European Food Safety Authority

LEGAL AND POLICY AFFAIRS

7th EFSA Stakeholder Consultative Platform

Parma, 24th and 25thApril 2008

Minutes[1]

Participants:

Members of the Platform: Annette Toft, Vice Chair, Geoff Thompson, Vice Chair, Sue Davies – Chair
BEUC, CELCAA, CIAA, COPA-COGECA, ECPA, EEB, EFFA, EFFAT, EMRA, EPHA, EUFIC, EUROCOMMERCE, Eurogroup for animals, Europabio, FEFAC, FEFANA, ILSI Europe.

Guest speakers: Frederic Paeps – FPA Market and Management Advice

EFSA: Catherine Geslain-Lanéelle, Riitta Maijala, Hubert Deluyker, Anne-Laure Gassin, Victoria Villamar, Dirk Detken, Luisa Venier, Alun Keith Jones, Alessandro Gianini, Matty García Gómez.

Apologies: CEFIC, ESA, EURO-COOP, Freshfel Europe, Friends of the Earth, Greenpeace, UEAPME

Observers: EU Food Law, IFAH Europe, AESGP, FVE, EHPM.

Note: on the first day, 24th April the meeting was chaired by Annette Toft. The second day, 25th April, by Sue Davies.

FIRST DAY, 24TH APRIL 2008

1. Welcome and introduction by the Chair

The Chair of the EFSA's Stakeholder Consultative Platform, welcomed all the participants and introduced the agenda. She apologised on behalf for the absence of Sue Davies, Chair of the Platform, and informed that she will have joined for the second day. Few organizations asked to include a discussion on pesticides on agenda under Any Other Business. After these introductory remarks, the Chair welcomed and thanked the EFSA Executive Director and gave the floor for her presentation.

Progress Report on EFSA's Activities – by Catherine Geslain-Lanéelle, EFSA's Executive Director

Catherine Geslain-Lanéelle welcomed all participants and thanked them to attend the meeting in EFSA's premises. Further to this she thanked all those who participated to EFSA's 5th anniversary celebrations in Brussels last November which have been a very useful occasion for sharing EFSA's scientific achievements with all stakeholders. The presentation of the Executive Director focused on three main areas:

- achievements of EFSA in the first five years with particular emphasis to the outcome of the 5th Anniversary celebrations;

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

- work programme for 2008 and the challenges that EFSA is facing;

- the strategic outline for 2009-2013.

The whole presentation can be found in:
http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_geslainlaneelle_7thmeet_en,0.pdf

At the end of her presentation the Executive Director informed the Platform about the new internal arrangements with regards the Secretariat of the SH Platform. The responsibility for it has been allocated to the Legal and Policy Affairs Unit, and the Secretariat will be provided by Luisa Venier (e mail: luisa.venier@efsa.europa.eu; direct phone: +390521036221).

The Chair She welcomed the fact that EFSA is working on the internal and external review on risk assessment methodologies and reminded the helpful communication with Members States. She welcomed the fact that the majority of the budget is allocated to scientific activities. Finally the Chair, on behalf of the Platform, thanked the Executive Director for her presentation and for her presence at the meeting

Questions from the floor:

EUROGROUP for animals: asked whether EFSA will consider amending its draft opinion on animal cloning in view of new recent publications.

EFSA: the Scientific Committee (SC) is considering in view of the final adoption the comments of the public consultation (more than 400 contributions from around 60 organizations) and any other relevant scientific publication. The SC will in depth consider the comments received and expects to adopt its opinion in July.

FEFAC expressed its appreciation for EFSA's work and welcomed the internal and external review of EFSA's scientific output, and the structure of the 2 Science directorates. It highlighted the added value of the separation between risk assessment and risk management and asked whether EFSA's Advisory Forum will encourage this separation at National level, where a different approach is sometimes adopted.

EFSA: EFSA was pleased about the appreciation of the internal and external review system adopted. EFSA will benchmark it as more as possible to implement it, with the aim to sharing best practices useful both for Member States and EFSA. EFSA is delivering every quarter of the year a set of performance- indicators useful for the implementation of the work plan. These indicators might be the basis for the development of future quality indicators for risk assessment.

EUROPABIO, regarding the strategy for the future, stressed the importance of having "feedback from the field" and mentioned whether EFSA is in cooperation with FVO.

EFSA: as regards the cooperation with Member States, EFSA underlined that this is a crucial aspect for EFSA's activity, and this is the reason why EFSA is involving all actors playing a main role in the food chain.

EUROGROUP for animals reminded that the British press "*The Independent*" gave bad emphasis to EFSA's draft opinion on animal cloning and in particular regards animal welfare aspects. It was asked if EFSA intends to reply.

EFSA: EFSA indicated that the animal welfare aspects were not forgotten in the draft opinion and the SC expressed its concerns about animal health and animal welfare.

CELCAA remarked the importance that EFSA is able to communicate risks timely, without prejudice to risk management, in order to build up trust and confidence among consumers and stakeholders.

BEUC asked whether there is any intention to consider the psychological behaviour as consequence of toxicological analysis and how this, if included in the risk assessment analysis, would be communicated.

EFSA highlighted that the EFSA's priorities as indicated in the ED presentation will welcome the comments and recommendations of the stakeholders platform, being one of the occasions the next meeting in

October. As regard the risk-benefit analysis, EFSA is currently considering this issue, and further steps will be taken in the course of the year.

2. **Risk Assessment at EFSA: selection of experts, modus operandi of the Scientific Committee and Panels, role of the secretariat of the SC/Panels –** by Riitta Maijala, Director of Risk Assessment

Riitta Maijala briefly presented her professional background both as risk assessor and risk management in food safety and chemicals area and then presented the way the Panels work in EFSA. Please find herein below the presentation of Riitta Maijala:

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_maijala_7thmeet_en.pdf

EPHA wondered whether the Panel comes back to its opinion in case it conflicts with the opinion of a National food safety assessor and what is the impact of external different opinions on EFSA's work. EPHA representative referred explicitly to the GMOs potato issue.

EFSA: EFSA explained that article 30 of founding Regulation 178/2002 foresees the cases of diverging opinions and the way how they can be handled. It was highlighted that the strengthening of the scientific cooperation within the Member States tends to avoid the potential diverging views.

CIAA recognised that NDA panel will be facing an enormous workload and asked how EFSA will cope with all the incoming requests and asked about a possible mechanism to ease EFSA work by delegating to Member States part of it.

EFSA: Regarding NDA's increase of work, several measures have been put in place. NDA is mainly concentrated on health claims, as agreed with the Commission and staff is increasing; also a pull of seconded national experts, particularly on health claims, has been created to expand the capability of the Panel, to fit the increase of work and to issue faster evaluations. Lastly, art 36 and procurement contracts is a useful tool for ensuring external and valuable expertise helpful to externalize part of the work in order to increase the time-efficiency of the Panel.

BEUC : asked how often minority opinions are recorded.

EFSA: Regarding minority opinions before adoption, EFSA experienced very few of them. This is because the discussions are in depth and the exchange of points of views helps in reaching a consensus.

ILSI questioned which kind of support is given by the SCA Department to the Panels and how new scientific developments are taken into consideration by the Panels members.

EEB asked why EFSA is not considering cumulative risk assessment of pesticides.

EFSA: replied that an opinion had been adopted and not published yet, but that it should be published in the forthcoming weeks[2].

BEUC asked what might happen to the advice of experts expressing minority views. It was then asked whether EFSA would be able to commission studies or research not basing its evaluation only on data provided by the private-funding. Finally it was asked how EFSA selects the experts for the Panels and Working Groups.

EFSA: replied that minority opinions are recorded and are part of the Opinion. On the funding question it was replied that EFSA has no funds for researching, except art 36 and procurement contracts, allowing EFSA to externalize studies in co-operation with Member States. This tool is the only present at current time. EFSA has a close cooperation with DG Research which has an independent budget to fund research projects

[2] Please find herewith the link to the recently published opinion
http://www.efsa.europa.eu/EFSA/Scientific_Opinion/ppr_op_ej704_cumulative_en,0.pdf

and EFSA's scientists may always address proposals to DG Research to start studies on emerging issues. It was finally explained that the list of selected experts in cooperation with Member States will be finalized by the Scientific Committee and it will be available over the following months.

3. **Pooling scientific expertise and assisting SC/Panels: the role and competences of the SCA Department at EFSA–** by Hubert Deluyker, Director of Scientific Co-operation and Assistance

Hubert Deluyker presented the *modus operandi* of the Scientific Cooperation and Assistance Department (SCA) through networks with the Members States and by sharing the best practices with Scientific Panels. SCA's remit on risk assessment is only limited to pesticides area. Herein below please find the presentation made by Hubert Deluyker:

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_deluyker_7thmeet_en.pdf

ILSI asked if the EFSA journal referred in the presentation might be available to all users as an independent scientific tool open to the public.

EFSA: thanked for the proposal, but, in a short-run, the official journal will be first shared with Member States and National Authorities.

COPA-COGECA wondered whether EFSA intends to financially support the experts coming to work for EFSA in Parma.

EUROPABIO asked what is the treatment that other EU agencies have in place for experts from Member States, by reminding that EMEA took 5 years to implement its policy on remunerating its own experts.

BEUC reminded what EU regulatory framework lays down rules for expert's remuneration.

EFSA: stressed the importance of having the best available scientists in the final phase of the discussion of the draft opinion, when scientists are asked to give the highest added value. In all the other phases (e.g. working groups) the videoconference system is helpful. EFSA needs the best Science in Europe and elsewhere for issuing trustful and reliable opinions; economic and travelling conditions may always be subject to revision, but the willingness to work without compensation is crucial. It was added that the system currently in place is in line with the EU rules and practice, allows reimbursement of travelling and accommodation expenses plus a daily allowance.

FEFAC welcomed the effort that EFSA has recently placed on industry feed additives. Regarding the collection strategy of data in zoonoses, FEFAC invited EFSA to publish guidelines on how to collect quantitative data and on what expertise EFSA needs, in order Stakeholders understand the way they might be helpful to EFSA.

At this regard a presentation on data collection was done

4. **Data Collection at EFSA -** by Hubert Deluyker, Director of Scientific Co-operation and Assistance

Hubert Deluyker introduced the scope and the objectives of data collections as laid down in Regulation 178/2002. please find herein below the presentation made by Hubert Deluyker.

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_deluyker_7thmeet_en.pdf

BEUC wondered if new development methodologies of data collection and statistics were planned for the future.

FEFAC asked if consumption data would have been available.

CELCAA expressed some doubts on the effective co-ordination on data collection by EFSA.

EFSA explained that all staff in the DATEX unit has an epidemiological background: this professional asset makes EFSA's scientific staff very keen to push out for a rigorous methodology, with a strong emphasis on the respect of all procedural steps in data collection. The accessibility of consumption data is a prerogative of Member States who collected data first and so it is also up to them deciding who to share these data with. Cooperation with Member States is the most reasonable and effective way to proceed, otherwise the system might collapse: this is why EFSA is recruiting staff also in view of reaching an harmonized approach for data collection methodologies and procedures with Member States across Europe. In order to accomplish this harmonized approach, it is crucial for EFSA to know perfectly how data were collected.

CIAA expressed the very same interest of EFSA in developing the food consumption database as well as to know the methodology behind the database itself.

EFSA said that some Member States have got a huge amount of data which fail to be useful because of the several and inconsistent approaches of researchers and analysts in collecting it.

FEFAC proposed to benchmark with the sectors were data collection methodologies are not yet fully harmonized with EU legislation, but, notwithstanding, the system is working.

EFSA stressed that it is essential to further work on the harmonisation of the data collected.

SECOND DAY, 25TH APRIL 2008

Sue Davies took up the role of Chair.

EFSA: the EFSA thanked all Stakeholders for their availability to take part to the survey. The Platform was informed that the outcome of this evaluation will be taken into account by EFSA when preparing the Stakeholders strategy to be endorsed by the MB at the end of the year.

The Chair, Sue Davies: thanked EFSA to undertake the external review and welcomed all comments and suggestions provided.

Frederic Paeps: adopted mainly a qualitative methodology by interviewing 26 key stakeholder organizations, mainly the members of the Platform. As a general positive overall conclusion, the survey demonstrated that EFSA is open and high-professionally committed to involve the stakeholders in its activities. The survey showed the variety of the SH's opinions and approaches, by highlighting their experiences, their suggestions and their commitment to achieve the best cooperation.

Please find herein with the link to the survey presentation.

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_fpa_7thmeet_en.pdf

EUROGROUP for animals: welcomed all technical meetings EFSA is organizing with the SH on specific topics**.** It was then asked the reasons why the evaluator has considered the FSA as good example of transparency and openness towards the Stakeholders.

Frederic Paeps: indicated that as part of the survey included a section of benchmarking with other organizations and the FSA was one of the best responding to the principles of transparency and openness in their dealings with the SH.

EUROPABIO: questioned whether it would be useful to have reciprocal presentations of the needs and interests in EFSA's activities in order to better focus with all other members the perspectives of the sectors of their interest and the common concerns. It was underlined that some SH can express different targeted needs as they hold different interests. It was suggested to EFSA to organize more technical meetings for applicants that would allow them to go in depth of the technicalities.

EEB: supported this position.

BEUC: acknowledged the fact that EFSA has improved and took steps forward to open up to the stakeholders. As a second remark it was underlined that the same level of transparency occurring during the exchanges with the SH should apply to the setting up of the priorities and to the work of the Panels and WGs. Finally it was highlighted that transparency is equal important in the risk management step.

CELCAA: was suggesting to have internal breakouts within the SH platform, allowing the members to focus on specific topics of their interests.

FEFAC reflected on what might follow from the presentation of the external evaluator, such as a track of recommendations for discussion with the secretariat of the Platform. He recognised that it is impossible for EFSA addressing the stakeholders' interests one-by-one, but he wished to structure targeted areas of interest. It was suggested to take the example of the EMEA which constantly has targeted meetings for applicants.

The Chair noticed that all the participants found the technical meetings very important and asked EFSA whether it might be possible increasing the number of these and to open it to a major number of stakeholders in order to ease the relations with Panels. It was underlined the importance of keeping a dialogue at two levels, by strengthening also the reciprocal direction in order to allow the stakeholder to be key-parts of this involvement process.

EFSA: "Communicating on risks: perspective and experience of EFSA" - by Anne-Laure Gassin, Director of Communications

Anne-Laure Gassin presented the role of EFSA in risk communications, the way it is conducted and she took a practical example to illustrate concretely how the communication activities are developed within EFSA (the work in progress on animal cloning).

Please find herewith the presentation by Anne Laure Gassin.

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_gassin_7thmeet_en.pdf

ILSI: raised a concern as regards the availability of data in the cloning technology and in particular who is responsible to provide scientific literature to the Panel.

EFSA: replied that, as for all its risk assessments, EFSA is taking into account all available data. One of the objectives of the public consultation on the draft risk assessment of the Scientific Committee was, in addition to receiving comments and feedback on the opinion itself, to provide opportunity for interested parties to submit any additional scientific evidence and data not yet considered by EFSA.

BEUC stated that EFSA was brave in looking at emerging technology on the cloning issue; nonetheless BEUC is not totally sure that Members States have fully understood EFSA's position and the fact that EFSA's advice on cloning is out of risk management concerns: in fact BEUC stated that the perceived line between risk management and risk assessment was quite thin.

EFSA: replied by saying that contacts with Members States are in place, notably through the Advisory Forum and its Communications Working Group, and that communications with them is an essential part of the daily work of the Authority. There is always room for improvements on communicating EFSA's role to Member States: in this regard, Focal Points are the dedicated network supporting the members of the Advisory Forum in helping to disseminate information from EFSA to risk assessors and managers at national level.

EUROGROUP for animals: informed EFSA about some new recent scientific developments on animal cloning. This information will be provided to EFSA. He stressed the fact that animal welfare should be more emphasized in the final opinion.

CELCAA: welcomed EFSA's activities in Communication and acknowledged the importance of addressing the consumers' perception in communication. He used a practical example on how the assessment on food residues is perceived by the consumers.

EFSA: reported that the Scientific Committee would carefully consider all comments received in finalising its opinion with respect to animal cloning. EFSA confirmed the importance of assessing consumer perception of risk and referenced also the contribution of social scientists through its Advisory Group on Risk Communications.

EUROPABIO reminded the importance of innovation which is crucial for stimulating the research. He indicated that a moratorium on animal cloning as first action might have the side-effect to not allow science to develop and improve. Moreover, he congratulated EFSA for its ability to address sensitive issues in a way that is open and understandable for the consumers.

EFSA: expressed the view that consistency and coherence are crucial in communication in general, and especially in very sensitive areas for consumers such as cloning. The importance of close co-operation in communications with risk managers was also underlined.

BEUC: wondered about the possibility that EFSA will share also the scope of the assessment and not only the final opinion and, if it might be possible to re-frame the opinion according to some Stakeholders' suggestions.

EFSA: indicated that all mandates are public and published on EFSA's website. With regards to the framing of the requests for scientific opinions, EFSA highlighted that when receiving a mandate, EFSA liaises with the requestor in order to further clarify and refine the mandate as/where appropriate. All EFSA mandates are published on this website in order to ensure all interested parties are kept informed of its work programme. EFSA provides regular updates to stakeholders at the Platform meetings on its scientific work, notably with respect to topical areas of interest. In such areas, open consultations are launched through the EFSA website, and in addition, technical meetings are organised to further present and discuss issues. This has been done for instance with respect to EFSA's work on claims and animal cloning.

FEFAC quoted the FAO/WHO report on 2008 which presents a consultation in 2007 on feed safety implications on food safety; this report recommends that risk assessors should explore more this area. FEFAC asked EFSA if has taken into account such a suggestion, especially since it comes from an independent organization.

EFSA: The FEEDAP Unit is closely monitoring all discussions of international organizations such as FAO and WHO, having close related links in common areas.

Presentation on EFSA's role in the risk assessment of pesticide residues by Hermine Reich, Senior Scientific Officer/Team Leader Residues-MRL

EFSA presented how the PRAPeR unit in EFSA assesses the risk related to pesticide residues according to the Regulation 396/2005, by explaining what *consumer risk assessment of pesticide residues* means, by explaining the current legislation on maximum residue level (MRLs) and EFSA's related tasks.

Please find herewith the presentation of Hermine Reich.

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_reich_7thmeet_en.pdf

EEB wondered whether and how EFSA include new consumers' concerns in its daily work on pesticides evaluations and, secondly, regarding the theoretical methodology, why EFSA is not considering the dossiers provided by National Authorities.

EFSA stated that the whole process of pesticide risk assessment in this area includes not only consumer risk assessment, but also operator and environmental risk assessment. Her presentation focused only on consumers' exposure, since this is certainly one of the key aspect the unit deals with.

The Chair invited the EEB and Hermine Reich to continue the technical discussions in a bilateral basis.

EFSA: Recent and up-coming communication activities, including planning on public consultations – by Alun Jones, Senior Press Officer

Alun Jones presented briefly the key scientific issues that EFSA intends to communicate shortly over the next months.

Please find herewith the presentation made by Alun Jones.

http://www.efsa.europa.eu/EFSA/DocumentSet/sh_presentation_jones_7thmeet_en.pdf

FEFAC asked whether EFSA's work on salmonella would have been considered scientific publications from other organization.

EFSA: replied that the baseline report on salmonella is conducted by the Zoonoses Unit which collates and analyses the data coming from Member States.

Any other business:

COPA-COGECA suggested including the risk- benefit analysis in the next agenda.

ILSI volunteered to introduce their methodology and the scope on risk benefit analysis.

BEUC proposed to restore the working groups within the Platform.

The Chair: took on board all suggestions proposed. She reminded the Platform about the dates for the next meeting: 16/17 October 2008 in Brussels. She indicated that the Secretariat of the Platform will be provided from now on by Luisa Venier of the Legal and Policy EFSA Unit. She finally indicated that potential dates for the 2009 dates will be circulated soon.