

LEGAL AND POLICY AFFAIRS

10th EFSA Stakeholder Consultative Platform meeting

Brussels, 4th and 5th June 2009

Minutes¹

Participants:

Members of the Platform: Andreas Varlamos, Chair, Geoff Thompson, Vice-Chair
BEUC-CEFIC-CELCAA-CIAA-COPA-COGECA-ECPA-EFFAT-EMRA-EPHA-ESA-EUFIC-EUROCOMMERCE-EUROCOOP-
EUROGROUP FOR ANIMAL WELFARE-EUROPABIO-FEFAC-FEFANA-ILSI-UEAPME
DG SANCO

EFSA: Catherine Geslain-Lanéelle, Olivier Ramsayer, Vittorio Silano, Victoria Villamar, Hubert Deluyker, Dirk Detken, Luisa Venier, Laurence Caratini, Karen Talbot, Herman Fontier, Tobin Robinson, Daniela Maurici, Nicoletta Manghi, Rita Lazar.

Apologies: EEB-FRESHFEL EUROPE-FRIENDS OF THE EARTH-GREENPEACE

Observers: IFAH EUROPE-BPI-AGRA ALIMENTATION-AESGP-FEDIOL-ISA-CELCAA (stagiaire)-EU FOOD LAW-AVC-ELC-AVEC-EU ISSUE TRACKER

FIRST DAY, 4TH JUNE 2009

The CHAIR welcomed all the members of the Platform to the 10th meeting, thanked EFSA for the organization of the meeting and gave the floor to the EFSA's Executive Director for the first presentation in agenda, the EFSA's progress report.

1. EFSA's progress report - by Catherine Geslain-Lanéelle, EFSA's Executive Director

The presentation of the Executive Director focused on EFSA's outputs and activities of the last three months.

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

CHAIR: thanked EFSA's Executive Director for the detailed presentation of EFSA's activities underlying the relevant amount of work carried out by EFSA in the last three months.

Questions from the floor:

Eurogroup for animal welfare: it was asked to the Executive Director when the self task opinion on the "fostering harmonised Risk Assessments approaches on animal health and welfare issues in the Member States" will be published. Secondly it was asked how EFSA decides to self task, which are the reasons leading EFSA to self task a mandate.

¹ The minutes follow the order of the agenda items: agenda is enclosed to the minutes.

EFSA: The EFSA's Executive Director informed the Platform that the opinion will be published Mid June. As regards the second question, it was pointed out that EFSA has an increasing number of requests and mandates, mainly coming from the Commission. Therefore EFSA has to carefully assess how to allocate its resources to deliver promptly and timely the opinions. Taking into due consideration this increasing workload EFSA carefully assesses the possibility to self tasking a mandate, deciding on the basis of a continuous dialogue with the Panels, when there is a need of more or new fundamental work to be done in certain areas in order to deliver the best output.

CELCAA: investigated about the work done so far on the evaluation of the GMOs Regulation carried out by the Commission. In addition it was asked about the evaluation of the Plant health Regime

EFSA: Catherine Geslain Lanéelle replied that the Commission created a Steering Group on the Evaluation of the EU legislative framework in the field of cultivation of GMOs under Directive 2001/18/EC and Regulation (EC) 1829/2003 and marketing of their other uses. This is a Commission initiative and EFSA has been asked to designate one member of the GMO unit to participate to the Committee. EFSA has asked the Head of the GMO Unit to participate. The steering group is still at its inception phase and only two meetings took place so far.

As regards the evaluation of the Plant Health Regime, Catherine Geslain Lanéelle underlined that the Plant Health Unit and Panel are quite recent, having been created only in 2006. EFSA is building up its experience in Plant health and results and background are to be consolidated. There are international organizations already working in these areas since many years (as for example EPPO) and it is important to collaborate with them and with other organizations already well experienced in this field. At this regards EFSA will meet the Secretary General of the EPPO in the week of the 20th June to discuss common items. EFSA would like to enhance a more science-based approach. Many pest risk assessments EFSA receives for evaluation are poor, lacking data and consistency. EFSA would like to improve the information it receives and to clearly set out the vision on the specific role EFSA has on Plant Health.

Action: The EFSA's Executive Director proposed to the Platform to launch a dialogue on how to improve the Plant Health approach. Such a dialogue and the related comments could be a point of one of the next Stakeholder Platform meetings

ECPA: asked for additional information on the EFSA's Scientific Committee scientific opinion on "existing alternative approaches incorporating replacement, reduction and refinement of animal testing: applicability in food and feed risk assessment".

EFSA: The Opinion of the Scientific Committee reviews guiding principles on the use of animal for experimental purposes. It summarises possibility for replacement, reduction and refinement of animal testing in the area of EFSA's activities to avoid, whenever possible, unnecessary testing on animals. This work has been carried out by taking in consideration the recent developments in this area and in close collaboration with the EPAA (European Partnership for Alternative Approaches to animal testing), a joint initiative from the European Commission and a number of companies and trade federations active in various industrial sectors.

2. Draft Preliminary Management Plan 2010:- by Catherine Geslain-Lanéelle, EFSA's Executive Director

EFSA's Executive Director briefly presented the main points and aspects of EFSA's draft Preliminary Management Plan 2010 that was presented to the MB in March, prepared by EFSA internally, in consultation with the Scientific Committee and Panels, the Advisory Forum, the Commission and to be open for consultation with the Stakeholders Platform. The draft preliminary Management Plan 2010 will be submitted to the Management Board in December for adoption.

Action: A copy of the draft Preliminary Management Plan 2010 will be circulated to the Platform right after the Platform meeting.

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

Eurogroup for animal welfare: by referring to the slides of the presentation indicating the budget of EFSA in 2010, it was asked whether it is in the plans of the Commission to increase EFSA's budget.

Commission: the Commission was kindly requested to reply to the question. The Commission indicated that DG SANCO is very sensitive to EFSA's requests, but there are many Directions Generals involved and a high number of Agencies. Therefore the budget must be in balance, with the general approach of keeping the status quo, in particular in terms of staff.

CELCAA: Congratulated the Executive Director for the work done with this document. It was particularly underlined that the focus of resources in the four areas indicated by the Executive Director (i) provision of scientific opinion and advice and risk assessment approaches, ii) evaluation of products, substances and claims subject to authorization, iii) data collection scientific cooperation and networking, and iv) communication and dialogue) provides additional strength to the EFSA's work and planning. In addition CELCAA encouraged EFSA to enhance its visibility in the international scene. Finally CELCAA indicated that an increased role of Communication is also welcomed by the Stakeholders, both to the specialist media and to the general public.

EFSA: the Executive Director thanked for the encouragement. She underlined that EFSA is very much focused on the improvement and development of the Communication activities. She indicated that EFSA plans to work on the review of the Communication Strategy.

<p>Action: it was indicated that the review of the Communication Strategy will be circulated to the Stakeholders Platform for consultation</p>

On the EFSA's international activities, the Executive Director underlined that EFSA is very interested in developing its international relations as highlighted in the International Strategy 2009-2013. EFSA is enhancing its international role in line within the framework of the provisions of the Founding Regulation 178/2002 and is inclined to have an exchange with the Stakeholders on potential developments. In this context the Executive Director underlined that a series of visits have to be planned with a number of international organizations (WHO, JECFA, JEMRA, JMPR) to investigate the possible ways to collaborate.

ILSI: asked about the international contacts EFSA has on the area of the health claims and in particular if EFSA has been approached by international organizations or third countries authorities on his work and role on the health claims.

EFSA: the Executive Director indicated that the scientific and technical guidance for the preparation and presentation of the application for authorisation of a health claim was subject to an open consultation which enabled EFSA to receive several comments coming from the general public, stakeholders, consumers and also from international organizations and partners. In addition to this wide exercise, EFSA did not receive particular requests on the role of EFSA in the area of claims, but has contacts on this particular subject with the Health Canada and the New Zealand food safety Authority (i.e. the two food safety authorities competent in their respective countries for the health claims).

CEFIC: asked whether the deadlines for the health claims authorisations will be respected.

EFSA: the Executive Director replied that EFSA is in line with the deadlines foreseen for July and November. Discussions with the Commission are ongoing as regards the deadlines for the list of Article 13 claims that

were attributed to EFSA but were incomplete and needed additional information. There are several requests from the food industry on how to handle the publication of opinions on Article 13 claim applications which were submitted in different periods. Discussions are ongoing with the European Commission on how to handle the publication of these opinions.

With regards to Article 14 and 13.5 Health Claim applications, so far EFSA has met all deadlines.

3. Stakeholders Platform Terms of Reference - by Andreas Varlamos, CHAIR of the Stakeholders Platform

The CHAIR indicated that the existing Terms of Reference setting up the Stakeholders consultative Platform (hereinafter ToR) were approved by the Management Board in June 2006. The CHAIR indicated that as foreseen in Article 9 of ToR which states that "*The terms of reference and membership of the Platform will be reviewed by EFSA's Management Board after 3 years of operation*" and as previously indicated in the Stakeholders Platform meeting in March, the ToR must be renewed in view of the elapsing, in September 2009, of the three years existence of the Platform.

The CHAIR indicated that EFSA has drafted a revised proposal for the ToR on which it extensively consulted the Platform members. The consultation on the text was carried out by EFSA that sent to the Platform members the revised proposal asking the CHAIR to collect the comments and the amendments proposed by the Platform. The CHAIR asked the Platform to provide comments. The CHAIR collected all comments and sent them all to EFSA, anonymously and without a prior screening. EFSA checked the comments received, their viability and their compliance with EFSA's legal framework, incorporating them in the proposal for the new text of the ToR. The resulting proposal is presented today to the Stakeholders Platform in the form of a document showing in the first column the 2006 ToR and in a second column the new proposal highlighting the changes incorporating the comments. The CHAIR proposed to carefully read each article and to seek for endorsement of the changes proposed or comments on them. The CHAIR informed the Platform that the new text will be presented to the Management Board on the 18th June which will take the final decision.

The document proposed to the Platform can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

Comments from the floor

ESA: indicated that article 1.2 point 3 of the new proposed ToR should be amended because not clear. ESA proposed to change the point from "*alert EFSA to key issues of current or emerging stakeholders concerns, as well on emerging and existing risks*" to "*alert EFSA to key issues of current or emerging stakeholders concerns, as well as concerns on possible emerging and existing risks*".

CHAIR: after a quick roundtable, the Chair agreed on the proposal and asked to amend the text accordingly.

CELCAA: proposed to add a new point (6) to article 1.2, proposing the following text: "*the Platform will advice on communication to different target groups*".

CHAIR: the Chair acknowledged that the great majority of the Platform endorsed this proposal and it was therefore proposed to amend the text of article 1.2 accordingly.

ESA: observed that the new statement introduced in the ToR in article 2.1, i.e. "*a balance between the above mentioned sectors will be endured upon selection of the membership*" was a repetition of what already foreseen in point 2.3 where it is stated that "*the membership of the Platform should be balanced to encourage a wide range of views*".

CHAIR: the Chair acknowledged that the great majority of the Platform agreed with the comment and therefore proposed to cancel the statement from article 2.1.

BEUC: observed that the amendment of article 2.3 following a comment of the Platform and increasing the number of the members from "20-30" to up to "35" had been taken on board. BEUC indicated that an increased number of the Platform members, although ensuring a wiser participation with the inclusion of additional members to the Platform, could lead to slow down the discussions and potentially decrease the effectiveness of the Platform.

EPHA: endorsed the BEUC opinion highlighting the risks of enlarging the Platform.

CELCAA: on the contrary, underlined the importance of including in the Platform more members which could increase the level of dialogue and the support provided by the Platform.

ILSI: endorsed CELCAA position, indicating that the increase proposed is not as such as to have an impact on the workability of the Platform (maximum 10 members to be added as extreme case) and on the contrary the advantages that could derive from additional input could be many.

UEAMPE: endorsed the positions in favour of the enlargement.

CHAIR: the Chair acknowledged the different positions indicating that the majority of the Platform seems to tend in favour of the enlargement of the Platform. The Chair concluded that the Management Board of EFSA will take a final decision on the proposal.

CELCAA: proposed to include a new article 2.5 proposing the following text: "*The Platform, on a case by case basis can decide to invite international organizations to attend its meetings*". CELCAA supported such proposal by indicating that it would be important to have different views, enlarging on a case by case basis the possibility to attend the Platform meeting to international organizations skilled on the specific topic to be dealt with.

ILSI: endorsed the proposal put forward by CELCAA.

CHAIR: the Chair indicated that such a proposal will have an impact on the structure of the Platform which foresees full Members and Associate Members taking active part to the meeting. The Management Board would take the final decision.

CHAIR: Some members raised the issue of openness of the Stakeholders Platform meetings. The Chair after a quick round table, underlined that indeed this is a very sensitive point. The Chair underlined that this issue will be put forward to the Management Board in the June meeting.

ILSI: On point 5.2 which states: "*EFSA Secretariat of the Platform will draft the agendas and the minutes in cooperation with the CHAIR*", ILSI pointed out that the draft minutes that are circulated to the Platform must be kept as confidential until they are confirmed, finished and endorsed in their final version. The final version is published, as a rule on the web and this ensures the openness and transparency of the whole procedure, but the intermediate draft versions collecting the comments of the Platform must be kept confidential by all recipients.

UPEAPME: pointed out that article 5.5 expressing the majority vote principle was unclear and that the version proposed in the ToR 2006 was clearer. It was proposed to go back to the previous version. It was pointed out that the proposal to have an unanimous vote to decide that a decision should be taken only by the majority complicates the working process. In addition it was pointed out that in its role, the Platform needs to produce advice and support, therefore it does not produce decision to undergo a specific vote.

ESA: Completely endorsed the UPEAPME position. It underlined that the main role of the Platform is to provide advice and not to take decisions to be voted. The softer approach taken in the ToR 2006 was better corresponding to the role of the Platform and therefore it was suggested to go back to that wording.

Commission: the Commission intervened in order to highlight the similar position of the Stakeholders Advisory bodies of the Commission. It was indicated that they have, similarly to the Platform, an advisory role, where the voting procedure does not play a role.

CHAIR: after a quick round table the CHAIR concluded that the great majority of the Platform agreed to use the text of the ToR 2006 for this article, without any change.

4. EFSA approach on public consultation on scientific output:- by Dirk Detken, Head of the legal and Policy Affairs unit

Dirk Detken provided a short background. The draft public consultation document was presented in its outlines to the Stakeholders meeting in March and discussed extensively. After the March meeting the document was circulated to the Platform that provided its comments. In addition the document was integrated with the comments provided by the Stakeholders Working Group on public consultation. For the input provided EFSA thanked very much the whole Platform and the WG in particular. The final proposal is presented to the Stakeholders. Dirk Detken indicated that if no other changes will be suggested to it, this document will be adopted by the EFSA's Executive Director and sent to the MB for information.

The presentation and the document can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

Questions from the floor:

FEFANA: thanked EFSA for the good work done with this document, congratulating EFSA for the integration of the work already done by the Stakeholders WG. There were no other comments from the WG to the final text that is agreed as such.

CHAIR: the CHAIR congratulated EFSA for the work done and indicated that there were no additional questions or comments on the document to be considered as final for the Platform.

SECOND DAY, 5th June 2009

5. Update on the communications activities:- by Karen Talbot - Communications adviser

Karen Talbot provided an overview on the recent communications activities carried on after the last Stakeholders meeting in March.

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

CELCAA: it was underlined that on the Novel flu an important role was played, especially by DG SANCO and the OIE, on the communication concerning the fact that the flu was not transmissible via pigs, rectifying the common name given to the flu as "swine flu".

EUFIC: underlined that in general the information provided by international and European institutions on the novel flu was good and focused on reassuring people. Nonetheless it was underlined that this kind of events should trigger a higher degree of communication in particular on the norms of hygenes and on the potential preliminary plans which are in place in case of higher alert.

Commission: indicated that the presentation of the Executive Director on the Preliminary Plan highlighted the need to reinforce the communication activities. It was asked how this will be concretely realised by EFSA.

EFSA: EFSA is currently focusing on four main tools for strengthening its communication activities.

- i) The first is the need to reinforce the work and the role of the Advisory Group on Risk Communication (AGRC). This forum exists since _ years and it is extremely helpful in providing advice and support on all matters related to the risk assessment communication.
- ii) The second tool is the preparation of the risk assessment communication guidelines. These guidelines are discussed internally and in the AGRC. Comments are expected in order to finalize the document.
- iii) The third tool is to reinforce the collaboration with EFSA international partners in the fields of the risk assessment communication. An international conference on risk communication will be organized in 2010.
- iv) The last means through will be the revision of the Communication strategy. The Communication department is still working on the draft of such a document and this will be a very important tool in enhancing the communications activities.

FEFAC: congratulated EFSA for the good communication carried out on the Irish case of the dioxin. It was pointed out that it was a good example of efficient communication on a crisis situation.

EPHA: asked about EFSA's perspective on how EFSA's health claims approach is reflected in the media.

EFSA: it was underlined that the work to be carried out on the health claims is very important and very complex. EFSA is requested to react to a very demanding work. The Communication activities related to such an important chapter of the work of EFSA comes at the end of the chain and tries to be as clearer and transparent as possible.

6. Activities of the emerging risks Unit:- by Tobin Robinson, acting Head of the Emerging risks Unit

Tobin Robinson provided a detailed overview on the activities of the Emerging Risks Unit.

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

CHAIR: pointed out that in the 38th slide it was indicated that the formation of a Stakeholder support group on emerging risks is proposed. The CHAIR asked how EFSA thinks to combine and relate the Platform and his supportive role in identifying concerns related to emerging or existing risks with this supporting group.

EFSA: it was replied that there is the intention to collaborate and coordinate the work to be done by the support group on emerging risks and the Platform. EFSA does not want to duplicate the work to be carried out by the Stakeholders and therefore before the formation of the support group there will be a coordination allowing avoiding any overlaps.

CELCAA: investigated on how the confidentiality aspect of the data to be shared will be ensured if cooperation with the Stakeholders is sought in the area of the emerging risks.

EFSA: the purpose of the creation of a support group is to face and solve all relevant problems of collecting relevant data and information which might be covered by confidentiality aspects.

CELCAA: asked why EFSA is closely monitoring aflatoxin. It was asked if there are signals or information about potential increasing risks concerning aflatoxin.

EFSA: replied that the study on aflatoxin is related to potential links between aflatoxin levels and climate changes. This is the reason why EFSA is further investigating on aflatoxin.

FEFAC: congratulated EFSA for the creation of such an important unit having a very relevant mandate. FEFAC asked whether EFSA can, in the absence of consolidated data, generate and collect them in order to assess the potential risks.

EFSA: indicated that the data can be generated by outsourcing them. The outsourcing can be done through the collection of data as it is usually done (calls for data) or through the public procedures aimed at outsourcing resources (namely through the article 36 procedure or through the procurement procedure).

ILSI: thanked EFSA for the clear presentation on the emerging risks. It asked whether EFSA coordinates with other international organizations which are quite active in the field of the emerging risks (namely FAO and FDA) and if EFSA uses normal research tools as Google to collect information and data.

EFSA: replied that there is coordination with other international organizations skilled on the specific field of the emerging risks. A good example on this exchange has been pointed out by the Executive Director in her presentation of the international and institutional activities in the progress report, when indicating the liaison activities with the US organizations particularly developed in this area. As regards the searching tools, Tobin Robinson, although indicating that Google can be a good resource, he referred to its own presentation where the main searching tools were identified (in particular the media monitoring chapter of the presentation).

7. The new Regulation concerning the placing of the Plant protection products on the market by Herman Fontier, head of the Pesticide Risk Assessment Peer Review Unit

Herman Fontier gave a very detailed and extensive presentation of the EFSA work on pesticides and a detailed overview of the new Regulation concerning the placing of the Plant protection products on the market.

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

Any other business

The CHAIR invited all members of the Platform to provide comments directly to the EFSA Stakeholders Secretariat on the Draft Preliminary Management Plan 2010 within the 30 July 2009 and to suggest to him potential items for the Stakeholders Platform agenda of the next meeting within the 20 September 2009.

8. Technical meeting on the Transparency in Risk Assessment carried out by EFSA - by Vittorio Silano- CHAIR of the EFSA's Scientific Committee

Vittorio Silano provided a detailed overview on the EFSA's Scientific Committee opinion on "transparency in the Scientific Aspects of risk assessments carried out by EFSA: general principles".

The whole presentation can be found here:

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902534579.htm

ILSI: thanked Dr Silano for his presentation and for the relevant work carried out by the Scientific Committee. ILSI asked whether there will be additional investigation on the role and involvement of the Stakeholders prior and during the risk assessment. Secondly ILSI underlined a general consideration related to the fact that there can always be a tension between the qualification of an expert and its independence.

Vittorio Silano: as regards the first question he underlined that the public consultation document discussed and endorsed during the first day of the Platform meeting goes exactly in the direction of a major role and involvement of the Stakeholders in the EFSA's activities. This is in line with EFSA aim at fully complying with the principle of openness and transparency always highlighted.

As regards the question on the independence of the scientific experts, Vittorio Silano underlined that the experts are human beings therefore by nature have their own background and experiences. Nonetheless it must be underlined that the experts working for EFSA take up their duties fully aware of their own responsibility in the work to be carried out for EFSA. In addition to this EFSA has put in place a very articulated system for the declaration of interests which guarantees an objective evaluation of the interests involved.

FEFANA: underlined that it exists a Stakeholders Working Group on Transparency in risk assessment that should be re-activated.

FEFAC: indicated that sometimes the mandates are very specific and detailed without leaving to EFSA the flexibility to eventually go beyond the mandate and assess general related aspects of the questions. It was then asked how EFSA is harmonizing its peer review with the Member States and other International Agencies.

Vittorio Silano replied that the mandates are given and discussed with EFSA but it is difficult to extend a mandate which is focused on a specific item and go beyond it, although with related general aspects interconnected with it. The analysis of related aspects can be done through an EFSA self task, which allows following up on aspects that were not targeted with the specific mandate. On the second question it was replied that it is a very sensitive point: EFSA is creating and enhancing the existing electronic tools to collect and coordinate the information. With respect to the harmonisation of data collection, EFSA's guidelines are as far as possible developed in collaboration with, or at least peer reviewed by, Member States.