European Food Safety Authority

41st Meeting of the EFSA Management Board
Minutes of the Public Session
Athens, 18 June 2009, 09.00 h

Members of the Management Board present

Diána Bánáti (Chair)	Marianne Elvander (Vice-Chair)
Bart Sangster (Vice-Chair)	Sue Davies
Milan Pogačnik	Roland Vaxelaire
Robert Madelin	Jiri Ruprich
Piergiuseppe Facelli	Peter Gaemelke
Sinikka Turunen	Marion Guillou

Staff of the European Food Safety Authority present

Catherine Geslain-Lanéelle	Hubert Deluyker
Olivier Ramsayer	Anne-Laure Gassin
Pedro Pinhal	Christine Majewski
David Caira	Dirk Detken
Djien Liem	Gisèle Gizzi

Also attending:

Mr. Antonis Zampelas, President of the Hellenic Food Authority (EFET)
Andreas Varlamos, Chair of EFSA's Stakeholder Consultative Platform

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SUMMARY OF DECISIONS

The Management Board:

- Adopted the agenda with an added item on feedback from the Management Board Away-Day.
- Noted the address of the President of the Hellenic Food Safety Authority (EFET), Mr. Antonis Zampelas.
- Congratulated the Italian authorities on the progress made on the Final Seat.
- Adopted EFSA's Financial Statements Accounts 2008 and asked for the accompanying Audit Report to be circulated to Members.
- Noted the document and discussion on cooperation with Member States and asked for regular updates.
- Agreed to extend the mandate of the Stakeholder Consultative Platform and adopted revised Terms of Reference.
- Noted the presentation of the Chair of the Scientific Committee.
- Noted the update by the Chair of the Audit Committee in particular the need to ensure that EFSA financial resources were deposited in a reliable bank.
- Noted the budget execution to end-May and the predictions for 2009.
- Noted the transfers in the EFSA budget.

The Management Board also:

- Took note of the Executive Director's Progress Report and congratulated EFSA and its staff on the many activities undertaken.
- Noted the declaration of interest of Roland Vaxelaire and Peter Gaemelke and the statement on interest by Sue Davies.
- Noted the venue and date of the next meeting of the Management Board in Parma, Italy on October 7-8, 2009.
- Noted the dates of the 2010 Board meetings.
- Thanked Konstantinos Yazitzoglou for his contribution to the organisation of the Board meeting and conference in Athens and sent him get well wishes.

Item 1: Welcome by Chair

1. The Chair opened the Public Session of the 41st Management Board meeting by welcoming Board Members, the EFSA executive and the President of the Hellenic Food Safety Authority (EFET), Mr. Antonis Zampelas, Andreas Varlamos, Chair of EFSA's Stakeholder Consultative Platform, the audience in Athens and online, and the members of EFSA's renewed Scientific Panels and Scientific Committee.

2. Apologies from Matthias Horst, Bernard Url and Konstantinos Yazitzoglou were acknowledged.

3. The Chair announced that Mr. Zampelas would address the meeting shortly.

4. Under declarations of interest (DOIs) of Board Members, Roland Vaxelaire and Peter Gaemelke informed the meeting of changes to their declarations and Sue Davies declared an interest in relation to item 9 of the agenda.

5. The Chair added an announcement of the dates for Board meetings for 2010 to the agenda under Any Other Business.

6. The Chair welcomed EFSA's new Director of Administration, Olivier Ramsayer, to his first Board meeting.

Item 2: Address of Mr. Zampelas

7. On behalf of the Greek authorities, Mr. Zampelas welcomed the meeting to Athens and thanked the Chair and the Executive Director for accepting the invitation. The establishment of EFSA had strengthened public confidence in the European food safety system, he said, and cooperation with national agencies was an integral part of EFSA's mission. Greece is happy to contribute to EFSA's activities so that collectively Europe can tackle the challenges and emerging risks it faces.

8. The Chair thanked Mr. Zampelas for his address and for the input of the Greek authorities both to the Board meeting and the previous day's conference.

Item 3: Adoption of draft agenda

9. The Chair suggested adding an item to the agenda on feedback from the Management Board away-day and this was agreed. The draft agenda was adopted.

Item 4: Executive Director's Progress Report

10. The Chair invited the Executive Director to present the progress report.

11. The Executive Director updated the Board on progress from mid-March to end-May 2009. A separate PowerPoint presentation is available for a detailed description.

12. The Chair congratulated the Executive Director on the achievements during the reporting period, in particular those related to the European School and Final Seat, and invited questions and comments.

13. A Board Member thanked the Italian authorities, at both the national and local Parma level, for the progress on the Final Seat project. This sentiment was echoed by the Chair and other Members.

14. Questions from Members included: management of the workload associated with applications; collating information from individual EFSA units for the progress report; key messages derived from the Executive Director's visits to national agencies; the outcome of the meeting with the Austrian national authorities in relation to GMOs; and building relationships with the new European Parliament and its various Committees.

15. The Executive Director thanked Members for their positive responses to the developments on the settlement issues. To manage the workload on applications for health claims, she outlined the measures EFSA had taken: trebling the size of the NDA unit; increasing the network of experts available for this work; streamlining of workflows; dialogue with DG SANCO on the delivery and prioritisation of the work; and organising a meeting with applicants to enhance the efficiency of the application process. Discussions on the timelines are still ongoing although it was noted that the Commission deadline for claims is 1 January, 2010. EFSA is committed to enhancing the transparency of its opinions making it easier for applicants to understand the reasoning behind decisions on claims. A more detailed report on the meeting with applicants will be published in the 3rd quarter 2009 and the Q&A section on applications on the EFSA website will be updated to incorporate the views expressed at the meeting.

16. In relation to the meeting with Austria, the Executive Director remarked that she had encouraged the Austrian authorities to involve their experts more in EFSA's activities and had suggested to them a regular meeting of European experts involved in GMO risk assessment to facilitate the harmonisation of methodologies. This would help foster understanding and ownership of EFSA's opinions on GMOs.

17. The Executive Director outlined the challenges in compiling the progress report, in particular that of keeping contributions concise. On visits to Member States, the Executive Director said that the agenda differed between countries and that the visits were important in understanding how the national food safety authorities were organised and in giving added impetus to cooperation. She added that the document on cooperation that would be discussed in a later agenda item would outline the discussions held during visits to Member States and reiterated EFSA's commitment to ensuring that Member States could engage with the Authority, particularly those countries with limited risk assessment capacity. The Executive Director confirmed that building good relations with the new European Parliament was a priority for EFSA.

18. In relation to the high number of health claims that EFSA was receiving, a Member pointed out that once the application process was in place, the demands on it had increased enormously and one of the strategic lessons to be learned from the exercise was the need for improved planning of likely demand. It was also important to ensure that demand is real and not spurious and one of the mechanisms to ensure a sensible volume of claims might be by charging a fee for speculative claims. Because the agreed deadlines did not take excessive demand into account and resources are not unlimited, delays would need to be effectively communicated to stakeholders.

19. In following-up on the issue of demand for applications, a Member pointed out that prioritisation was essential. He asked the Executive to circulate a copy of the EFSA-DG SANCO roadmap to the Members.

20. In summing up the item, the Chair noted that in 2008 EFSA was ranked among the top 3 EU agencies by the Court of Auditors in relation to planning, objective setting and measurement, tracking of results, reporting and external evaluation and asked that the Board's appreciation of the work of EFSA's staff be minuted. She added that it must be re-emphasised to all external parties that EFSA is a risk assessment and not a risk management body. In relation to the workload on applications, she remarked that there is an onus on legislators to plan demand for that legislation that impacts on EFSA. She concluded by informing the Board that she planned to visit the Scientific Panels and the Scientific Committee to personally thank them for their contribution to EFSA.

Item 5: Financial Statements Accounts

21. EFSA's Accounting Officer introduced the item; a separate PowerPoint presentation is available. The provisional 2008 accounts have been audited by the Court of Auditors and its report will be adopted in September 2009.

22. A Member commented that it is standard practice to receive both the financial report and the audit report simultaneously. The Accounting Officer responded that the report from the Court of Auditor had only recently been received and would be circulated immediately to the Board. The report indicated that the accounts are legal and regular.

23. A Member comment that when closing annual financial reports in future an analysis of lessons learned would be useful.

24. The financial statements accounts were adopted.

Item 6: Cooperation between EFSA and the Member States: the way forward

25. The Chair reminded Board Members of the background to the discussion and asked the Executive Director to present the document.

26. The Executive Director summarised the context of the document, i.e., the review of the Strategy on Cooperation and Networking and the input of the members of the Advisory Forum to the January 2009 meeting of the Management Board. EFSA had continued that dialogue with the Scientific Committee and the Advisory Forum and the document under discussion presented EFSA's initial thoughts based on that dialogue. In addition, the Executive Director told the meeting that she had discussed the issue in depth during her visits to national authorities. It is being presented for discussion with the Board and to seek its guidance. It would be followed up with further discussions with the Scientific Committee and the Advisory Forum and an action plan would be formulated. She invited the Director of Scientific Cooperation and Assistance to present the document.

27. The Director of Scientific Cooperation and Assistance set the scene by reminding the meeting of the basis for cooperation laid down in the Founding Regulation and subsequent vertical legislation. Noting that the Founding Regulation strikes a delicate balance between independence and cooperation, the Strategy on Cooperation and Networking identifies 4 priority areas: data exchange; sharing risk assessment practices; harmonisation of risk assessments; and coherent risk communication. The Scientific Cooperation and Assistance Directorate was created in 2008 to underpin these activities and

the main achievements of the Directorate were summarised, including the Focal Point and Advisory Forum networks, other scientific networks, Article 36, the experts database, the Information Exchange Platform, ESCO Working Groups, and the growth in grants and contracts.

28. In light of recent discussion, the Director of Scientific Cooperation and Assistance noted the requirement to boost risk assessment capacity across the EU, taking into consideration the different *modus operandi*, interests to serve and degree of engagement with EFSA. It was important to move beyond the sharing of annual plans to multiannual plans to enable national agencies to plan their activities. To achieve these goals, he envisaged a process of natural evolution rather than revolution. The document also prioritises the need to strengthen existing networks, such as those on GMOs, and the training of experts.

29. In summary, the Director of Scientific Cooperation and Assistance mentioned that the Strategic Plan provided a natural foundation on which to build EFSA's cooperation activities with Member States and provided a useful multiannual basis that enabled Member States to respond.

30. In subsequent comments, the paper was well received by Board Members; one mentioned that it had the right level of ambition and that if cooperation were to be sustainably increased, funding must be not be constrained as it provided an unlimited return to scale. He also emphasised that EFSA was building on an existing solid basis for cooperation.

31. A Member queried whether EFSA had the right engagement at all levels within Member States, from strategic input within the Advisory Forum down to practical networking. She supported the idea presented in the document of establishing networks on a more formal basis and asked whether there is interaction between EFSA Scientific Panels and their equivalents within Member States.

32. According to a Member, the document would benefit from an introductory passage that outlined the context of the recent discussions with the Advisory Forum and that acknowledged the differences in position within the national authorities.

33. The meeting was reminded by a Member of the provisions for cooperation with Member States outlined in EFSA's Strategic Plan and the need to ensure that those plans were implemented. He emphasised the need to ensure the situation did not revert to the pre-2002 situation with many sources of sometimes conflicting risk assessments.

34. Noting the progress made in cooperation between agencies, a Member queried the level of engagement with evaluation agencies in relation to risk assessment. Scientific risk assessments raised many legitimate questions on issues such as health, animal welfare and the environment, and it was suggested that these questions should be mapped on a national basis. It is important to identify where skills lie in Member States so that EFSA can organise its activities with them. In addition, stakeholders' views should be solicited via the consultative platform to understand their expectations in relation to risk assessments.

35. The need to avoid reverting to the pre-2002 situation was reiterated by another Member who emphasised the need for international platforms. He said that national borders were opening up as never before and urged both the Commission and national ministers to recognise this. While EFSA was obliged to interact with all countries, it was equally important for Member States to support EFSA.

36. Noting the recent agreement between national agencies from two of the larger Member States, a Member pointed out that the issue under discussion was highly sensitive. There are significant differences between Member States in risk assessment capacity and operating principles and he suggested a survey to obtain information on the various national risk assessment systems. A national voluntary audit undertaken with the input of the Advisory Forum might be one way to implement this.

37. In response to the questions/comments raised, the Director of Scientific Cooperation and Assistance noted in relation to the collection of information that the Information Exchange Platform had been launched and a review of its activities would present *de facto* information on what was being shared. The characterisation of risk assessment activities in Member States is ongoing with the Advisory Forum. He emphasised the need to get the right balance between engaging European expertise, i.e. cooperation, on one hand and independence, EFSA's *raison d'être*, on the other. Acknowledging the different practices across Member States, he said that this was a delicate exercise. The need to implement the Strategic Plan was noted and this would provide Member States with the opportunity to identify which areas they wanted to be involved in. The option for Member States to specialise in certain areas is also available. For example, diets – and hence exposures – vary widely across the EU so Member States may want to develop specialist risk assessment systems while ensuring that their national exposure data are taken into consideration in the overall EU picture.

38. In relation to engagement of Member States at all levels, the Executive Director noted that the situation was very diverse and that EFSA's aim was to increase engagement with those countries that were not fully engaged at present. Exchange between Panels and national committees could be explored with the Advisory Forum, she added. In relation to stakeholders, this is an important question for EFSA: how does its work address the concerns of society? EFSA has achieved much with stakeholder engagement but, as discussed in a later item, this would need to be developed. The area of GMOs, which generated many questions from society, might be a good place to start. She stressed that nobody, including the Advisory Forum, wanted to revert to the pre-2002 situation, and the manner in which some criticisms of cooperation were expressed suggested that what was really needed was further and enhanced cooperation with EFSA.

39. A Member pointed out that EFSA was the body to draw up the position on cooperation for all 27 Member States and that while it was important to acknowledge differences between countries it was also important that the differences were not so great as to endanger unity. He also emphasised the need to prioritise tasks.

40. In summing up, the Chair noted, *inter alia*, that the document could be improved with an introductory contextual text and that the Executive Director would provide regular progress updates to the Board.

Item 7: Presentation of the Chair of the Scientific Committee

41. The title of the presentation was *Mission and Activities of EFSA's Scientific Committee* and is available separately for further detail. The Chair of the Committee provided a comprehensive account of the legal basis, terms of reference and workload of the Committee and the highlights of its activities in the period 2003-2009. Specific sections were dedicated to the identification of emerging risks, animal cloning, nanotechnology, botanicals, and the provision of advice on EFSA strategic planning. The

presentation concluded with a perspective on the Scientific Committee's priorities for 2009-2012 and a summary of the media coverage of its activities.

42. The Chair and Members thanked the Chair of the Scientific Committee for the very informative presentation. Questions and comments were received on the following aspects: framing of questions for scientific experts; use of the term nanotechnology as distinct from nanoparticles; follow-up of the opinion on transparency in risk assessment; identification of emerging risks; aspects of opinions or discussions that remain open; ensuring that Scientific Committee guidelines are followed; communication of scientific opinions in terms understood by the general public; follow-up of risk assessments at the European level; measurement of ethics in EFSA's scientific work; communication of EFSA's remit in the field of nanotechnology; the role of the Scientific Committee in the review of mandates; and the need for the Scientific Committee to become more assertive in dealing with complex risk assessment issues such as those presented by nanotechnology.

43. In response, the Chair of the Scientific Committee outlined the differences in risk assessment procedures in the various Member States and emphasised that cooperation with the national agencies should concentrate on scientific issues. The terminology used in the nanotechnology opinion reflected the broad scope of the mandate received, he added. He outlined the quality assurance systems in place at EFSA to ensure that guidelines are adhered to: self-review, internal review and external review. In relation to emerging risks, he noted the work being carried out with the European Commission and the resource implications of this work. The Scientific Committee works closely with EFSA's Communications Directorate to reach what is a very diverse European audience. He pointed out that ethics is not part of EFSA's remit *per se* and responsibility for it rests with other European bodies. The Scientific Committee has an excellent interface with the Panels, he remarked, but it would welcome the opportunity for greater involvement in the development of mandates.

44. In summing up, the Chair thanked the Scientific Committee on behalf of the Board for its valuable work for EFSA and noted that that it would have an important role in developing a common risk assessment language. She expressed the hope that the media would report on EFSA's activities in a proportionate manner and cover scientific as well as political issues.

<u>Feedback on Away-Day on Impact Assessment</u>

45. The Vice-Chair of the Management Board described the day's activities. The first session, facilitated by a DG SANCO expert, was devoted to understanding what impact assessment meant within an EU context. The second session was facilitated by an external consultant and focused on impact assessment in relation to public health. The third and final session provided an opportunity for Board Members to discuss what impact indicators were needed to enable Members to discharge their responsibilities. The impacts, he said are two-fold: the impact of EFSA as an organisation and the impact of its outputs and other deliverables on the regulatory system. EFSA's Strategy and Prospective Unit was tasked with producing a draft document on the away-day for discussion at the next Board meeting. He concluded by saying that the process was a first step in understanding the role of EFSA and might generate useful qualitative performance indicators.

46. The Board agreed to merge the related items 8 and 11 and moved to item 9.

Item 9: Renewal of the Stakeholder Consultative Platform

47. Introducing the item, the Chair welcomed the Chair of the Stakeholder Consultative Platform, Andreas Varlamos, and asked the Head of the Legal and Policy Unit to present the item.

48. The Head of the Legal and Policy Unit described the background of the Platform and reminded the meeting that the three-year mandate it received in 2006 would soon expire. He presented two documents: Review of activities 2006-2009; and Proposed Terms of Reference which are available for further detail. He pointed out that the review of activities document was based on qualitative research carried out by an external advisor in consultation with stakeholders in 2008 as well as on more recent discussions with stakeholders on renewal of the Platform mandate. The former Chair of the Platform, Sue Davies, had also been consulted. The terms of reference had also been developed in an intensive process of dialogue with the Platform. The Board was asked to agree an extension of the Platform and, upon agreement, EFSA would launch calls for full and associate membership with a view to presenting a proposed list of candidates to the Board at its October meeting.

49. A Member stated that it was his view that the Platform was successful and should be continued on a more permanent basis. He was sceptical about increasing membership and suggested that the introduction of rules of assiduity might be appropriate. The text on eligibility for membership should be amended, he added, and the schedule for launching calls for membership was unrealistic in light of the summer holiday season.

50. It was suggested that EFSA should write to current Platform members to ascertain whether they wished to continue their membership.

51. In support for the continuation of the Platform, a Member pointed out that it is working well and that its it achieves a good balance between being a forum to update stakeholders and providing the opportunity to debate important issues. The interaction of the Platform with scientists is effective, she said, quoting the examples of animal cloning and health claims. She was also wary of increasing membership and asked whether any particular part of the food chain was unrepresented on the Platform. Coordination of discussions at the Platform with the Management Board agenda and the engagement of the Platform to comment on the questions received by EFSA Panels were suggested. In relation to the last point, another Member urged caution as it could compromise independence and transparency.

52. The Chair summarised the debate, noting, *inter alia*, the Board's wish to see the Platform continue and the lack of support for expansion of membership.

53. In further discussion, the Chair confirmed that it was the Board's responsibility to decide on membership of the Platform. The Executive Director confirmed that membership was for three years renewable and she added that rules of assiduity in line with those of the Management Board could be introduced. A Member pointed out that initially annual colloquia were used to engage non-Platform stakeholders and these could be re-introduced as an alternative to expansion of membership.

54. A Board Member reiterated the need to revisit the wording of Article 2 of the Terms of Reference. The Executive Director summarised the recommended changes to the text that would be implemented and the Terms of Reference were adopted.

Item 10: Update from the Audit Committee

55. The Chair of the Audit Committee told the meeting that the European Court of Auditor draft report for Quarter 4 had been reviewed and that the accounts were found to be legal and regular. Some remarks had been received on procurement and increases in carry forward. The need to ensure that the financial resources at EFSA's disposal, more than €19 m, were deposited in a financially secure bank was emphasised. An Internal Audit Service report had identified deficiencies in controls in relation to declarations of interest and the Executive Director had acted swiftly to issue new guidance on conflicts of interest. The IAS had been invited back to EFSA in September 2009 to re-audit this function. The IAS had also issued a report on recruitment at EFSA which showed that improvements had been implemented. Communication on the IAS Charter had also been discussed at the Audit Committee meeting and it was noted that the opinions of the other EU agencies were required.

56. Members expressed their agreement with the Audit Committee on finding an appropriative bank.

Items 8 and 11: Budget Execution and Forecast 2009 and Transfers in the EFSA Budget

57. The Director of Administration presented both documents; separate presentations are available for further information. It was noted that 40% of budget was committed at the end of May 2009, slightly behind forecast but not of concern at this stage. Commitment was about 3% better than the corresponding period of 2008.

58. No transfers between budget titles were reported with some relatively minor transfers within titles.

Item 14: Any other business

59. The Chair confirmed Parma as the venue for the next Board meeting on October 7-8 and announced the 2010 meeting dates. She reported that she had received notification from DG-SANCO that Mrs. Paola Testori-Coggi had been appointed representative of the Commission on the EFSA Management Board effective from July 1, 2009. On behalf of the Board, she expressed her gratitude to Robert Madelin for his significant contribution to EFSA during the past years and asked him for his continuing interest in and support for the Authority which he confirmed.

60. In closing, the Chair thanked the Greek authorities, especially the Ministry of Rural Development and Food for hosting the Board meeting and the conference on June 16 in Athens, the Hellenic Food Safety Agency, Mr. Zampelas for his address, Members of the Board, the Consumer Secretary General for assistance in organising the June 16 conference, the Chair of the Scientific Committee, the Chair of the Stakeholder Platform, the experts working in EFSA Panels and Scientific Committee, the audience in Athens, the webcast team and those watching via webstreaming, the staff of the Authority and the interpreters. Special thanks were sent to Konstantinos Yazitzoglou, who was very active in the preparatory work for the meeting and she wished him a speedy recovery on behalf of the Board.

Actions arising

Meeting reference	Action	Deadline	Status
June 18, 2009	Amend DOIs of Board Members (Roland Vaxelaire and Peter Gaemelke)	asap	Open
June 18, 2009	Distribute copy of roadmap on applications agreed with Commission to Board Members	End-June	Open
June 18, 2009	Establish relations with new European Parliament	Ongoing	Open
June 18, 2009	Organise annual meeting of European experts on risk assessment of GMOs	Ongoing	Open
June 18, 2009	Distribute report of Court of Auditors to Board Members	asap	Open
June 18, 2009	Amend document on cooperation with Member States, in particular to include preamble on context of discussions	End-June	Open
June 18, 2009	Update the Management Board on discussions related to cooperation with the Advisory Forum and Scientific Committee	3rd quarter 2009	Open
June 18, 2009	Invite Chair of new Scientific Committee to Management Board meetings	When elected (end-July)	Open
June 18, 2009	Circulate draft report on Management Board away-day	End-June	Open
June 18, 2009	Amend text of the Terms of Reference for the Stakeholder Consultative Platform, particularly in relation to rules of assiduity	End-June	Open
June 18, 2009	Enlarge text size in presentations from Director of Administration	Next Board meeting	Open