Ljubljana , Slovenia specialised in animal pathology.. The Chair introduced Liviu Rusu, the General Director of the General Division for Food Safety at the National Sanitary and Veterinary and Food Safety Authority of Romania. In his speech, Dr Rusu said that it was an honour for the Romanian Authority to host the Board meeting and wished the participants a successful meeting.

The Chair asked if members wished to make any declarations of interest. Marianne Elvander declared that she would be accompanying the Food and Veterinary Office (FVO) on a mission to Brazil in October-November, to carry out inspections on beef production. Diána Bánáti declared that she had received an honorary doctorate from the University of Szeged and served on the Agro-economic Judicial Expert Board.

No points suggested under any other business. The Chair raised the matter of the meeting dates for 2008 as there had been a suggestion to change the March date. The Secretariat would circulate a proposal for further discussion. The proposed extra date of 16 October 2007 would be deleted.

1. **Adoption of Agenda (Document MB 11.09.2007 -1)**

   1.1 The Chair asked the Members of the Management Board if there were any changes or additions they would like to make.

   1.2 No items were added to the agenda. The agenda was adopted.

2. **Adoption of draft minutes of the previous meeting and matter arising from the minutes (Document MB 11.09.2007 - 2)**

   2.1 The minutes 19 June 2007 were adopted and would be published on the Authority's website.

   2.2 Matters arising from the June Board meeting would be dealt with in agenda item 4, the update of the Internal Rules for the Scientific Committee and Panels and the split of the AFC Panel would be dealt with under agenda item 5. A Board member referred to point 3.5 from the June minutes and enquired when the Board would benefit from a presentation about the work of the Advisory Forum. The Executive Director suggested that a presentation could be made at the December meeting.

3. For information: Progress Report (Document MB 11.09.2007 – 3 and power point presentation)

3.1 The Chair invited the Executive Director to update the Board on progress made at EFSA since the last Board meeting. The Executive Director updated the Board on the progress of ongoing work in the relevant Panels. In particular EFSA had been informed by the UK Food Standards Agency (FSA) of a new study, commissioned by the FSA, on the possible impact of certain mixtures of colours on the behaviour of children. EFSA had received additional data from the FSA and the AFC Panel would consider the study and come back with a preliminary review on the study at the end of September. The Commission had sent a request for an opinion.

3.2 The Executive Director welcomed the Chair of the GMO Panel who would make a presentation later in the day and mentioned that the secretariat of the Panel had been very active in preparing two calls which would be launched under the Article 36 procedure, on proteins and the impact of herbicidal non-GM plants on non-target organisms.

3.3 The Scientific Committee had developed for a review system to assess the quality of EFSA's scientific work. In the proposed strategy, the quality of EFSA's scientific activities would be comprehensively reviewed, both by internal review and by independent, external review processes, together with additional consultations with institutional and non-institutional stakeholders.

3.4 EFSA had also received advice from the Scientific Committee on the responsiveness to urgent questions. The Scientific Committee's advice had been taken into account in the update of the internal rules of the Internal Rules for the Scientific Committee and Panels (discussed under item 5).

3.5 The Advisory Forum had met in Bratislava at the end of June. Member States discussed the issue of the establishment of focal points with the responsibility to support the representatives of the Advisory Forum to gathering data and transferring information between EFSA and relevant bodies in the respective Member State in the fields of risk assessments within EFSA's remit. The Advisory Forum had also agreed on mandates for projects related to the harmonisation of risk assessment approaches, the analysis of the risks and benefits of fortification of food with folic acid, on emerging risks and on the harmonisation of chemical occurrence data collection for food and feed.

3.6 In the area of external relations, EFSA had signed an agreement with the Food and Drug Administration (FDA) on confidentiality arrangements, EFSA had also met with the Japanese Food Safety Council to discuss a draft Memorandum of Understanding.

3.7 Representatives from EFSA had participated in meetings in the European Parliament on issues covering pesticides, fish meal and food improvement agents.

3.8 The Human Resources department had made progress with regard to recruitment and it was foreseen that by early 2008 EFSA would have some 300 temporary agents employed. The Executive Director presented the new head of EFSA's press office, Stephen Pagani, who was in the audience.

3.9 The Board thanked the Executive Director for her presentation and congratulated her on the many activities EFSA had been able to cover in such a brief period of time. The Board asked to be updated on the progress of the work on the opinion on nanotechnology, and she replied that EFSA would

probably be in the position to agree on the mandate with the Commission in September. The Board also asked to be informed about the high number of requests for opinions that EFSA had received, mentioned in the progress indicators report that had been sent to the Board at the end of July. The Executive Director replied that she would address the matter under agenda point 5.

3.10 Robert Madelin raised the matter of EFSA's possible cooperation with Japan and noted that this should of course be done within the normal legal framework for such collaboration. for such The Executive Director replied that EFSA was cooperating with colleagues in the Commission on that matter.

3.11 The Board suggested that it could be useful to plan a Board meeting in conjunction with an Advisory Forum meeting in the future, congratulated EFSA on the new website and underlined the importance of EFSA issuing an opinion on the food colours study as soon as possible.

3.12 The Executive Director thanked the Board for their encouraging words.

4. Declarations of Interest (MB 11.09.07 – 5.1, 5.2, 5.3, 5.4 and power point presentation)

4.1 The Executive Director introduced the draft proposals on a Policy on Declarations of Interest (DOI's) and Guidance and Procedures documents to implement the Policy. The approach was to have a general policy in which a set of DOI's would be described. An updated guidance document reflecting in detail the issues to be subject to a declaration and a set of procedures that would formalise the follow-up or the way EFSA would handle DOI's, were also presented to the Board.

4.2 Dirk Detken and Hubert Deluyker explained that the intention of EFSA was to make even clearer and transparent the way EFSA dealt with DOI's. The new policy includes a detailed procedure for screening these Declarations, identifying any potential conflicts of interest and taking appropriate action. It also contains full guidance on how to make a Declaration of Interests in order to harmonise the process across EFSA.

4.3 The Chair thanked Mr Detken and Mr Deluyker for their presentations and opened the floor for discussion. The Board pointed out that there was a need to clarify the consequences of not declaring interests, or only declaring some interests. The Board asked for the notion of family to be further clarified and also which interests of family members had to be declared and whether a declaration of the exact number of shares would be necessary. Other clarifications were asked in relation to the notion of employment and the scope of the DOI which should relate to Article 22 of the founding Regulation. It was also suggested that the person signing the DOI should sign a statement that he had read EFSA's policy on DOI's, and to add the possibility of experts to state themselves what they considered possible conflicts of interest and sign off that there were no interests that they had omitted to declare.

4.4 Professor Silano offered the possibility to present the new DOI policy also at the plenary meeting of the Scientific Committee of 18-19 September.

4.5 The Chair pointed out that it was fundamental to EFSA's philosophy of openness and transparency that the DOI's were comprehensive. He concluded that the document had received constructive comments but the present draft could not be adopted. He added that changes would be made in line with the comments received from the Board Members and the Scientific Committee before adoption.

4.6 The Executive Director thanked the Board for their input and stressed that DOI's would be evaluated on a case-by-case basis. The process would be applied to a context where the DOI's would be made and examined in the context in which they were given. There would be annual DOI's but also DOI's given in the context of meetings, and these would be recorded in the minutes of that meeting. She suggested that the documents should be amended taking into consideration the comments of the Board.

4.7 A Board member suggested that the new Vice Chair could coordinate the comments and consult with Board members. She suggested that this might be a practical way of handling the follow-up procedure.

4.8 The Chair agreed and suggested that the Vice Chair should capture the views of the Board, that the Scientific Committee would look at a document which incorporated the comments from the Board made at the meeting and that the documents would be circulated to the Board members and adopted via written procedure. The Vice Chair agreed, provided that he received an amended draft on which he could base further comments.

4.9 The Executive Director agreed to this procedure.

5. For adoption by the Board: Amendment of the Internal Rules of procedure for the Scientific Committee and Panels, split of the AFC Panel to create a new Panel (Document MB 11.09.2007 - 4)

5.1 The Executive Director introduced the point by explaining that the Board had made a series of recommendations relating to improving the work conditions for scientists and in particular to looking at greater support from EFSA staff to Panels looking at easing workloads, the reimbursements of experts and the location of the meetings. She explained that the tabled proposal addressed two points: the creation of new Panels and the change in the internal rules of the Scientific Committee and Panels. The proposed changes were made to enable EFSA to respond to the increasing workload and take into account the opinion of the Scientific Committee on urgent questions. She also explained that in 2008 some 90 per cent of recruitment would be made to the science department, compared with some 65 per cent in 2007. Resources would focus mainly on the areas where EFSA was expecting a large workload which mainly related to safety evaluations: GMO, nutrition, pesticides, food additives and feed additives. In order to reduce the burden on Panels, EFSA was also revisiting its draft 2008 work plan, together with Member States, and would seek to avoid duplication of work and assess how EFSA could benefit from work being done in the Member States.

5.2 The Director of Science introduced the documents. Given the workload of the AFC Panel it was suggested to create a new Panel. The current AFC Panel was able to adopt some 50 opinions per

year. However the number of requests for opinions was very high. This was the reasoning behind splitting the AFC Panel in two.

5.3 The proposed focus for the first Panel would be on food additives and have its main focus on toxicology. The other Panel would focus on food contact materials which also included aspects of toxicology but was an area strongly linked to chemistry. Therefore with toxicology and food additives in one panel and chemistry and food contact materials in another it was felt that there was a logical basis for the two proposed panels. The Chair recognised the need to split the Panel and said that he hoped that the existing scientists would be retained. He enquired about the process for fast-tracking the applications of the existing scientists for the new Panels.

5.4 The Director of Science explained that the proposal to split the Panel would have to go through a comitology procedure in the Commission and that a simplified procedure for the reappointment of the current experts of the AFC Panel could be examined. There would be an external call for experts with the objective of being able to start the work of the 2 new Panels as soon as possible.

5.5 The Chair supported the suggestion and asked Professor Silano for the view of the Scientific Committee on the proposal. Professor Silano explained that the Scientific Committee was supportive. The Chair asked the Board support the proposal to create a new Panel and the Board indicated its approval.

5.6 The Executive Director indicated her support for flexibility in the remits of the Panels however experts needed to know in which areas of work they would be expected to contribute. She suggested clear titles for the Panels, and that the mandates should be clearly defined. Flexibility would be ensured through maintaining a unique unit dedicated to the support of the two panels with two separate teams within this unit.

5.7 The Director of Administration introduced the proposal to amend the Internal Rules for the Scientific Committee and Panels. The proposed changes were reflected in Article 13 and 21 of the document.

5.8 The Board commented on the proposed changes and highlighted the need for a clear fast track procedure to be used in an emergency or a crisis which should reflect the existing available legal framework.

5.9 The Authority needed to be very clear on how external experts would be appointed to working groups set up in relation to fast track procedures in urgent situations.

5.10 The Chair asked the Board to agree to the proposal subject to the suggestions made. The Board supported the proposal.

6. Presentation of the GMO Panel by its Chair, Dr Harry Kuiper (Power point presentation)

6.1 The Chair of the GMO Panel introduced the work of the Panel and legal framework for the risk assessment of Genetically Modified Organisms (GMO's). There were 2 different procedures for the assessment of GMO's according to the legal bases i.e. one under Directive 2001/18 on the deliberate

release of a GMO into the environment for cultivation and a second one under Regulation 1829/2003 on GM food and feed. The Panel currently had 20 members with one vacancy, three standing working groups and ad hoc working groups on dossier evaluation; molecular characterisation, the food and feed evaluation and environmental risk assessment. He explained that to date, the Panel had adopted 23 opinions. The Panel had also produced guidance documents. Dr Kuiper informed the Board that an extensive report on the use of animals to assess the safety of GM foods and feeds would be available soon.

6.2 The Panel had received correspondence and enquiries from the European Commission, Member States authorities', European Parliament members, environmental NGOs, general public, applicants and other stakeholders. The Panel had also addressed the safeguard clauses invoked by some Member States. Petitions in countries could lead to statements such as the one the panel had made on the potential labelling of products from animals fed with GM feed. The challenge for the Panels was to look at these aspects seriously but the issue was to which extent the Panel should be involved in answering these questions. Such issues were growing and the Panel would be faced with resource problems if this demand continued.

6.3 The GMO Panel had liaised significantly with Member States, consulted on documents via the internet and held public consultations. Links had also been established with the FAO, the WHO and Codex Alimentarius. EFSA was planning a meeting with the Advisory Forum and with GMO experts on risk assessments involved at national level on the general principles of risk assessment.

6.4 Dr Kuiper suggested that EFSA could be more active in the area of new developments at the international level, where there were important issues concerning risk assessment and management. He added that the Panel should not be overburdened with recurring questions Prioritisation was important and EFSA staff, the Panel and the Commission should work together in that area more to find agreement on priorities.

6.5 The Chair thanked Dr Kuiper for his presentation and acknowledged the work of the scientists. He agreed that scientific panels could not be expected to deal with non scientific issues.

6.6 A Board member suggested that how concerns and uncertainties had been taken into consideration should be transparently presented in opinions as should minority views. He indicated that the perception of NGO's and consumers was that the Panel worked very hard to find the best scientific process but that it was important to indicate different views where these exist. Another Member of the Board asked whether assessments could be speeded up to enable risk managers to carry out their responsibilities.

6.7 Robert Madelin thanked Dr Kuiper and indicated that EFSA has the power specifically laid down in the founding regulation to reject requests. The work load would still be overwhelming because more and more GMO's were being put forward for the European market. The Board could decide that more members were needed on the Panel if there was a work load issue. He suggested that EFSA needed to provide more information on the issues linked to feeding studies and that EFSA could look at

feeding studies as a communication issue, go further into the technicalities and explaining in words for the general public to understand, and explain EFSA's risk assessment responsibilities.

6.8 The Chair noted the questions and comments from Board members related to the composition of the Panel, their increasing workload and the implications to risk managers.

6.9 The Board noted that the GMO Panel was the Panel for which there was probably the highest risk that risk assessment and risk management issues were mixed up. Some stakeholders were seeking very detailed answers about the methodology of the Panel whereas others only wanted to know of the GMO was safe or not. Dr Kuiper was asked if the Panel received any feedback on how the output of the Panel was perceived. The Board also asked whether the Panel was consulted when research programmes were agreed in the Commission and if the Panel was consulted when the priorities of research programmes were decided. The Board asked Dr Kuiper for his opinion about the future membership in the Panel and whether the Panel was able to attract and keep the most prominent independent scientists because of the work load.

6.10 Dr Kuiper thanked the Board for its questions. He noted the question about transparency in the Panel's opinions. The issue had been discussed in a meeting with NGO's some 18 months ago where the NGO's had expressed the view that uncertainties should be better than previously where there were uncertainties in the opinion. The Panel had made an effort to pay attention to noting uncertainties and stated that the Panel was constantly aware of the issue. He gave examples of where opinions had shown the differing views within a Panel and noted that uncertainties in risk assessment were vital to identify and communicate. The Panel was making all efforts to deal with the applications for GMO evaluations but with an increasing number of "additional" questions sometimes the part of the Panel's activities in relation to dossiers had to be prioritised. He agreed that there were communication issues but also noted that there was general agreement among risk assessors at Member State level. On setting priorities for research he suggested that this could be a topic also for the Scientific Committee and added that he was optimistic about being able to attract the best scientists to the Panel.

6.11 The Chair thanked Dr Kuiper again for presenting the work of the GMO Panel to the Board.

7. Amending Budget 2007

7.1 The Director of Administration introduced the document which concerned two technical amendments to the 2007 budget. She explained that the first one was related to the pre-accession programme for Turkey and Croatia. As follow up of the recommendation from the court of auditors EFSA had to reclassify specific funds under specific nomenclature, and call them internal signed revenue. The second point related to the signed revenue as the CDT, the Translation Centre of the European Commission, was returning funds back to EFSA and if the Authority want to obtain the money it had to be added to the budget. She asked the Board to adopt the amendments.

7.2 The Board adopted the document.

8. Update from the Audit Committee

8.1 Roland Vaxelaire updated the Board on the meeting of the Board's audit committee the previous day. The members had met with the new internal auditor, Stefano Penati, and been informed about the final conclusion of the Commission's internal audit service, which had audited EFSA one year ago and made 36 recommendations. Out of the 36 recommendations the audit committee was pleased that 26 had been closed, nine were currently being addressed, and one related to the corporate risk analysis will start to be implemented in September 2007. The members of the committee suggested to concentrate work on the risk analysis and to produce a progress report on all the other audits that were made for the last year. The last point of the meeting had been to review the process governing the preparation of EFSA scientific opinions.

8.2 The Chair thanked Roland Vaxelaire for his presentation.

9. For information: Transfers in the EFSA budget (Document 11.09.2007 - 6).

9.1 The Director for Administration introduced the point on transfers in the EFSA budget. The transfers made from title to title and chapter to chapter amounted to some 1,8 million €.

9.2 The Board took note of the transfer.

10. Concluding remarks

14.1 The Chair thanked the members of the Board, the audience, the Authority's staff, the interpreters, Professor Silano, Dr Kuiper and wished everyone a safe journey.