

### **European Food Safety Authority**

# Draft Minutes of the Management Board Meeting 27 April 2004 Palazzo Ducale, Parma

#### **Members of the Management Board present**

- Angeliki Assimakopoulou
- Ernst Bobek
- Giorgio Calabrese
- Peter Gaemelke
- Catherine Geslain-Lanéelle
- Matthias Horst
- Deirdre Hutton

- Robert Madelin
- João Pedro Machado
- Pirkko Raunemaa
- Bart Sangster
- Stuart Slorach
- Roland Vaxelaire
- Patrick Wall

#### Staff of the European Food Safety Authority present

- Marie-Noelle Costa
- Antoine Cuvillier
- Lucia De Luca
- Anne-Laure Gassin
- Marisa Giminez
- Katharina Herrmann
- Herman Koeter
- Christine Majewski

- Silvie Mateljan
- François Monnart
- Geoffrey Podger
- Nicole Poupart
- Lionel Rigaux
- Ingela Soderlund
- Anja Van Impe
- Katty Verhelst
- Victoria Villamar

#### Members of the Scientific Committee and the Scientific Panels present

Vittorio Silano

#### Italian dignitaries

- Cesare Cursi, Undersecretary of Health, Ministry of Health
- Elvio Ubaldi, Mayor of Parma
- Vincenzo Barnazzoli, President of the Province of Parma
- Luigi Solari, Plenipotentiary Minister, Ministry of Foreign Affairs

# **MB 22.06.2004 – 2 Adopted Minutes**

#### **Preliminary Formalities**

Stuart Slorach opened the meeting by welcoming the Board members, the Authority's staff, those watching on the webstream and the live audience in the room. Apologies were received from Carlos Escribano-Mora.

It was the first meeting of the Authority's Management Board in Parma, the permanent seat of the Authority.

No declarations of interest were made for any agenda items. The Board members have renewed their annual declarations of interest, declaration of independence and declaration of confidentiality.

#### 1) Adoption of Agenda (Doc MB 27.04.2004 – 1)

- 1.1 The agenda was adopted.
- 1.2 Additional items were added and discussed in agenda item 10.

# 2) Draft minutes of the previous meeting and matters arising from the minutes (Doc MB 27.04.2004 – 2) (Adoption)

- 2.1 The minutes of the Management Board meeting of 10 March were adopted.
- 2.2 The minutes of the meeting of 10 March would be published on the Authority's website.
- 2.3 The Board members had approved the report on the Authority's activities in 2003 by written procedure, following the changes made in the last Board meeting. The final document would be distributed to the Board members as soon as the published version would be available.

### 3) Information and update from the Geoffrey Podger on the move of EFSA to Parma

- 3.1 The Executive Director informed the Board members that the Seat Agreement, governing the legal arrangements for the Authority's presence in Italy, would be signed during the meeting by Minister Luigi Solari on behalf of the Republic of Italy and Stuart Slorach and Geoffrey Podger on behalf of the Authority. The Executive Director expressed his appreciation of the cooperation with the Italian authorities in Rome and thanked Antoine Cuvillier, the Authority's chief legal adviser, for the work done from the Authority's side.
- 3.2 Following the agreement from the Board in the previous meeting, the Parma authorities would conduct a feasibility study for the Authority's permanent building. As part of those discussions, the Authority welcomed a team from the city of Parma in Brussels whose visit aimed at understanding and assessing the Authority's current situation and its requirements. The Authority has stressed the need to be fully engaged in the project as it progresses. The negotiations are still in an early stage and any proposals would come to the Board for discussion and agreement.
- 3.3 The Executive Director reported on the good progress being made in negotiating the conditions for the use of the DUC complex building in Parma

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as the Authority's temporary working building. The negotiations are led by François Monnart, the Authority's new head of finance. A specific proposal would be sent to the European Parliament's Budget Committee for approval and then to the Management Board. The availability of a temporary building is considered to be a key issue so that the move of the Authority can actually start to take place. The Board agreed that it is in the Authority's best interest to move as quickly as possible, recognizing that certain matters need to be in place first, such as a suitable building and schooling.

- 3.4 The Italian authorities have made a significant effort to be ready to start preschool and primary school education in English and French as of September 2004. The Executive Director expressed his appreciation of the work done by the authorities in Rome and Parma in order to find a suitable solution. As for secondary school, the Authority continues to explore the options in Parma and nearby cities such as Piacenza and Modena. Further discussions are taking place and should lead to further progress.
- 3.5 The Authority stressed the need for the airlink between Parma and Brussels, already offered by the Italian Authorities as a key part to function effectively. The city of Parma would need a more specific date on the Authority's move before it could be put in place.
- 3.6 The Executive Director stressed the excellent level of communication in Rome and Parma. Although real progress has been made, there are inevitably still some issues that would need to be resolved. The Board would be kept updated.
- 3.7 Cesare Cursi, Undersecretary of the Italian Ministry of Health, welcomed the Board and the Authority to Parma. Mr Cursi stated that the enlargement with 10 new member states offers an opportunity for Europe to collaborate in terms of scientific excellence and to develop new safety standards which could be used as a reference on an international level. The Italian authorities, together with the regional and local authorities, wished to guarantee the best opportunities in terms of infrastructure, logistics and education that would be offered so that the Authority can work effectively and efficiently.

#### 4) Geoffrey Podger – General update on developments

- 4.1 The Advisory Forum had met on 6 April in Helsinki. The Executive Director reported on the items covered during the meeting:
  - The Advisory Forum and the Authority staff members were warmly welcomed by the Finnish authorities
  - A useful meeting between the Authority and the WHO had been held to see how both organisations could usefully cooperate with each other, exchange information and look ahead at work programmes in order not to duplicate activities
  - Herman Koëter updated the meeting on the guidance document for the assessment of GMOs
  - Herman Koëter informed the Forum that the Authority has been in discussion with the Commission on MRLs
  - Anne-Laure Gassin updated the Forum on the Authority's website and its new functionalities

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- Herman Koëter updated the meeting on the issue of investing in food science, the Authority's priority projects and its cooperation with national research centres
- The members of the Advisory Forum exchanged information on topical issues such as the issue of methyl mercury in fish, analytical data requested on SEM, amongst others.

The minutes of the Advisory Forum meeting would be circulated to the Board members as well as published on the Authority's website.

- 4.2 The Authority received around 240 applications following a call for expression of interest for membership in one of the Authority's Scientific Panels. The Authority is currently in the process of evaluating the applications. A shortlist of desirable candidates would be sent to the Management Board and Advisory Forum around mid-May. The final list should be ready to be presented to the Board for approval in its meeting of 22 June.
- 4.3 The Executive Director reported the Board on the staff situation as of mid-April 2004. Although the Authority has a good spread of nationalities, the highest proportion of the staff members are of Belgian, French and Spanish origin. The ratio of men to women amounts to 28% / 72% while the ratio men/women of A level posts is 37% / 63%.
- 4.4 The first monthly newsletter has generally been well received as a way to keep people informed. The newsletter is available in paper copy and online (<a href="http://www.efsa.eu.int/press\_room/efsa\_journal\_2004/355/newsletter\_01\_fin\_al\_en1.pdf">http://www.efsa.eu.int/press\_room/efsa\_journal\_2004/355/newsletter\_01\_fin\_al\_en1.pdf</a>).
- 4.5 The Authority is in the process of defining its mission and vision. A series of interviews have been conducted by a consultant to get an initial view of stakeholders regarding strengths, weaknesses and opportunities. A report would be produced, keeping the confidentiality of the interviewees, focussing on the main themes which could be considered by the Board. The Executive Director emphasized that this is not a substitute for the evaluation exercise as required by the Authority's Founding Regulation 178/2002, article 61<sup>1</sup>. More information on the terms of reference and the framework of this work would be discussed in the next Management Board meeting.
- 4.6 The Board was informed that the register of questions is available on the Authority's website (<a href="http://www.efsa.eu.int/register/qr disclaimer en.html">http://www.efsa.eu.int/register/qr disclaimer en.html</a>). The register is continuously being updated. More information and features, such as the underlying documentation and the possibility for stakeholders to add documents, will be provided and hopefully be operational by the summer. The questions have been regrouped and the total number of questions in 2003 is 229. 35 opinions were adopted in 2003. Since the Scientific Committee and the Panels have only been established in May 2003, the work

Before 1 January 2005 and every six years thereafter, the Authority, in collaboration with the Commission, shall commission an independent external evaluation of its achievements on the basis of the terms of reference issued by

commission an independent external evaluation of its achievements on the basis of the terms of reference issued by the Management Board in agreement with the Commission. The evaluation will assess the working practices and the impact of the Authority. The evaluation will take into account the views of the stakeholders, at both Community and national level. The Management Board of the Authority shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices. The evaluation and the recommendations shall be made public.

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is in 2004 at full speed. 25 opinions have been adopted and the number is likely to be more than 150 in 2004.

- 4.7 The Authority has started some initiatives to include involvement of stakeholders in its processes:
  - The Panel on additives and products or substances used in animal feed (FEEDAP) invited national competent authorities and stakeholders including consumer and industry associations and their members to meet with the Panel in an open public session in the context of its 10th plenary meeting from 5 to 7 May in Barcelona.
  - The Panel on genetically modified organisms (GMO) invited interested parties to consult before the final adoption of the guidance document on GM plants. On 25 May 2004, a stakeholder consultation is planned to discuss the comments received. The outcome of this consultation will be taken into account during the final adoption of the guidance document.
- 4.8 Following the publication of an article in 'Science' on 9 January 2004 on the global assessment of organic contaminants in farmed salmon, a number of Member States suggested that a thorough analysis should be carried out of the methodology for the evaluation of the food safety risks of contaminants in oily fish, taking into account the respective toxicities and concentrations of the various contaminants. The Authority is organizing its first colloquium and invites experts in the field to participate in an interactive exchange of expert views regarding methodologies and principles for setting tolerable intake levels for dioxins, furans and dioxin-like PCBs. The meeting will take place on 28-29 June 2004 in Brussels. The announcement and registration form is available on the Authority's website.

(http://www.efsa.eu.int/science/colloquium\_series/389\_en.html).

- 4.9 The Authority received the first question from the European Parliament. The question has been in discussion with the Parliament over the past few months and an agreement on the wording has been made. The question is related to human consumption of wild and farmed salmon marketed in the EU.
- 4.10 Prof. Vittorio Silano thanked the Board for the opportunities and being able to participate in the works of the Authority. Prof. Silano found the progress and development of the Authority satisfactory and considered the work being done in the Scientific Committee and the Panels very acceptable.
- 4.11 Following a concern from some Board members, the Board was informed that the number of Scientific Panels would not be reconsidered in the near future. In addition to allocating work to the Committee and Panels, scientific expert services would be developed within the Authority assisting the Panels in both an administrative and scientific way. Also, the Authority is contacting universities in various member states to check what the possibilities are in involving them in the Authority's work.

### 5) Time frames for scientific opinions (Document MB 27.04.2004–3) (for information and endorsement)

5.1 The Executive Director introduced this item by drawing attention to provisions on "Administrative Review" (document 3 - annex) which suggests that the European Commission could review any scientific opinion from the Authority

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or take action if the Authority failed to deliver an opinion. The text has already been inserted in the legislation already in force (e.g. Regulation 1829/2003 on GM food and feed) and in proposals for Regulations on MRLs of pesticides for products of plant and animal origin and on materials and articles intended to come into contact with food.

- 5.2 The Board members agreed and supported the Executive Director that the Authority must be allowed to stop the clock rather than to publish poor opinions. Both the Authority and the Board are strongly opposing the new clause which undermines the independence of the Authority.
- 5.3 The Executive Director stressed that the Authority is not consistently missing deadlines and that it is essential to negotiate timeframes which correspond with reality.
- 5.4 The Executive Director supported the Board's suggestion to discuss the development of formal performance indicators in the Authority's work programme in order to measure progress and performance. A discussion on this matter would be held in a future Board meeting.
- 5.5 The Board members have asked the Chair to write to the Council of Ministers, the European Parliament, the European Commission and the Permanent Representations to state that:
  - The Authority is committed to delivering work against reasonable timeframes as a matter of institutional efficiency and meeting the legitimate interests of its stakeholders;
  - Exceptions to properly established timeframes need to be justified and documented and may include situations where new data has to be requested or there is in depth scientific discussion which has to take place and cannot be accommodated within the given timeframe.
  - Proposed powers to allow the Commission to review and require withdrawal of the Authority's decisions are unnecessary, contrary to the principle of separation of function between the Authority and the Commission and unlikely to have any practical value. Similarly there are already sufficient control mechanisms in place should the Authority fail to respect properly set timeframes and the additional proposed power for the Commission is pointless.
- 5.6 The Authority would draft the letter for informal consultation within the Management Board. The Authority would modify the text in document 3 according to the suggestions made in the meeting.

#### 6) Financial Rules (Documents 27.04.2004 – 4 with annexes)

- Implementing rules of the EFSA's Financial Regulation
- Amendments to EFSA's Financial Regulation
- 6.1 Following the forthcoming adoption of the implementing regulation of article 36 ("Networking of organisations operating in the fields within the Authority's mission") of the Authority's Founding Regulation 178/2002, the Board agreed to consider some implementing rules for the Authority's Financial Regulation and to introduce some technical adjustments to its Financial Regulation. The

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implementing rules would be formally submitted for adoption by written procedure at a later stage.

6.2 The Board also considered technical adjustments to the Authority's Financial Regulation. The amendments would be formally submitted by written procedure upon approval of the changes by the European Commission and following an opinion from the Court of Auditors, in accordance with article 25 para 9<sup>2</sup> of Regulation 178/2002.

#### 7) Budget Rectification for 2004 Budget (Doc MB 27.04.2004 – 5 + annexes)

- 7.1 The Authority's budget 2004 was adopted by the Board on 3 December 2003. However, now that the overall budget had been agreed by the European Parliament and the detailed work programme for 2004 adopted by the Board, the Executive Director updated the Board on the need to consider the changes to the allocation between titles and chapters in the Authority's budget 2004 in view of the move to Parma and the adoption of the work programme 2004.
- 7.2 Although a further revision is likely to be needed as soon as the budgetary implications of the move to Parma are known, the Board adopted the proposed budget rectification.

# 8) Update on progress of EFSA Crisis Preparedness Plan and Commission's General Crisis Plans. (Doc MB 27.04.2004 - 6) (for information)

- 8.1 Following article 55 of Regulation 178/2002, the Authority developed an inhouse crisis plan, complementing the Commission's plan. It aims to provide practical information for those who may be called upon in a food safety crisis to provide scientific data or advice, technical support or other support functions.
- 8.2 The Board noted that since the last discussion on the matter, the Authority has introduced an "out of hours" contact system to support its readiness in case of a crisis.
- 8.3 The Board had a constructive discussion on the crisis paper presented by the Commission. This paper, drawn up with the crisis managers in the member states and other stakeholders in the EU, is a general plan which is called for in Regulation 178/2002 to coordinate an EU wide operation in case a crisis is declared.
- 8.4 The Authority would amend document 6 in light of the discussion in the Board. A crisis scenario is in development with the Commission and the national authorities, and would be played out later in the year.

<sup>&</sup>lt;sup>2</sup> The Management Board, having received the Commission's approval and the opinion of the Court of Auditors, shall adopt the Authority's financial regulation which specifies in particular the procedure for drawing up and implementing the Authority's budget, in accordance with Article 142 of the Financial Regulation of 21 December 1977 applicable to the general budget of the European Communities (1) and with the legislative requirements concerning investigations conducted by the European Anti-Fraud Office.

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# 9) Revision of the Rules of Procedure – (Document MB 27.04.2004–7) (for adoption)

- 9.1 At the Board meeting of 10 March 2004, the Board indicated its intention to discuss the quorum requirement set out in article 8<sup>3</sup> of its Rules of Procedure. The Board members are invited to provide the Chair and the Authority with proposals for modification of the existing text on the quorum, based on some questions by the Authority. The Authority would then make a proposal for discussion in a future Board meeting.
- 9.2 The Board agreed that the possibility to adopt documents by written procedure was needed, considering the limited number of Board meetings and the quantity of documents that need to be adopted. The Authority would change the document on Rules of Procedure in light of the discussion in the meeting and would present a proposal to the Board for adoption in its meeting of 22 June.

#### 10) Any Other Business

- 10.1 Following an invitation from the Voedsel en Waren Autoriteit (VWA) in the Netherlands, the Chair would respond and accept their invitation to have the Board meeting in December in Den Haag. The Board and the Authority would attend a dinner the evening before with an informal group of European food safety authorities but would then need to meet for the whole of the following day.
- 10.2 Since some Board members have prior engagements on the provisional dates for Board meeting in 2005, EFSA staff would provide the Board with modified proposals.
- 10.3 Following the introduction to develop a policy on risk assessment methods on animal testing, the Authority would prepare a document on the subject to be considered at a future Board meeting.
- 10.4 Following a concern by the Board on the different outcome on risk assessment carried out by the Authority and by the national authorities, for instance in the case of BT11 Maize, the Authority informed the Board that the GMO Panel is addressing the development of a guidance document especially in relation to regulation 1829/2003. A stakeholder consultation meeting is planned on 25 May in Brussels (please see also point 4.7).
- 10.5 In response to a question on GMOs dealing with human health, the Authority informed the Board that GMOs have so far been addressed in the context of the use for human consumption. In future the Authority will undertake environmental risk assessments where approvals are sought for cultivation.
- 10.6 The Commission updated the Board on the initiative by the EC to start research on e.g. BSE in various member states and spine in cattle. The tenders for these studies would be launched in the near future and would be published in the Official Journal.

<sup>&</sup>lt;sup>3</sup> A quorum of at least two thirds of all the members of the Board (i.e. 10) shall be physically present in order for the meeting to be valid

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- 10.7 With the enlargement of the European Union as of 1 May 2004, the Authority would consider organising a meeting with the 10 new member states in order to get them acquainted with the Authority's work. The Executive Director reminded the Board that the New Member States have been involved in the Advisory Forum from the very outset. As of 1 May, their status will change from observers to members. The Advisory Forum meeting on 8 June would be held in Budapest. In addition, experts of these countries are part of the Scientific Panels. Regulation 178/2002, however, does not have any provisions for them being a member in the Management Board in the immediate future. It was agreed a note should be put to the Board on the general issue.
- 10.8 The Board agreed to have its next meeting on 22 June in Brussels. The Board is invited to inform the Authority on items to be put on the agenda.

The Chair closed the meeting by thanking the members of the Board, the City of Parma for the invitation and their hospitality, the audience, the Authority's staff for the preparatory work, the interpreters, and the team responsible for the web streaming.