European Food Safety Authority

STAKEHOLDERS MEETINGS OF THE SCIENTIFIC PANEL ON ADDITIVES AND PRODUCTS OR SUBSTANCES USED IN ANIMAL FEED (FEEDAP PANEL) AND THE SCIENTIFIC PANEL ON GENETICALLY MODIFIED ORGANISMS (GMO PANEL)

A BRIEF REPORT

OPEN SESSION OF THE FEEDAP PANEL WITH STAKEHOLDERS, BARCELONA, 6TH MAY 2004

Background

1. The European Food Safety Authority (EFSA) invited stakeholders including authorities, consumer and industry associations and their members to meet with EFSA's Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP Panel) in a Special Informative Session of the Panel in the context of its 10th Plenary Meeting.

2. The purpose of the special informative session was for the Panel to hear the views and concerns from stakeholders on issues related to the new Regulation (EC) No 1831/2003 on additives for use in animal nutrition, in particular as regards the assessments to be carried out by EFSA and its FEEDAP Panel. These views and concerns would be considered as invaluable input to a Guidance Document for applicants and the Panel itself that will be drafted by the Panel in the near future.

3. The Open Session was announced on EFSA's public website on 16th April and interested individuals were requested to register before the end of April. The size of the meeting room was considered the limit and registrants were accepted as participants on a first-come-first-served basis. Participants were requested to submit their questions and comments in writing prior to the meeting.

Audience

4. The FEEDAP Open Session attracted approximately 80 participants from various stakeholders. The largest proportion of participants was from a range of companies dealing in animal nutrition field. Industry associations (European, national and local) were also well represented. In addition, there were a number of representatives from governmental authorities dealing with food safety; other associations, universities, research institutes and consumers were also represented. There was no need to deviate from the first-come-first-served basis for selection of participants.

Introduction

5. Dr Herman Koëter, Deputy Executive Director of the European Food Safety Authority, welcomed the participants to the Open Session and opened the meeting with an introduction of the European Food Safety Authority.

6. Prof Andrew Chesson, Chair of FEEDAP Panel, gave a short overview of the Work and the Scope of the FEEDAP Panel and introduced the new feed additives Regulation (EC) No 1831/2003 which gives a number of important changes to Directive 70/524/ECC currently governing the Community authorisation of additives for animal nutrition. Prof Chesson highlighted that in the coming months, EFSA through its FEEDAP Panel will need to develop a number of guidance documents in relation to the new Regulation to help petitioners develop the requested data sets.

Questions and Discussion

7. Several points for discussion were raised by 16 organisations or participants in writing before the Open Session. They were used as the basis for structuring the meeting.

8. The main topics that were discussed included the following. The need for advance communication and dialogue with the scientific experts before the publication of opinion and transparency of the process in general, as well the confidentiality of data in the company dossiers. An interest was expressed in some of the self tasks of the Panel and the expected outcomes. There was a lively discussions on setting MRLs and the methodology for addressing undesirable substances in feed additives. There was also discussion of the requirements for demonstrating efficacy that will be applied by the Panel under the new Regulation and for reevaluation of additives (e.g. trace elements/minerals). The audience was also very interested to be informed of the details of data to be requested when natural/herbal products are considered for authorisation as feed additives.

9. The audience was active in addressing questions to the Panel and they were mainly replied by the Chair of the Panel but also other members used the opportunity to bring clarifications to the subjects under discussion. Several requests were related to general procedures in the evaluation process of EFSA and these were addressed by the Deputy Executive Director.

10. Before closing the Open Session, EFSA's Deputy Executive Director thanked the audience for its kind participation to the Open Session and Spanish hosts for the facilities provided to hold this meeting and for their assistance in organizing the session.

Conclusions

11. The Open Session of the FEEDAP Panel with its stakeholders was very well received. The opportunity for the interaction, the session itself and the response given to

the questions and issues raised, were welcomed by several stakeholders. The large number of participant can be considered as an indication of the need for such meetings.

STAKEHOLDER CONSULTATION MEETING OF THE GMO PANEL ON THE DRAFT GUIDANCE DOCUMENT FOR THE RISK ASSESSMENT OF GENETICALLY MODIFIED PLANTS AND DERIVED FOOD AND FEED, BRUSSELS, 25TH MAY 2004

Background

12. On 25 May 2004 the European Food Safety Authority (EFSA) and its Scientific Panel on Genetically Modified Organisms (GMO Panel) organised a stakeholder consultation on the '*Draft guidance document for the risk assessment of genetically modified plants and derived food and feed (April 2004)'*. The meeting was held in Brussels, in the prestigious Bibliothèque Solvay.

13. In accordance with Regulation (EC) No. 1829/2003, EFSA was requested by the European Commission to publish detailed guidance to assist the applicant in the preparation and presentation of applications. The GMO Panel has prepared the '*Draft guidance document for the risk assessment of genetically modified plants and derived food and feed (April 2004)* ''. Guidance on GM micro-organisms and animals will follow at a later stage.

14. EFSA and the GMO Panel decided to consult interested parties on the draft Guidance Document before its final adoption.

15. The draft Guidance Document was published on the EFSA website on 7th April 2004. Interested parties could submit written comments through an on-line consultation process until 9 May 2004. The internet consultation was clearly very successful: some 38 contributors (GMO competent authorities and risk assessment bodies, scientific institutions, environmental organisations, and consumer and industry associations) had made together approximately 460 specific comments, covering every chapter and section of the document.

Objectives of the meeting

16. The objective of the meeting was to provide all stakeholders with the opportunity to comment on the draft Guidance Document and to exchange views on their comments with the GMO Panel members and for the Panel to understand from the stakeholders what their concerns are and how these could be addressed in the Guidance Document.

Participants

17. Invitations were sent to experts in GMO risk assessment from consumer organisations, NGOs and industry associations, from the EU Members States (through the EFSA Advisory Forum and Competent Authorities for Regulation 1829/2003 and Directive 2001/18) and the European Commission, from some food safety authorities outside the EU and from international organisations with an interest in the subject. About 80 stakeholders registered for the meeting.

Presentations

18. The meeting was opened by Dr Herman Koëter, Deputy Executive Director of EFSA who apologized the Executive Director, Geoffrey Podger, who had other commitments. Following a general introduction of the Panel and explanation of the Panel's procedure for the development of the Guidance Document by Dr Suzy Renckens, Scientific Coordinator of the GMO Panel, the GMO Panel presented the draft Guidance Document in the form of concise presentations by Panel members of defined elements of the risk assessment process followed after each presentation by a lively discussion of the corresponding part of the Guidance Document. During the various discussions the main comments on the document that had been received through the internet consultation were also addressed. Given EFSA's mandate, the consultation only focused on the scientific assessment of the safety of GMOs and their possible environmental impact and did not cover considerations related to risk management aspects (e.g. labelling, traceability, coexistence) or socio-economic or ethical concerns.

19. The programme of the stakeholder meeting was as follows:

Welcome and Science at EFSA - Herman Koëter, EFSA, Deputy Executive Director and Director of Science

Introducing the GMO Panel; Internet consultation on guidance document - Suzy Renckens, EFSA, Scientific co-ordinator GMO Panel

General introduction of the guidance document: 'Risk assessment of genetically modified plants and derived food and feed' - Harry Kuiper, Chair GMO Panel

Scope and legal background – Sirpa Kärenlampi, Member GMO Panel

Molecular characterisation – Howard Davies, Member GMO Panel

Food and feed safety – Comparative analysis – Hans Christer Andersson, Member GMO panel

Food and feed safety – Toxicology – Willem Seinen, Member GMO panel

Food and feed safety; Allergenicity/ Post market food/feed monitoring – Jean-Michel Wal, Member GMO panel

Environmental risk assessment – Jeremy Sweet, Vice-chair GMO panel

Post market environmental monitoring – Detlef Bartsch, Member GMO panel

Concluding remarks and follow up – Harry Kuiper, Chair GMO Panel

Outcome and follow-up

20. The meeting appreciated the presentations by the GMO Panel and the lively discussions of specific issues. Especially the underlying philosophy and rationale of the draft Guidance Document was much better understood. Furthermore, the summaries of the main comments/suggestions received as a result of the recent internet consultation were greatly appreciated.

21. The introduction of the stakeholders to the GMO Panel was considered by all parties as very welcome, and the Panel's mandate and activities were better understood as a result of this meeting. Various participants specifically expressed their appreciation for taking the initiative of involving them in this consultation process.

22. As a next step the GMO Panel will revise the draft Guidance Document taking into account all comments received. Prior to the publication of the final document on the EFSA website it will be sent to all participants for a final confirmation that major concerns expressed at the Consultation Meeting have been addressed appropriately. Response time for this final check will be fairly short.