European Food Safety Authority

SCIENCE STRATEGY AND COORDINATION DIRECTORATE

Brussels, 13 June 2013
EFSA/SHP/LdL/2013

Records of the views expressed in the

1ST MEETING OF THE
EFSA STAKEHOLDER CONSULTATIVE PLATFORM DISCUSSION GROUP ON PROCESS TRANSPARENCY AND INFORMATION ACCESS
BRUSSELS (BELGIUM) 13 JUNE 2013

MEMBERS OF THE DISCUSSION GROUP

Chair: *Per Bergman*

AESGP – Association of the European Self-Medication Industry	*Hubertus Cranz*	EEB – European Environmental Bureau	*Tatiana Santos*
AMFEP – Association of Manufacturers and Formulators of Enzyme Products	*Henk Aalten*	ELC – Federation of European Speciality Food Ingredients Industries	*-Frances Hunt* *-Mary O'Callaghan*
Bee Life	*Carolina Cardoso*	ENSSER – European Network of Scientists for Environmental and Social Responsibility	*Diederick Sprangers*
CEFIC – Food & Feed Cluster	*Line Jensen* *Liesbeth Timmermans*	EPHA – European Public Health Alliance	*Leonardo Palumbo*
ClientEarth	*Anaïs Berthier*	EUROPABIO – European association for bio-industries	*Nathalie Moll*
COPA-COGECA – European Farmers-European Agri-Cooperatives	*Corrado Finardi*	GREENPEACE	*Marco Contiero*
Corporate Europe Observatory	*Martin Pigeon*	Inf'OGM	*Eric Meunier*
ECPA – European Crop Protection Association	*Euros Jones*		

APOLOGIES

BEUC – The European Consumer Organisation – *Ruth Veale*

EFAD – European Federation of the Associations of Dietitians – *Mary Flynn*

EUROCOMMERCE –*Els Bedert*

FEFANA – EU Association of Speciality Feed Ingredients and their mixtures – *Didier Jans*

FoodDrinkEurope – *Beate Kettlitz*

OBSERVERS

Andreas Varlamos - Chair of EFSA's Stakeholder Consultative Platform

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Stakeholder Consultative Platform Secretariat: *Lucia de Luca, Muriel Pesci*

Per Bergman	*Dirk Detken*

1 WELCOME AND ROUND TABLE PRESENTATIONS

The Chair, Per Bergman, Director of Scientific Evaluation of Regulated Products at EFSA, welcomed participants to the first meeting of the Discussion Group on the transparency of EFSA's scientific process, a subject which is of interest to many representatives of the civil society as reflected in the high number of organisations who expressed interest and in the large and balanced membership of the Discussion Group. Before starting, Per Bergman introduced himself and then gave the floor to his EFSA colleagues Dirk Detken and Lucia de Luca, before inviting the other participants to present themselves.

2 INTRODUCTION TO THE WORK OF THE DISCUSSION GROUP

With no further points added to the draft agenda circulated to participants in the invitation sent via email, the Chair adopted the agenda. The Chair started the meeting by highlighting the importance for EFSA of having the opportunity of hearing the views expressed by the members on how to improve the transparency of EFSA's work. Before presenting the task of the Discussion Group, the Chair summarised the discussions which have been taking place in the EFSA Stakeholder Consultative Platform since the launch of the Transparency initiative at the beginning of 2013, aimed at actively involving stakeholders in shaping EFSA's future Policy on openness and transparency. The Chair reported that the Platform found it beneficial to the two-year initiative to set up a Discussion Group involving a wide range of interested stakeholders going beyond the members of the Platform. The key aspect of this Discussion Group is that it would be well placed to put forward proposals and highlight the needs of the civil society in terms of transparency, subsequently to be taken into account by EFSA when writing the new policy.

The Chair pointed out that EFSA is aware that more transparency will foster a better understanding of EFSA's work and therefore considers the initiative and the topic very important. He also added that addressing requests for public access to documents was becoming an onerous exercise and that EFSA had a general interest in streamlining such procedures within, of course, the boundaries defined by the existing EU regulation. As such EFSA must find a suitable balance between reactive transparency and proactive transparency. He also added that EFSA receives requests which focus more and more on draft documents. To the question of who was requesting information through this procedure, the Chair responded that while EFSA is not in a position to release the specific names of the requesters, demands were mainly received by Non-Governmental Organisations, followed by journalists and, in the third instance, by the food industry.

To the question from EEB of whether the Discussion Group was meant to discuss reactive or pro-active disclosure of documents, the Chair confirmed that EFSA is seeking the views of stakeholders regarding the balance between reactive and proactive availability of, for example, documents.

The Chair presented the draft Terms of Reference of the Discussion Group, which participants had received in their participant packs, and clarified that during the meeting participants were invited to express their views in the area of information and data access. The Chair clarified that the Discussion Group would subsequently address the aspects linked to transparency of the process of EFSA's risk assessment. The Chair concluded by going through the deliverables of the Discussion Group and in particular clarified that the informal record of views expressed would be circulated to members at the latest by end of September 2013 and that members will have the opportunity to clarify if the reference to their views is accurate or not.

3 Presentation of the Transparency Initiative

Lucia de Luca, EFSA's Stakeholder Relations Officer, presented the transparency initiative launched by EFSA in January 2013 and said that the work of the Discussion Group would fit into this wider initiative which aims to consider how to further ensure transparency in EFSA's scientific decision-making process with the help of the Authority's partners and stakeholders. In particular, one of the key objectives of the initiative is to consider how to facilitate public access to information and data used by EFSA in risk assessment as well as when and how this could be done.

Lucia clarified the important role of stakeholders and of the Discussion Group not only in the first phase, but also in the second phase which will look at enhancing transparency of the risk assessment process as such. A roadmap with the key milestones of the project was also shared with the audience.

Dirk Detken, Head of Legal Regulatory Affairs, clarified the regulatory framework in which EFSA was operating. Dirk responded to a question on the need to discuss the meaning of "common interest" saying that although this was indeed an important point,

the concept is already defined by the Court of Justice of the European Union and proposed that it might not be necessary to discuss during the meeting.

4. Kick-off statements by members and discussions

The Chair pointed out how the structure of the agenda of the meeting reflects the wish of EFSA to hear suggestions from participants. As indicated in the invitation to the meeting, EFSA invited participants to express their interest in coordinating the presentation of their views prior to the general discussion. Five participants expressed interest, namely ENSSER, ECPA speaking on behalf of various regulated industries, Greenpeace speaking on behalf of various NGOs, ELC, and CEF.

The Chair gave the floor to the representative of ENSSER who while clarifying that the experience of the organisation was limited to the area of GMOs, pointed out that access to documents through formal requests seems to work. The same can be said when requesting access via the website area "requests & mandates", but EFSA's website could be improved to clarify whether it is possible for a third party to request access to a specific document, so that the requestor does not need to spend time wondering whether this will be feasible or not.
Regarding the format of data, it was suggested that EFSA should publish files in Word or Excel format (not in pdf) to allow the requestors to use the content of the documents to carry out their own evaluation.
The aspect of third parties being able to reproduce the results of scientific studies was one of the key aspects mentioned by the representative of ENSSER. To be able to carry out a safety assessment, the organisation also expressed interest in the following kind of data to be made publicly accessible through the EFSA website: I) methods and protocols used; II) research materials used; and III) information about the funding sources of the study should also be disclosed in order to assess potential conflicts of interest of the authors.

Another point brought up by the ENSSER representative was whether it would be possible for third parties to publish scientific evaluations based on data they have gained access to. Since this is not possible now, the representative requested that public access to application documents should be unrestricted so that the scientific evaluation, once reproduced, can be published in scientific journals. The points raised by the ENSSER representative can be found in Annex I.

The Chair gave the floor to the representative of ECPA who, on behalf of various regulated industries (see Annex I), pointed out that increased transparency is a positive element in enhancing trust in authorisation processes but that it should be balanced with other interests such as protection of confidential business information and copyright and investment climate in the EU. The ECPA representative highlighted the importance of further understanding the concept of "overriding public interest", discussing ways and formats for making the information available and the possible negative impact linked to the disclosure of data, including misuse or unfair commercial use of the information

made public. Access to data and information should be non-discriminatory, and the representative of ECPA stressed the importance of ensuring equal treatment for all, both applicants and requesters. Predictability and legal certainty for applicant and business operators should be a guiding principle in any policy approach. The representative also pointed out that public access to non-confidential business information (CBI) versions of applications should be granted on request only, and that applicants should have the procedural opportunity to review data to be made public, as well as be informed about who has requested access to their data and when it will be released – this aspect was also highlighted by the representative of CEFIC. Moreover, the need for consistency of general principles and procedural rules between EU agencies was highlighted, as well as the need to ensure that any actions by EFSA are in line with national and international legal obligations.

The Chair gave the floor to the representative of Greenpeace who, on behalf of various organisations (see Annex I), indicated that in order to allow the scientific community to play its role in generating knowledge and carry out counter-experiments and new experiments, it is crucial to provide access to the entire content of a dossier presented to EFSA by an applicant and is also in the best interests of the public decision-makers involved (i.e. EFSA experts and staff), as is the case of the French food safety agency (see reference in Annex I).

In principle, proactive transparency on information and elements leading to a product's authorisation can be seen as a necessary requisite for all product marketing authorisations. While relieving EFSA from the excessive workload imposed by the present reactive transparency regime, the representative of Greenpeace clarified that proactive transparency would also enable EFSA to improve its reputation with the public and among scientists.

He stressed that this approach would be in line with International (Aarhus convention) and European legislation (Regulation (EC) 1049/2001, Regulations (EC) 178/2002, Regulation (EC) 1367/2006, Regulation (EU) 503/2013) which make it mandatory for the administration to grant citizens complete access to any documents and information it retains, with clearly delineated and limited exceptions, which the organisations highlight, should be interpreted in a restrictive manner, taking into account the public interest served by disclosure.

The representative of Greenpeace clarified that such exemptions, e.g. those related to public authorities' proceedings, commercial and industrial information (including intellectual property), personal data and voluntarily supplied information but also information relating to inspections, investigations and audits "may under no circumstances be applied to information that relates to emissions into the environment". It was also stressed that rules on confidentiality to protect the privacy of officials must be balanced against the public's right to know these persons' interests in their performance of public duties.
He highlighted the necessity for a study to be reproduced by other scientists following the same protocol and using the same research materials, and of the possibility for third par-

ties to be allowed to disseminate the results and indicate the source, as well as publish quotation and partial reproduction in other publications.
The requests entails: I) Complete, unrestricted and proactive online publication of applicants' files when these reach EFSA; the data contained must be accessible to everyone without justification or identification, and must be re-publishable; II) Applications should not only include the raw data but also the detailed protocols and research material used (whether biological or technical, such as the name of the software used by the applicant and all information needed for the exhaustive comprehension of the operation, use of the software and the obtained results: design of experiments and the materials used are indeed critical for making sense of the raw data), the names of the laboratories that led the experiments, and funding sources for this experiment; III) The available data (including raw data) should be published in a usable, editable format (e.g. spreadsheet) so that reanalysis work is possible; IV) Declarations of interests of EFSA's main experts and employees should be proactively published and kept online for five years after their employment at EFSA has expired.

The Chair gave the floor to the representative of ELC, who highlighted the fact that it is important, as mentioned by the representative of ECPA previously, to differentiate between access to information and dissemination of such information. Industry, she clarified, allocates millions of euro to carrying out studies to ensure the safety of the products to be put on the market and although the organisation has no objections to scientists other than those sitting on EFSA's Panels to carry out safety evaluations, transparency of data should not pave the way to groups, also outside Europe, to copy the product under assessment. The risks linked to possible use of disclosed data by business competitors to copy a specific product, was also mentioned in the discussions by the representative of CEFIC, Europabio and ECPA as being a major concern for the European food industry sector. The ELC representative agreed with asking for non-pdf files to be available, but pointed out that some data are quite old and would only be available in a scanned pdf version. She also asked the Chair why there was a need to revise EFSA's current transparency approach regarding information access and what the implications in terms of human resources were. Questions were also raised regarding the role of EFSA's Advisory Forum in the current discussions on transparency.
The Chair answered that to evaluate each single request of public access to documents is very resource intensive and a more transparent approach on this front could not only increase the efficiency of the Agency but also build more trust in the organisation. However, EFSA has to investigate whether the publication of each single dossier on EFSA's website would be the right approach and the main aim of the discussion is indeed to define the best way forward. Regarding the EU Member States representatives in the EFSA Advisory Forum, they are fully aware and support the transparency initiative.

A representative from CEO followed up by saying that transparency at EFSA is very much linked to the level of communication relating to EFSA's scientific work and that industry has the responsibility to prove what part of a study needs to be kept confidential. This aspect should be communicated in a transparent way by EFSA, and the Authority has already developed some good practices in this regard such as the Open Panels meet-

ings. The representative asked if there was a need to have different approaches depending on the applicable regulation, to which the Chair answered that EFSA had to work within the framework of the various regulations. The representative from AMFEP stated that industry believes it is very important to have a process which is very clear.

The Chair gave the floor to the representative of CEFIC who stated that it should not be forgotten that industry people are also consumers and they want to live in a healthy and safe world.

Andreas Varlamos, Chair of EFSA Stakeholder Consultative Platform took the floor to say that increased transparency will enhance in EFSA and allow for better science able to protect the consumers and the environment. He also added that if data cannot be made available to the wider public, the reasons should be explained and communicated in a clear and understandable way. He concluded by saying that as long as there are more than 30 regulations for different kind of products, there could be a need for an approach which looks at the kind of product and takes into account the different regulatory environment.

5. Planning of future work and dates for further meetings

The Chair thanked all participants for their contributions which are crucial to the development of EFSA's new policy on openness and transparency. The Chair reminded participants that EFSA will organise a conference with stakeholders on 3rd October 2013 in Parma, Italy which will focus on the transparency of EFSA's risk assessment process. He said that EFSA has been organising these kind of conferences since 2003, and that this year, the conference is intended to contribute, as is this Discussion Group to the new Openness and Transparency policy EFSA aims to finalise in 2014.

Dates regarding future meetings of the Discussion Group will be communicated at a later stage following discussions also with the EFSA Stakeholder Consultative Platform.

6. ANY OTHER BUSINESS

No other topics were raised under this point.

7. CLOSURE OF THE MEETING

The Chair invited members to send any written information in support of the views expressed in the meeting, to facilitate the writing of the summary report. Once the report has been circulated, members will be invited to comment in case they think the text does not reflect the comments or proposals made by them during the meeting.

The Chair thanked the members for their participation and active contribution and the Secretariat for its support. As no other points were raised, the Chair closed the meeting.

Annex I

ENSSER statement on access to EFSA documents *as delivered June 13, 2013 at Brussels*

1. *Scope*

ENSSER only has experience with access to GMO related information and documents.

2. *Getting started*

Access to GMO application documents: access through formal request seems to work; ENSSER had no problem to access the SmartStax files and the NK603 files, for example.

Access to other EFSA documents: when starting at the GMO panel web page, access to EFSA documents under "requests & mandates" is easy.

But in both cases, it is not obvious from the beginning that access to the documents is possible and where to go at the web page. In the case of access to the application, the web page obviously provides no information how to do it and whom to contact, for example "access to information/document" is not an issue under "topics a-z".

ENSSER received this information from scientists who accessed applications earlier. This needs to be improved at the web page.

3. *Data format*

The format of the information which is made available as pdf-files, severely hinders independent evaluation of the data, e.g. testing of the applied statistics or perfoming different statistical analysis than the applicant. The data cannot easily be extracted from the files.

EFSA needs to provide the original computable files, e.g. xls-files.

4. *'Publishability'*

The conditions under which access to the application documents is given are hindering, essentially preventing, the publication of independent scientific evaluation of e.g. GMO dossiers in scientific journals. For example, it is not allowed to make available publicly the Technical Dossier contained in the documents to which access was granted, without the consent of the copyright holder, e.g. corporations.

As we recently experienced, a scientific publication was rejected by a reviewer on the grounds that the analysis is based on a document (the Technical Dossier) that is not publicly available – although everybody could get access within 14 days.

Although EFSA's policy enables independent scientific analysis, it essentially blocks publication of the results. Thus, to a scientist, this makes the scientific study quite useless if it cannot be published on grounds of non-repeatibility – since a scientific study that is not published, does not 'exist'.

Hence, the availability of data from EFSA does not serve its purpose as long as there are limits to publication. So, there is a paradox here: 'access' to EFSA data is not always complete access, i.e. unrestricted public access. This should be changed so that anybody can carry out a re-analysis.

5. *Transparency requires more than data*

If we are to independently assess a GMO safety study, we need more than just the data from the study. We further need:

a. to know the methods and protocols used

b. to have access to the research materials used

c. to know the funding sources of the study.

This is because (a) developers display great creativity in designing protocols and choosing organisms for 'safety' testing. Also (b), we cannot repeat their tests or do additional independent tests, without access to the original products for testing, e.g. Bt toxins as expressed in their Bt crops. Complete transparency and easy access to the research materials is mandatory. If an EFSA opinion refers to a biosafety publication that was not carried out by the GMO developer, openness about the funding sources of this publication (c) is also required, to assess potential conflicts of interest of the authors.

Even if all data from a GMO safety study were fully available but methods, protocols, materials or funding sources were kept secret, there is no way an independent scientist could assess the validity of the data.

6. *Bottom line*

As far as transparency of GMO risk assessment is concerned, the bottom line for ENSSER is: the consumers' safety interest must always prevail over the GMO developer's interest.

ENSSER consists of scientists working for the public interest and the environment's interest. We cannot do this if access to and publication of any GMO data is blocked or hindered to protect the developer's interest beyond their immediate product confidentiality interest which on principle does not include safety related data. ENSSER cannot endorse EFSA's work as long as CBI takes precedence over public interest in safety data (disclosure and repeatability).

Ends ---

Annex II

"Complete transparency of the decision-making process and public access to all its elements is the minimum EFSA can do to restore public trust"

EFSA's Transparency Initiative, Position of :

APSODA, Cancer Prevention and Education Society, ***ClientEarth, Corporate Europe Observatory, Earth Open Source, European Environmental Bureau,*** *Firab, Fondation Sciences Citoyennes,* ***Friends of the Earth Europe,*** *GMWatch, GIET,* ***Inf'OGM, PAN Europe,*** *TestBiotech* [1]

July 2013

Political context

European legislation makes it mandatory for a large range of food-related products (including food additives, pesticides, GMOs...) to be authorised prior to their marketing. This authorisation is considered on the basis of an application, transferred by the European Commission to the European Food Safety Authority (EFSA) for a scientific opinion before EU authorities take a final decision. This application contains different information, depending on the product, but typically provides results of experimental analysis led by the applicant on this product to test its safety (for instance compositional analysis, toxicity analysis, feed analysis, allergenicity, impacts on non-target organisms...). Applicants in general tend to consider these dossiers as commercially sensitive, and most have so far refused to disclose them unless legally forced to.

Having the applicant performing and reporting the tests on which its product will be assessed is casting doubt on the validity of the entire decision-making process: in such a context, and in the light of EFSA's institutional and financial limitations, full transparency and public scrutiny is the only real additional defence mechanism available to EFSA against potential capture by industry. This means providing access not only to the entire content of the applicant's dossier but also to the interests of the public decision-makers involved (EFSA experts and staff)[2]. Such a transparency would allow the scientific community to play its role of generating knowledge through counter-expertise and new experiments as detailed below.

Legal aspects

Such transparency is not only politically indispensable but legally required. International (Aarhus convention) and European legislation (regulation 1049/2001, regulations 178/2002 and 1367/2006, regulation 503/2013) make it mandatory for the administration to grant citizens complete access to documents and information it retains, with clearly

[1] *This note has been signed also by some organisations which are not members of EFSA Stakeholder Consultative Group on Process Transparency and Information Access (whose name is indicated not in bold characters (Stakeholder Consultative Group Secretariat).*

2 See for instance the approach followed by French food safety agency, http://www.anses.fr/fr/liste-membres.

delineated and limited exceptions. Such exceptions are to be interpreted in a restrictive manner, taking into account the public interest served by disclosure. Particularly, the exemptions relating to (inter alia) proceedings of public authorities, commercial and industrial information (including intellectual property), personal data and voluntarily supplied information but also information relating to inspections, investigations and audits may under no circumstances be applied to information that relates to emissions into the environment. Individual confidentiality considerations to protect the privacy of officials must be balanced against the public's right to know these persons' interests in their performance of public duties. Finally, World Trade Organisation regulations stipulate that regulations should be science-based according to the Agreement on the Application of Sanitary and Phytosanitary Measures, as illustrated by the conclusion in 2006 of the case brought to WTO against European moratorium on GMOs, which has strong transparency implications.

Scientific methodology

The basic consideration for a scientific experiment is indeed the reproduction of its results by other scientists having followed the same protocol and used the same research materials. Accordingly, scientific papers published in peer-reviewed journals ensure that the following information is published: protocols followed and materials used, names of the laboratories that conducted the experiments, and the complete data obtained. Freedom of dissemination (sourcing, quotation, partial reproduction in other publications...) of those results is also guaranteed. If EFSA's decisions are to be science-based, they have to comply with these methodological requirements, enabling other scientists to reproduce experiments performed by applicants in order to confirm or challenge their results, and experts of national committees to re-analyse the applicant's results. But EFSA is not a peer-review journal and having this key public administration adopt a genuinely scientific approach would have very concrete consequences.

We submit that these should include the following:

- Complete, unrestricted and proactive online publication of applicants' files when these reach EFSA; the data contained must be accessible to everyone without justification or identification, and must be re-publishable.

- Applications should not only include the raw data but also the detailed protocols and research material[3] used (whether biological or technical, such as the name of the software used by the applicant and all information needed for the exhaustive comprehension of the operation, use of the software and the obtained results: design of experiments and the materials used are indeed critical for making sense of the raw data), the names of the laboratories that led the experiments, and funding sources for this experiment;

3 In the case of GMOs, transparency and replicability demands that industry make freely available to all researchers the necessary research materials – the GMO and the closest non-GM isogenic comparator, for research purposes. Without access to these materials, no independent research can be carried out.

- The available data (including raw data) should be published in a usable, editable format (e.g. spreadsheet) in order for the re-analysis work to be possible;

- Declarations of interests of EFSA's main experts and employees should be proactively published and kept online for five years after their employment at EFSA has expired.

We consider that proactive transparency on information and elements having led to a product's authorisation are necessary conditions to any market authorisation of this product. While relieving EFSA from the excessive workload imposed by the present reactive transparency regime, proactive transparency can also enable EFSA to fight regulatory capture and improve this administration's reputation with the public and among scientists.

Association pour la suppression des OGM dans l'alimentation (APSODA)
Cancer Prevention and Education Society
ClientEarth
Corporate Europe Observatory (CEO)
Earth Open Source
European Environmental Bureau (EEB)
Fondation Sciences Citoyennes
Fondazione Italiana per la Ricerca in Agricoltura Biologica e Biodinamica (Firab)
Friends of the Earth Europe (FoEE)
GMWatch
Groupement International d'Etudes Transdiciplinaires (GIET)
Inf'OGM
Pesticide Action Network Europe (PAN Europe)
TestBiotech

Ends ---

Annex III

Discussion Group on Process Transparency and Information Access
Brussels 13 June 2013
View expressed by Regulated industries

Overview

Regulated industry groups are in general :

Open and positive to more and better transparency if it increases trust in authorisation processes and the assessed products…..BUT

- Recent examples have brought to the fore legitimate concerns about how transparency initiatives are implemented, and what impact they may have.
- Current implementation does not always acknowledge legitimate rights and disregards other processes (i.e. reading rooms, etc.).

Key issue?

How do we achieve a balance between transparency and equally valid interests (IP, protection of confidential business information, copyright protection, investment climate in EU, integrity and effectiveness of decision making process, etc.).

5 proposed discussion areas

1. Goals to be achieved through providing greater transparency.
2. Understanding "overriding public interest".
3. Legal and treaty issues.
4. Manner and format information is made available.
5. Negative impacts of undue data disclosure, including misuse or unfair commercial use of information made public.

Principles that should underlie transparency

- Procedure for making information available to the public should allow for a fair weighting of interests exercise, as required by law
- Access should be non-discriminatory – equal treatment for all – applicants and requesters.
- Predictability and legal certainty for applicants should be a guiding principle.
- Public access to non-CBI versions of applications be granted on request only and not by publication.
- Applicants should be granted the procedural opportunity to review data to be made public.
- Applicants should be informed who has requested data, and when it will be released.
- Need for consistency of general principles and procedural rules between EU agencies.
- Need to ensure any actions by EFSA are in line with national and international legal obligations.

Euros Jones
ECPA
September 2013

Ends ---