Brussels, 12 December 2013
EFSA/SHP/LdL/2013

Records of the views expressed in the

2ND MEETING OF THE
EFSA STAKEHOLDER CONSULTATIVE PLATFORM DISCUSSION GROUP ON PROCESS TRANSPARENCY AND INFORMATION ACCESS
BRUSSELS (BELGIUM) 12 DECEMBER 2013

MEMBERS OF THE DISCUSSION GROUP

Chair: *Per Bergman*

AESGP – Association of the European Self-Medication Industry	*Kinga Adamaszwili*	ELC – Federation of European Speciality Food Ingredients Industries	*Chris Downes*
CEFIC – Food & Feed Cluster	*Marc Vermeulen*	ENSSER – European Network of Scientists for Environmental and Social Responsibility	*Diederick Sprangers*
CEFIC – Food & Feed Cluster	*Liesbeth Timmermans*	EUROPABIO – European association for bio-industries	*Carel du Marchie Sarvass*
ClientEarth	*Anaïs Berthier*	FEFANA – EU Association of Speciality Feed Ingredients and their mixtures	*Eleonora Bastino*
Corporate Europe Observatory	*Martin Pigeon*	FoodDrinkEurope	*Beate Kettlitz*
ECPA – European Crop Protection Association	*Euros Jones*	GREENPEACE	*Marco Contiero*

APOLOGIES

EFSA Stakeholder Consultative Platform, Chair – *Andreas Varlamos*

AMFEP – Association of Manufacturers and Formulators of Enzyme Products – *Henk Aalten*

Bee Life – *Carolina Cardoso*

BEUC – The European Consumer Organisation – *Ruth Veale*

COPA-COGECA – European Farmers-European Agri-Cooperatives – *Javier Valle*

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

EPHA – European Public Health Alliance – *Dorota Sienkiewicz*

Inf'OGM – *Eric Meunier*

OBSERVERS

Giulia Bertezzolo – DG Health and Consumers (SANCO)

Stella Thano – DG Health and Consumers (SANCO)

REPRESENTATIVES OF THE EUROPEAN FOOD SAFETY AUTHORITY

Stakeholder Consultative Platform Secretariat: *Lucia de Luca*

Per Bergman	*Dirk Detken*

1 WELCOME

The Chair, Per Bergman, Director of Scientific Evaluation of Regulated Products at EFSA, welcomed participants to the second meeting of the Discussion Group on the transparency of EFSA's scientific process and stressed the importance of their contribution to the discussions of the Group regarding EFSA's future policy on transparency. Per clarified that, as in the first meeting, EFSA will be carefully listening to proposals and suggestions put forward by the representatives of civil society. Such proposals reflect conflicting interests and needs, as shown in the first meeting, and EFSA is aware of the legal boundaries it has to work within but the Authority is committed to ensuring a honest attempt to shape its future policy on transparency.

Moving on to the adoption of the draft agenda, the Chair referred to a proposal received by some NGOs to shorten the duration of the meeting and suggested not changing the agenda but evaluating, during the course of the meeting, the possibility of finishing earlier. Per also referred to a request put forward by ECPA and other organisations to discuss the topic of dialogue with applicants in the risk assessment process and clarified that this would be discussed under point 4 of the agenda since is one aspect of the key topic of the meeting. Regarding the proposals also received by ECPA and other organisations to discuss the topics of "procedures for access to data submitted by notifiers within the framework of a regulatory evaluation" and "legal issues in considering access to data", Per suggested to address them under point 6 of the agenda. With these changes to the draft agenda circulated prior to the meeting, the Chair adopted the agenda.

2 UPDATE ON THE WORK OF THE DISCUSSION GROUP

The Chair reminded participants that the focus of this second meeting is the further enhancement of transparency during the phases of the risk assessment process, as indicated in the Terms of Reference of the Group which calls for participants' suggestions in this area. To shape the agenda, the Chair clarified that EFSA capitalized on the discussions held on the occasion of the Conference with stakeholders on Transparency in October 2013 in Parma. The Chair also said that proposals gathered on the occasion of the two meetings of this Discussion Group and the Stakeholder Conference will inspire the draft policy on transparency that EFSA shall start drafting early 2014. The draft policy should be ready for public consultation in May or June 2014 and revised in October 2014 in light of comments received in the public consultation phase. EFSA aims to table the draft policy for adoption by the Management Board in December 2014.

3. Phase 2: Process Transparency

Lucia de Luca, EFSA's Stakeholder Relations Officer, highlighted the fact that risk assessment in itself is multifaceted, and to ensure EFSA gathers the most relevant feedback to possibly shape the Authority's future transparency policy, EFSA identified three key questions for participants' feedback, namely: I) stakeholders' information needs regarding the risk assessment process, II) the role of stakeholders in increased transparency of such process, and III) stakeholders' suggestions to further clarify EFSA's scientific work.

Lucia also said that EFSA would benefit from specific answers with concrete proposals to these three questions for each single aspect of the risk assessment process, as indicated in the document circulated prior to the meeting. Lucia added that the document was not intended to be exhaustive; suggestions on other aspects not mentioned in the paper would be welcomed during the meeting. Views gathered will be considered by EFSA not only when drafting the transparency policy but also when formalising other initiatives in the area of transparency, such as the Authority's approach to stakeholder engagement scheduled for 2016.

4. Kick-off statements by members and discussions

Before giving the floor to the participants for their statements, Greenpeace asked to clarify that they have no interest in undermining the legitimate interest of companies but only in ensuring that transparency and public access to documents and other important information are guaranteed by the Authority. Greenpeace stressed that ensuring civil society access to the entire content of a dossier presented to EFSA by an applicant, including research materials and methodologies, is key to allowing the scientific community to play its role in generating independent knowledge and repeating the study.

Process: Work programs and Mandates

The representative of ECPA said that one of the challenges industry faces is to have clarity regarding the rules to follow when preparing a dossier and that EFSA's scientific officers have the role of translating EFSA's Guidance into practical directions. The Chair said EFSA may consider how to improve I) the clarity regarding the number of versions of Guidance on specific topics, so that interested parties would be aware of which version to follow, and II) harmonise whenever possible Guidance among scientific Panels to improve transparency and consistency for business operators active in different sectors.
ECPA also wished the European Commission could be more consistent regarding the various pieces of legislation to facilitate the work of EFSA. Mandates could better clarify the work EFSA is requested to carry out to support the risk management process and the goal the regulator wants to achieve. The practice of the European Medicines Agency (EMA) was mentioned as a positive example.
The Chair said that when EFSA receives a mandate which is not clear, EFSA clarifies the non-scientific elements with the requestor. In cases of self-tasking the Panel Chair seeks the approval of EFSA's Executive Director before initiating the work. EFSA may in future consult with civil society before initiating the work as was for example done in the case of the on-going self-task work on acrylamide, when EFSA consulted its Stakeholder Platform.

Greenpeace suggested that it is important that EFSA's opinions clearly highlight uncertainties, data gaps and limitations of the risk assessment and not venture into responsibili-

ties of risk managers. Despite the difficulty, this is a very central aspect. It is also important that Panels work together to ensure consistency among their assessments.

FoodDrinkEurope said that the pre-consultation on the mandate on acrylamide worked very well and could be repeated. This exercise enabled the clarification of many scientific aspects, the availability of scientific data and to define real uncertainties. Consultations could help in defining uncertainties, which should also be very well clarified to risk managers. The organisation reaffirmed the importance of having clear guidance on what has to be delivered by the Panel, and that the service offered by EFSA's Applications Desk allows all enterprises, regardless of size, to receive equal treatment. The Chair thanked participants for the suggestions.

The Chair clarified that it is crucial for EFSA to ensure uncertainties are clear to risk managers, so that they can take appropriate actions. Sometimes, the Chair continued, due to the short time allocated to EFSA for the finalisation of an opinion – which can range from six to nine months – the Authority cannot wait for some applicants' late responses to questions raised during the risk assessment. EFSA's Scientific Committee is currently revisiting the format of EFSA's scientific Opinions to ensure, for example, clarity in the materials and methods used. Translating complex scientific issues into material for risk managers is not easy and EFSA is happy to receive proposals on how this could be further enhanced.

Greenpeace suggested EFSA could ask stakeholders on which mandates and for which Panels stakeholders would like to be consulted on. This could be a regular exercise, the onus would be on stakeholders to ensure they provide EFSA with appropriate feedback.

Process: Outputs: Materials and Methods

Greenpeace also said that it is important to clarify which studies were taken into account in the scientific evaluation and which were not despite them being published in scientific journals. ECPA agreed with the proposal to ask stakeholders on which mandate they would like to be consulted on; in general public consultations are needed for generic mandates of public interest, and in some instances a "light" approach could be helpful so as to give stakeholders a 30-day period to comment

CEO referred to recent discussions at European Parliament where it was pointed out that systematic literature review is an interesting protocol although not suitable for all opinions. CEO welcomed EFSA's work in this area.

FoodDrinkEurope said scientific opinions should be updated when fresh criticism is based on new evidence, and that it would be helpful to have clarity about what triggers the re-opening of an opinion. The Chair clarified that it would be impossible for EFSA to re-open most opinions but that decisions to proceed with a re-evaluation are taken in light of scientific and regulatory needs as well as resources of EFSA. CEO commented that transparency of raw data is fundamental to any discussions since it would be impossible to ask EFSA to re-open each single opinion due to workload and lack of scientific resources.

The Chair said that while consultations for some opinions is of paramount importance, it remains to be decided when and to what extent EFSA should proceed with public consultations for outputs other than Guidance Documents.

ENSSER called for "coherence in the Authority's scientific scrutiny". EFSA should refrain from accepting mandates from the European Commission which request assessing only specific studies and from applying different criteria and levels of rigor to studies. In particular, EFSA should avoid following different approaches ("double standards") when evaluating studies performed by applicants and other third parties, to ensure equal treatment for all studies and avoid some of them having more influence than others on regulatory decisions. The representative illustrated this by handing over a new scientific study showing that EFSA applied double standards to the Séralini study on NK603 maize and Monsanto's own study on this maize (Meyer H, A Hilbeck. 2013. Rat feeding studies with genetically modified maize - a comparative evaluation of applied methods and risk assessment standards. Environmental Sciences Europe 25: 33; http://www.enveurope.com/content/25/1/33).

ECPA stated that all applicants' studies are submitted for review by the respective authorities as requested by the legislative process and that even if applicants do not like the conclusions of EFSA's assessment they have to respect the view expressed by the evaluators.

The Chair said that EFSA's Scientific Committee has been reflecting thoroughly on how to guide better the Panels in the selection and evaluation of studies. Greenpeace added that the role of peer review is acknowledged by everybody but it remains difficult for EFSA to decide how to proceed in situations which are not clear-cut. Accessibility to studies and replicability by third parties is an important point. ENSSER reaffirmed that comparison between studies is the thrust of the issue when it comes to information access, and that fair and equal treatment of all studies is the thrust of the issue when it comes to process transparency.

Process: Plenary meetings

Regarding plenary meetings of EFSA's Scientific Committee and Panels, ENSSER said that any initiative – open plenaries, webcast, audio-records – aimed at making the meetings more accessible to third parties is welcomed. ECPA pointed out that it is much more important to contextualise the topics discussed at meetings than provide audio or video broadcasts of two-day panel meetings. It should also be taken into account that in some instances, the Panel may opt for closed-door discussions if business commercial issues are to be discussed.

The Chair said that the recently-concluded pilot project for attendance of observers at plenary meetings showed that mainly representatives from the business sector attended such meetings with very few representatives of Non-Governmental Organisations. EFSA is discussing if audio or webstreaming could complement the open plenary initiative. CEFIC praised EFSA for the good initiative and said that the attendance of students showed it could function as an eye-opener and help people understand the process of risk assessment. Next possible steps could be engagement and dialogue, for instance pre-submission meetings for the re-evaluation of food additives, as happened in the past for the Scientific Steering Committee of the European Commission, which worked together with stakeholders to define the protocol to identify data. Such data were then presented and scrutinised by the respective scientific Panel which decided whether to accept them.

Dirk Detken, Head of Legal Affairs at EFSA, clarified that EFSA has to pay attention to stakeholders in general to ensure equal treatment for those stakeholders – NGOs and in-

dustry competitors – who are not in a position to attend Panel plenary meetings held in Parma.

CEO pointed out the need to differentiate between listening to and influencing discussions at meetings. Attendance should not pave the way to influence the risk assessment process or for industry to challenge EFSA's opinions when they are not liked.
The Chair took the floor to clarify that observers have never been invited to follow Panels' discussions on confidential business information, and no applicant has ever been present during an agenda item where substances for which they were seeking authorisation were discussed.

ECPA clarified that dialogue is meant to help the notifiers to comply by better understanding EFSA's needs, and should not lead to undue influence.
The Chair clarified that observers in the room cannot dialogue and influence Panel's experts, and they are only allowed to question the Chair regarding the discussions they have just witnessed. This is a crucial aspect for EFSA: if there is a wish to ensure dialogue with SMEs, it should not be done in plenary meetings.
FEFANA said that discussions at Panel meetings allow the organisation to gain a better understanding of which Guidance companies should comply with when they submit new data. However, companies should be able to obtain such answers through dialogue with EFSA and not by attending meetings.
CEFIC clarified that it is important for industry to know what kind of studies to run to fill the lack of data so that EFSA can receive the most appropriate data and reach full conclusions.
CEFIC pointed out that science evolves in between or during the risk assessment process and the possibility to dialogue with EFSA would contribute to more clarity for companies. The Chair clarified that Guidance Documents are the preferred way to clarify the needs of risk assessors and give precise direction to industry, the Panel and other interested parties.
ClientEarth stressed the importance of avoiding dialogue at Plenary meetings in order to not exert undue influence and inquired about the possibility for EFSA to put in place a system similar to that of the European Chemical Agency (ECHA). FoodDrinkEurope reaffirmed that pre-submission meetings would avoid stop-the-clock procedures and observers attending plenary meetings would get a better understanding of how Panels reach conclusions. Audio-recordings, such as the ones provided by the European Parliament, allow interested parties to tune in, understand the process and ultimately increase trust in the organisation.
CEFIC made it clear that industry does not wish to attend plenary meetings to influence Panels' decisions but to provide specific information and answers when requested by the risk assessors, like in the case of the EMA which calls upon industry to provide answers to specific questions to ensure risk assessment relies on good data. CEFIC clarified that when an EMA Panel has uncertainties on a specific topic, they launch a call so that interested parties have the possibility to answer questions asked by the Panel. This is exactly the kind of dialogue CEFIC would like EFSA to establish to avoid other organisations, also at international level, reaching different conclusions on the same subject thereby jeopardizing EFSA's work and ultimately Europe's reputation. CEO stated that it is important for EFSA to be able to call on experts and hear their answers, and that hearing experts should however only answer questions asked by the Panels.

ELC highlighted that adequate dialogue between those providing data and risk assessors is a valuable element in the risk assessment process, in particular in the context of the re-evaluation of food additives where data are provided by multiple producers. The following information needs were mentioned; (I) publication of a list of those who responded to the call for data to facilitate coordination information; (II) well-defined procedures with specific re-evaluation-process guidelines; and (III) greater clarity on the scientific approach followed in the evaluation. ELC considered that allowing meetings with petitioners, when EFSA requests additional data for risk assessment, would enhance efficiency and overall quality of the re-evaluation process. Such meetings should be documented or recorded to demonstrate their legitimacy and ensure transparency.

Process: Minutes of Working Groups and Panel plenaries

On the topic of greater transparency of minutes of working groups and panel meetings, ECPA said that more comprehensive summaries of meetings would ensure a higher degree of transparency and asked EFSA to evaluate the possibility of having listening rooms.

EUROPABIO suggested opting for the publication of action points complemented by audio recordings for those who want more details. ENSSER stated that although minutes do not need to be too exhaustive, they should mention all key points and should be published right after the meeting.

No comments were received on the form and timeline of publication of meeting agendas.

Process: Clarity of Risk Assessment & Communications

On the topic of laymen summaries, Greenpeace said that when looking at development in this area, EFSA should refer to its target audience. Most summaries are understandable and the representative did not see any need for layman summaries or further clarifications of acronyms.

Regarding pre-submission meetings, EUROPABIO pointed out the different approaches and sets of rules of the various EU agencies. Although this possibility is not mentioned in EFSA's founding regulation, as Dirk Detken clarified, EUROPABIO, ELC, AESGP and CEFIC pointed out how the evaluation process could benefit from having such meetings.

In particular, AESGP said that meetings with applicants on Guidance Documents are helpful but do not always address the issue at stake which refer to specific applications. Since risk assessment is application-specific dialogue with EFSA Panel members on single applications would help. In this context, AESGP referred to the conclusions arising from the EFSA external review calling for increased dialogue with applicants. EUROPABIO said that EFSA should look at different ways to get better applications while ensuring efficiency and transparency and possibly look at processes in place in other EU Agencies. CEO asked what proposals could industry come forward with to ensure data scrutiny, ensure replicability while safeguarding companies' business interests.

When discussing the clarity of communications of EFSA's work, the Chair referred to the videos EFSA made on various aspects of its work and which received more than 100,000 viewings on YouTube, and asked members if they had constructive proposals in this area. EUROPABIO was appreciative of the videos and welcomed further ones on for example Public Access to Documents and for applicants.

5. Final Summary Report of views expressed by the SHP DGTI (by February 2014)

The Chair gave the floor to Lucia de Luca who explained that records of the meeting will be shared with participants and published on the EFSA website when finalised; members will have the opportunity to clarify if their views have been accurately reflected. Lucia also clarified that views expressed by the group in the two meetings and other suggestions gathered by EFSA during the Conference on Transparency on 3rd October 2013, will be summarised in a Report which will be weighed in by EFSA when drafting its new Policy on Transparency. This Report, which is due by February 2014, will also be made available in the dedicated section on EFSA's website.

6. ANY OTHER BUSINESS

The Chair asked participants if they still wanted to discuss the two topics proposed at the beginning of the meeting ("procedures for access to data submitted by notifiers within the framework of a regulatory evaluation" and "legal issues in considering access to data"). No discussions took place since participants believed both topics had been addressed in the course of the meeting.

7. CLOSURE OF THE MEETING

The Chair thanked the members for their active participation and their contribution which will be important to the development of EFSA's new policy on transparency. As no other points were raised, the Chair closed the meeting and thanked all participants for their contributions.

Ends---

Annex I - ENSSER Comments on "Process Transparency – discussions with the SHP DG TI" – delivered at Stakeholder Meeting, 12 December 2013 in Brussels

Annex II - ELC Statement: "What are stakeholders information needs regarding the risk assessment process and their contribution to the process?" – delivered at Stakeholder Meeting, 12 December 2013 in Brussels

Annex III – Copa-Cogeca Contribution in the Framework of the Discussion on Process Transparency and Information – Stakeholder Meeting, 12 December 2013 in Brussels

Annex I - ENSSER Comments on "Process Transparency – discussions with the SHP DG TI" – delivered at Stakeholder Meeting, 12 December 2013 in Brussels

1. Process: Work programs and Mandates

1.1 Risk Assessment (RA): EFSA to become more pro-active in self-tasking to complement requests assigned by the European Commission;

ENSSER: A general theme that ENSSER wishes to see implemented by EFSA is coherence in its scientific scrutiny. We have in the past been pointing out multiple occasions and issues with regard to GMOs where EFSA applies a double standard in its conduct: be this by accepting selective mandates from the Commission (e.g. 'scrutinize this study' but not others) or applying different criteria and levels of rigor to different studies - triggered by their results. EFSA only subjects methods of studies to intense scrutiny if their data are problematic for applicants, but accepts the same methods at face value if no inconvenient results for applicants are reported. As case in point, see a recent publication by ENSSER members (former coordinator and current chair) where we clearly describe how such double standard strategy works and reveal its non-precautionary, biased outcome. In essence, ENSSER members did the work for EFSA and applied the same criteria EFSA only applied to the Seralini et al study, also to the Monsanto study. They discovered that Monsanto's study is riddled with similar 'fatal flaws' that according to EFSA disqualified the Seralini study but not the Monsanto study. Many other such studies that EFSA has taken absolutely no issue with and has routinely based its opinion of safety on are also riddled with similar 'fatal flaws'.

At least until 2009, it was routine practise by the EFSA GMO Panel to submit scientific publications that show risks of GMOs to a greater scrutiny than those claiming safety, as indicated by Dr. Schiemann, a former member of the GMO Panel in an interview.[1] Result-driven evaluation of scientific publications is not justified.

Likewise, in its Opinions, EFSA follows predominantly the lines of arguments offered by applicants and their associated circles of scientists instead of fully appreciating ALL published evidence (regardless of the source of its funding) with EQUAL rigor in its methodological evaluation and applying the same criteria with EQUAL rigor to ALL studies. In fact, if precaution were taken seriously by EFSA, such maximum 'biased' rigor would have to be applied to applicant studies and applicant methodologies as a) these studies have a disproportional influence on regulatory decision making which has serious consequences for millions of EU citizens and b) most of these studies have never undergone an independent peer-review - hence, not been subjected to external, disinterested scrutiny!

1.2 EFSA to better inform stakeholders on mandates which are particularly relevant to them;

ENSSER: EFSA should in the first place not accept selective, biased mandates from the European Commission, i.e. mandates to subject particular studies to a special evaluation which is not requested from all studies EFSA evaluates.

1.3 Call for greater procedural clarity of the RA process, including timeframe and sequence of meetings.

[1] "Of course, studies that describe potential negative environmental effects of GMOs are discussed particularly intensively" Biosicherheit.de, 10.06.2009, EFSA: New members for GMO Panel, http://www.gmo-safety.eu/news/622.efsa-members-gmo-panel.html

2. Process: Outputs : Materials and Methods

2.1 More harmonised and clear description of uncertainty and limitations in the risk assessment;

2.2 Call for consistency – that is, the same level of scientific scrutiny should be applied to all applications - and different EFSA panels should co-operate to ensure consistency when the same substance is evaluated by different panels;

2.3 Clearly specify methods to search data and information and criteria applied for exclusion and inclusion of data and information. Specify data gaps;

2.4 Update opinions with the arrival of new evidence (or fresh criticism).

MAJOR POINT OF ENSSER: *See ENSSER general statement!*

3. Process: Plenary meetings

3.1. More or all plenaries open to observers;

3.2. Webstream Panel meetings on the Web and some other scientific technical meetings;

3.3. Audio-records of Panel meetings to be released on web shortly after meeting.

ENSSER: Opening up plenary meetings, webstreaming other meetings and quick release of audio-records of panel meetings are all desirable measures which would be welcomed by ENSSER. Recording and accountability are important aspects of science.

4. Process. Minutes of Working Groups and Panel plenaries

4.1. Publish summaries of key decisions of Plenaries shortly after the Panels's meetings;

ENSSER: This should indeed be done shortly after the Panels' meetings in order to get optimal benefit from stakeholders' attention.

4.2. Publish more exhaustive minutes.

ENSSER is NOT in favor of 'exhaustive' minutes but of concise and all inclusive minutes.

5. Process: Clarity of Risk Assessment & Communications

5.1 Increase services offered and clarify rules, e.g. dialogue during clock-stop;

5.2 Laymen summary for opinions on certain topics, message to be consistent with science;

5.3 Publish detailed glossary of the acronyms, abbreviations and specialist terms used in scientific outputs.

Ends ---

Annex II - ELC Statement: "What are stakeholders information needs regarding the risk assessment process and their contribution to the process?" – delivered at Stakeholder Meeting, 12 December 2013 in Brussels

In the context of the revaluation of food additives, the ELC urgently needs processes in place that can ensure the efficient gathering of the information required for EFSA to undertake high-quality risk assessments.

The revaluation of food additives currently on the European market is an important exercise which is very much welcomed by the ELC. Seven years after its initiation in 2006 around 10% of food additives have been reevaluated. The gathering and coordinating of information required for the revaluation is a process recognised by all involved to be highly complex and requiring great efforts from all sides. The existing process will have to be improved to ensure the successful completion of the evaluation and to recognise the specifities of this reevaluation.

As stakeholders in previous meetings in this Consultation on Transparency have already indicated, adequate dialogue between those providing data and risk assessors is a valuable element of the risk assessment process. This need is particularly marked in the context of the revaluation of food additives that involves the assessment of generic substances on the basis of data provided by multiple producers.

ELC has already highlighted to EFSA a number of information needs including:

- publication of a list of those who respond to the call for data to facilitate coordination information;

- well-defined procedures with guidelines specific to the revaluation process;

- greater clarity on the scientific approach being undertaken in the evaluation.

In particular, where additional data is requested by EFSA, petitioners with an interest in a particular additive should have the opportunity to meet with experts to understand what data is required, to clarify the concerns which necessitated the request, and to ensure that all petitioners are aware of relevant data gaps to avoid data requests being misdirected.

ELC considers that allowing meetings of this sort to take place will greatly enhance the efficiency of the revaluation, save on the time and resources currently being expended, and improve the overall quality of the evaluation.

ELC believes that with the variety of technological and communication means currently available, it must be possible to have these data facilitation meetings documented or recorded in a way that demonstrates the legitimacy of these encounters and can adequately satisfy demands for transparency. ELC would welcome suggestions from other stakeholders as to what checks and balances could be put in place to meet expectations in this respect.

DECEMBER 2013 *Ends ---*

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Brussels, 20th February 2014

COPA-COGECA'S CONTRIBUTION IN THE FRAMEWORK OF THE DISCUSSIONS ON PROCESS TRANSPARENCY AND INFORMATION ACCESS IN EFSA

Copa-Cogeca fully acknowledges the need for risk assessment (RA) to take place in an environment of transparency and independence, in order to secure unbiased RA. EFSA has been responsive to meeting these very important overarching principles in its work. Therefore, Copa-Cogeca supports an independent and efficient EFSA. Since 2008, Copa Cogeca contributed to the drafting of the very core principles on Public Consultation, which, in turn, led to the disclosure of the EFSA's report on the comments received. We are therefore happy to further contribute to the wider issue of transparency and independence

EFSA must maintain its integrity by being transparent and working in an efficient manner in order to safeguard food safety, consumer confidence and to support innovation, growth and employment in the EU-food sector.

We need to ensure that the work of EFSA is applicable to real life situations. This is our primary need and concern in the RA process. This means working with/listening to experts from outside EFSA who have gained experience in making RA operational and working in real-life situations. For that reason, Copa-Cogeca appreciates the efforts made by EFSA to improve general communication with stakeholders (e.g. publication of minutes, stakeholders meetings etc.).

Copa-Cogeca also appreciates the efforts made by EFSA into the translation of RA into viable RM suggestions, as it has happened in a number of cases. This is quite useful for our members, and at the same time, for the wider acceptance of EFSA's work by the public opinion.

Nevertheless, Copa-Cogeca considers that an improved communication and better interaction with applicants would improve the efficiency of EFSA's work. It would also reduce the administrative burden to the European food sector and would create a more predictable regulatory environment, conducive to innovation and growth. Copa-Cogeca believes that this can be done without compromising the integrity of EFSA.

This communication with individual applicants could be improved both prior to submission of a new dossier and during the risk assessment process. In some situations, the lack of clarity and feedback from EFSA can lead to misunderstanding. It is important to ensure good communication between EFSA and applicants in terms of EFSA's requirements in order to avoid incomplete dossiers and requests for additional data that can lead to costly delays and waste of resources in EFSA as well as in applicant companies. Therefore, in order to improve this communication, pre-submission meetings (as in the case of the European Medicines Agency) and better feedback should take place during the risk assessment.

The view that EFSA's scientific experts cannot produce valid scientific work if engaged in stakeholder's dialogue does not correspond to the reality of all the positive efforts that were made to enhance food safety, e.g. animal health and welfare.

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EU Transparency Register Number | Copa 44856881231-49 | Cogeca 09586631237-74

Clearly this further level of interaction should be balanced by a higher degree of transparency and independence. In some cases, this can be achieved by multilateral and not strictly bilateral meeting, in order to avoid the external perception of "regulatory capture" or conflict of interest, providing organizational tools such as "reading rooms" or a regulated way to grant access to key documents without harming intellectual property rights.

Copa-Cogeca believes that it is possible to ensure unbiased RA through an open and transparent RA process, including dialogue with stakeholders. EFSA has shown that this is indeed not only feasible but even desirable.