

Final Minutes

69th MEETING OF THE EFSA ADVISORY FORUM

Meeting location:	EFSA (MTG 07 & MTG 08)
Meeting date:	17 September 2018
Meeting hours:	09:00 – 17:30
Chair:	Bernhard URL
Co-chair	Barbara GALLANI

Members	
Austria	<i>Klemens Fuchs</i>
Bulgaria	<i>Georgi Georgiev</i>
Croatia	<i>Darja Sokolić</i>
Cyprus	<i>Stelios Yiannopoulos</i>
Czech Republic	<i>Jitka Götzová</i>
Estonia	<i>Martin Minjajev</i>
Finland	<i>Matti Aho</i>
France	<i>Charlotte Grastilleur</i>
Germany	<i>Reiner Wittkowski</i>
Greece	<i>Eirini Tsigarida</i>
Hungary	<i>Ákos Bernard Jóźwiak</i>
Iceland	<i>Jon Gíslason</i>
Ireland	<i>Wayne Anderson</i>
Italy	<i>Alessandra Perrella</i>
Latvia	<i>Vadims Bartkevičs</i>
Lithuania	<i>Jurgita Bakasėnienė</i>
Malta	<i>Ingrid Borg</i>
Netherlands	<i>Antoon Opperhuizen</i>
Norway	<i>Danica Grahek-Ogden</i>
Poland	<i>Joanna Gajda-Wyrębek</i>
Portugal	<i>Pedro Portugal Gaspar</i>
Romania	<i>Monica Mariana Neagu</i>
Slovenia	<i>Urška Blaznik</i>
Slovak Republic	<i>Petra Vanková</i>
Spain	<i>Ana Canals Caballero</i>
Sweden	<i>Per Bergman</i>
United Kingdom	<i>Jesus Alvarez-Pinera</i>

Observers	
Albania	<i>Pamela Radovani</i>
FYR of Macedonia	<i>Svetlana Tomeska Mickova</i>
Republic of Kosovo ²	<i>Valdet Gjinovci</i>
Serbia	<i>Tamara Bošković</i>
Switzerland	<i>Barbara Engeli</i>
Turkey	<i>Serap Hanci</i>
Belgium	<i>Martine (Rohl) - audioconference¹</i>
European Commission	<i>Luis Vivas-Alegre</i>
European Chemicals Agency	<i>Elina Karhu – videoconference¹</i>
European Chemicals Agency	<i>Claudio Carlon – videoconference¹</i>
European Chemicals Agency	<i>Pia Korjus – videoconference¹</i>

EFSA Representatives	
AF Secretariat: <i>Sérgio Potier Rodeia, Deimante Bikneryte</i>	
<i>Bernhard URL</i>	<i>Marta Hugas</i>
<i>Barbara Gallani</i>	<i>Juliane Kleiner</i>
<i>Guilhem de Seze</i>	<i>Claudia Roncancio Pena</i>
<i>Ilias Papatryfon</i>	<i>Tobin Robinson</i>
<i>Ana Afonso</i>	<i>Martin Moravek</i>

1. Welcome and Opening of the Meeting

Barbara Gallani, Co-Chair of the meeting, welcomed participants to the 69th Advisory Forum (AF) meeting. Apologies were noted from Belgium, Denmark, Luxembourg, Bosnia and Herzegovina, and Montenegro, and as well the brief absence of the Chair of the meeting (Bernhard Url) who was opening the 90th plenary meeting of the Scientific Committee.

The Co-Chair welcomed the new members of the AF – Darja Sokolić from Croatia, Monica Neagu from Romania and Valdet Gjinovci from the Republic of Kosovo², and as well Luis Vivas-Alegre from DG-SANTE (EC).

2. Matters Arising

a. Action Points from last meeting

The Co-Chair informed that a summary document of action points from last meeting was shared with AF members³. There is one single action item ongoing, concerning the proposal for a single scientific network on chemical monitoring data collection. This action will be brought back for discussion at the 70th AF meeting (28-29.11.2018).

¹ Only for Agenda item 6 on EU collaboration on Bisphenols

² This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo Declaration of Independence

³ <https://dms.efsa.europa.eu/otcs/cs.exe?func=//&objaction=overview&objid=19827238>

b. Collaboration Agreement EFSA - JRC

Marta Hugas provided a report on the renewed Collaboration Agreement signed between Vladimír Šucha, JRC Director-General, and Bernhard Url, Executive Director of EFSA, highlighting the objectives, action and duration. Both institutions emphasised continued information exchange and joint activities, in particular on the sectoral food and feed legislation, alternative methods to protect animals, combined exposure of chemicals and chemical mixtures, and collection and use of landscape and environmental data for use in risk assessment.

SE underlined positive benefits, asking whether the memorandum is publicly available. EFSA confirmed the public availability of the document⁴ and explained that its economic and social background is very much linked to JRC's working areas. As an example in the pesticides domain, data collection activities carried out by EFSA can be analysed from an economical perspective by JRC. FR advised to conduct EU-wide toxicological studies.

3. Strategic Issues

a. AF input into EFSA's Work Planning and Strategy setting cycles

Ilias Papatryfon updated members on inputs collected from AF members (received from AT, IE and IT) in the context of the preparation of the Programming Document 2019-2021, such as identifying possible synergies, avoiding duplication of activities and seeking opportunities for the contribution of MS to EFSA's multi annual work program 2019-2021 as well as the development of an action plan to address the results of the 2017 customer/stakeholder feedback exercise and next steps. In addition, AF members have been informed on the kick-off of the next strategic cycle by the upcoming strategic environment analysis and their foreseen involvement throughout the process.

b. Scientific Committee Work Programme 2018-2021

Tobin Robinson presented an overview of the draft work plan of the Scientific Committee for the coming three years, with a focus on the shift towards better implementation of existing EFSA guidance documents (as important instruments for the harmonisation of risk assessment across the EU).

NO noted that the WG on capacity building is entrusted with tasks concerning harmonisation of legislation and DE enquired about the principles behind the implementation of reference documents in a harmonised manner across the EU. The Chair noted both comments and replied that future tools supporting such harmonisation might include artificial intelligence, and higher involvement of MSs and EU sister Agencies in EFSA's activities.

c. Overview of EFSA activities on crisis response and preparedness

Ana Afonso briefly presented an overview of legal requirements for food-feed crisis preparedness and response, focusing on EFSA's responsibilities in rapid risk assessment and communication, including examples of its use, crisis preparedness trainings performed so far and an overview of future trainings. The EC noted full support to these initiatives, reminding that the current EC plans on this matter are yet to be approved.

ES asked whether EFSA procedures are publicly available and underlined that instead of "crisis" the expression "severe incidents" should be used. EFSA noted the comments from Spain, highlighting that the "*EFSA procedures for responding to urgent advice needs*"⁵ and other guidelines for cooperating with MSs during an incident⁶ are all available online. NL highlighted the importance of the EU coordination role on this matter. IT reiterated their willingness to host future crisis preparedness trainings.

⁴ <https://www.efsa.europa.eu/en/press/news/180626-0>

⁵ <https://www.efsa.europa.eu/en/supporting/pub/en-1228>

⁶ <https://www.efsa.europa.eu/en/press/news/160315>

d. Update on the EC proposal for a targeted amendment of the GFL

Luis Vivas-Alegre (EC) delivered an update on the state-of-play of the proposals for a targeted amendment of the GFL as well as next steps and respective calendar. The EC proposal is being discussed at the Ad-hoc Council Working Party (CWP) on the GFL under the auspices of the Austrian Presidency, and at EP Committees (ENVI, AGRI, PECH and JURI). The preliminary views expressed by the CWP and the EP Committees on the different pillars of the EC proposal show general support, while addressing the elements that need clarification in preparation for future trilogues.

FR noted the anticipated new role of the Food and Veterinary Office in the context of audits to be implemented to laboratories (at an EU or wider scale). NL requested more details on the budgetary framework for this review process and how MSs are expected to support it. The Chair noted that the major part of complementary funding will be used to enforce collaboration with MSs through the strengthening of the risk assessment agenda within the EU. ES highlighted the role of Permanent Representations on this matter and raised the question on whether EP reports have been published already. The EC replied that the draft EP reports (e.g. ENVI Committee) might not be published yet⁷ and that the final EP position would become available at the time of the mandate to start the trilogues.

The Chair thanked the EC for this update, highlighting that EFSA and MSs will continue following closely the ongoing discussions at the Ad-hoc Council Working Party on the GFL and EP Committees.

4. Focal Point Agreements for 2019-2022

Sérgio Potier Rodeia provided AF members with an overview of the proposal of the operational framework for the new FP Agreements to be implemented during the period 2019-2022, with specific reference to the key principles behind the proposal, namely the flexibility on the choice of activities and the performance-based approach. The Chair highlighted that, despite the limited possibilities to invest more in the FP network, this activity is a success story in the context of collaboration and networking, and in raising trust among EU and national partners.

ES expressed support, acknowledging that doubts on activities had been clarified, and appreciated the fact that trainings to FPS in the field of regulated products are already being considered. Concerns were raised on the capacity of the FPs in 2019 as their workload is expected to include the implementation of the new Art.36 approach. DE expressed its full support to the proposal of a flexible approach and the reviewed FP tasks, including the support tasks on data management / collection. DE also raised the question on the procedures to follow when specific data management / collection activities are located in several national competent bodies. IT opposed to the inclusion of certain new activities in the new agreements, for example those related to data and those on regulated products. IT noted that it was not in a position to support the proposal. Martin Moravek provided an overview of the methodology used for calculating the new maximum grants per country. GR expressed support to the proposal. However, GR also expressed disappointment on the limited recognition of the FPs that had been consistently delivering beyond expectations. GR also asked for additional information on the parameters and methodology used for estimating the new maximum grant ceilings to be included in the final version of the document. NL expressed full support to the proposal asking for clarification on whether the endorsement process would be by simple majority.

Sérgio Potier Rodeia clarified the points raised, informing that: in case data related activities fall under the remit of other competent bodies, it will be possible to subcontract those activities or alternatively implement them through a grant agreement consortium; in reply to ES, Sérgio clarified that the new activities are all discretionary; in the field of

⁷ <http://www.europarl.europa.eu/committees/en/envi/draft-opinions.html> (meanwhile made available)

regulated products, Sérgio further clarified that FPs will be trained on how to carry out this new support activity, without duplicating the role of EFSA's Application Desk, nor through direct contacts with applicants. The Chair proposed additional bilateral discussions with IT on concerns raised. More information on the methodology for estimating the new maximum grant ceilings per country will be included in the final document. Sérgio briefly summarised the next steps and the Chair concluded that the proposal was endorsed by majority. NL congratulated the endorsement of the new FP grant agreements.

Action 1 – EFSA (ENCO) to share with AF members the updated final version of the main framework for the new Focal Point Agreements (2019-2022)

5. Scientific divergence

Barbara Gallani and Guilhem de Seze presented an overview of the legal framework, occurrence and tools to prevent, address and communicate on scientific divergence. Discussions highlighted the importance of information exchange, dialogue and cooperation among all parties in order to swiftly resolve or confirm the scientific divergence, and, when needed, clearly communicate with different target audiences. The Chair highlighted that science without diverging opinions is not possible, and that diversity makes the difference, raising the question whether available guidance and tools are sufficient.

NL underlined that, in the context of preventing or addressing scientific divergence, a fundamental issue that merits being looked into in more detail concerns the data and methodologies used in similar scientific studies. FR stressed the need for clear communication and strategies on the most sensitive topics (e.g. in the context of Glyphosate). It was also noted that tools for early detection of potential scientific divergence are already in place and that these will become overtime more efficient through the continued sharing of risk assessment plans via the R4EU database. Any scenarios of possible duplication could also possibly be looked into by an appointed Task Force. Finally, it was also expressed the need for giving more visibility to past and current (confirmed or resolved) divergences. SE underlined the importance setting up such a Task Force (or Working Group), acknowledging that it would be a major step forward in preventing/addressing scientific divergence. DE expressed the need for more emphasis on communication and, before coming up with statements, for all possible efforts to be carried out for addressing scientific disputes. DE also raised the question on whether the current procedures are sufficient to support the implementation of such efforts.

The Chair thanked FR for underlying the importance of higher visibility on scientific divergence through clear communication, noting a relative low number of confirmed scientific divergences when compared to all scientific outputs produced by EFSA. The Chair also noted that MSs ask for more support in communication and engagement activities vis-à-vis EU citizens so to raise more awareness and better understanding of EFSA's work. The EC noted that the current proposal for a targeted amendment of the GFL should provide more tools for EFSA to achieve benefits in preventing and addressing scientific divergence.

Action 2 – EFSA (ENCO Unit) to identify possible new ways for better sharing information on past and current (confirmed and resolved) scientific divergences (e.g. via the EFSA website)

6. EU collaboration on Bisphenols

Claudia Roncancio Pena, jointly with ECHA (on videoconference) and Martine Rohl from BE (on audioconference) provided an update on different activities on Bisphenols at EU level, highlighting the need for better collaboration between European Agencies and MSs in the future. ECHA acknowledged the need for better communication and expressed interest for initiatives to identify synergies taking into account different timelines and scopes e.g. via a pilot project to highlight opportunities and test practicalities for synergic actions.

Claudia suggested that Bisphenol S (BPS) could be a good case-study to improve Inter-Agency and MS cooperation while keeping in mind the broader picture of all other Bisphenols. Support to this initiative - a collaboration with EFSA on the assessment of BPS - was expressed by BE and ECHA. Interest to join a BPS Pilot Group was also expressed by FR, NO and SE.

As a first action, Claudia proposed the organisation of a follow-up videoconference EFSA – ECHA – BE to clarify the exact mandate (ToR) of this Task Force. EFSA noted that it will not be enough to exchange information on the assessment of this substance and that the scope should aim to align the information basis of the assessment and ensure the outcome is coherent taking into account the different regulatory frameworks. As a second step, the Pilot Group shall seek the participation and involvement from other MSs and define their exact roles (contributor / observer MS).

Action 3 - EFSA (FIP Unit) to initiate a Pilot Group on Bisphenol S (BPS) jointly with ECHA and other interested MSs, including the setting up of the respective ToR under the umbrella of an EU-wide collaboration on Bisphenols

7. Risk Assessment

a. Update on the publication of the EFSA Dioxins risk assessment

Juliane Kleiner updated AF members about the status and publication plan of the opinion on Dioxins and Dioxin-like PCBs ((PolyChlorinated Biphenyls) in Food and Feed. This opinion was adopted by the EFSA CONTAM Panel at its plenary meeting held on 14.06.2018. Given the new scientific evidence contained in the opinion, EFSA decided to organise a physical meeting in Parma where the methodologies applied and the outcomes of the opinion will be presented to the EU MS. To this end, AF members were reminded to indicate experts for this meeting, which will allow for an open dialogue with EFSA and the experts who worked on the opinion, and as well to provide clarifications ahead of its publication.

FI congratulated EFSA on the work done and acknowledged the importance of consultations carried out with MSs. It was also pointed out that dioxins are widely spread, persistent environmental pollutants and that the opinion will need to be well communicated. Finally, FI stressed that communication without a risk-benefit analysis may prove complex, expressing interest in attending the physical meeting. DE welcomed the idea to discuss the findings ahead of the publication of the opinion, noting that dioxins are inextricably linked to environmental pollution, and confirming interest in joining the meeting. EE questioned about the timelines of publication in order to best prepare a national strategy for its communication, confirming interest in attending the meeting. IE and SE expressed interest in participating in the meeting, and ES noted again the added value of a risk-benefit analysis before conveying information to risk managers.

The Chair stated that the mandate to perform a risk-benefit analysis has so far not been granted by the EC. The Co-Chair acknowledged the challenging communication on this topic, noting that the CEN network had been informed of the planned meeting with MSs. NL stressed the need to share the opinion at ministerial level and asked how to best deal with issues concerning confidentiality. It was also asked whether US-EPA had been contacted. Marco Binaglia confirmed US-EPA was contacted as part of the work with the Panel. However, Marco noted that the scope of the most recent US-EPA assessment was limited to the most important dioxin congener (TCDD) and, as such, differed from the mandate issued to EFSA. The Chair concluded that the opinion can be shared under confidentiality with relevant national authorities and that publication was foreseen at the end of November.

Action 4 - EFSA (BIOCONTAM Unit) to draw a list of MS attendees of the information session on the opinion on Dioxins and Dioxin-like PCBs in Food and Feed

b. EFSA Mandates

Guilhem de Seze noted in plenary the EFSA call for data on the safety assessment of Astaxanthin, the call for data concerning the hazard assessment of Bisphenol A and the current plans for EFSA to launch a call in the context of the SynBio mandate and the Gene drive mandate.

Juliane Kleiner noted in plenary a new mandate for update and review of control options for *Campylobacter* in broilers at primary production; a new mandate for an acute human exposure assessment to tetrahydrocannabinol; and a new mandate for an exposure assessment of nickel in feed.

c. MS Mandates

From the list of MS mandates collected during the period 21.05.2018 - 27.09.2018, Juliane Kleiner noted the entry from Poland on tetrahydrocannabinol formation in hemp food, highlighting the new EFSA mandate on the same substance. Reference was also made to input from BfR and KEMI (Sweden) in relation to the risk assessment of combined exposure to chemicals, noting that EFSA's Scientific Committee is also developing guidance in this field.

DE provided an oral update on their assessments on fosetyl-Al and phosphonates (phosphonic acid). Guilhem de Seze noted the need for the renewal process to be concluded as per the normal legislative practice before any action is taken from EFSA side. The Chair proposed bilateral discussions between EFSA and DE for further follow up.

d. Upcoming public consultations

Juliane Kleiner highlighted the upcoming public consultation on the revised Scientific Committee opinion on TTC, with expected launch date of 15 November 2018. Guilhem de Seze noted two public consultations on the pesticides domain, namely the Rapporteur MS assessment report of *Purpureocillium lilacinum* (*paecilomyces lilacinus*) strain 251; and the Rapporteur MS assessment report of diuron.

8. Communications

Barbara Gallani presented an update on recent communications activities, highlighting the good work carried out by the CEN network. Barbara noted the publication of two new EFSA guidance documents: one on the identification of endocrine disruptors; and another on Pesticide Residues. Information was also provided about the ongoing work on the guidance for communicating uncertainty, acknowledging the good input received during the public consultation. Finally, a demo of Focal Point timeline was presented, illustrating the successful work achieved during the 10 years of existence of the network.

9. Any Other Business

a. Upcoming EREN meetings

Ana Afonso briefed AF members about upcoming EREN meetings, highlighting the upcoming meeting in November hosted by BE. Though the dates for 2019 are yet to be defined, Ana noted that FR will be hosting the 2nd EREN meeting in 2019 and that DE will be hosting the 2nd EREN meeting in 2020. Finally, reference was made to the joint EREN - Stakeholder Discussion Group on Emerging Risks meeting, to take place during 2019.

b. AF Meetings 2018 and 2019

Sérgio Potier Rodeia provided an overview to AF members on upcoming meetings in 2018 and 2019, noting the upcoming 70th AF meeting to be held in Vienna, Austria, and the 2nd meeting of the AF Task Force on Data Collection and Data Modelling, to take place in AGES (AT) just the day before the AF meeting.

c. SafeConsumeE project

Józwiak Ákos (Hungary) briefly presented the SafeConsumeE project and invited members to participate on the ongoing survey⁸ for mapping European food safety risk communication policy models, aiming to contribute to the development of a more effective policy model that will help to mitigate risks of foodborne illnesses at European level.

Action 5 - Interested MS to answer the survey on mapping European food safety risk communication policy models

CLOSURE OF THE MEETING

The Chair closed the meeting, thanking Barbara Gallani for her support in chairing the meeting; and thanking all those who participated and actively contributed to the fruitful discussions held during the meeting.

SUMMARY OF ACTION POINTS	
Number	Action
1	EFSA (ENCO) to share with AF members the updated final version of the main framework for the new Focal Point Agreements (2019-2022)
2	EFSA (ENCO Unit) to identify possible new ways for better sharing information on past and current (confirmed and resolved) scientific divergences (e.g. via the EFSA website)
3	EFSA (FIP Unit) to initiate a Task Force on Bisphenol S (BPS) jointly with ECHA and other interested MSs, including the setting up of the respective ToR under the umbrella of an EU-wide collaboration on Bisphenols
4	EFSA (BIOCONTAM Unit) to draw a list of MS attendees of the information session on the opinion on Dioxins and Dioxin-like PCBs in Food and Feed
5	Interested MS to answer the survey on mapping European food safety risk communication policy models

Document history	
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Prepared by	Deimante Bikneryte
Reviewed by	Sérgio Potier Rodeia
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⁸ https://www.soscisurvey.de/safeconsume_policy/