EUROPEAN COMMISSION
Health and Food Safety Directorate-General

Science, stakeholders, enforcement

Minutes of the
Ad hoc meeting of the Advisory Group on the Food Chain and Animal and Plant Health on transparency and sustainability of the EU food and feed safety risk assessment model

5 February 2018
Brussels, CCAB -5B

1. Nature of the meeting

The purpose of the meeting was to consult stakeholders in the framework of the preparation of the *Commission Proposal for a Regulation on transparency and sustainability of the EU food and feed safety risk assessment model amending Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*. The meeting was chaired by the DG SANTE Director for *Food Chain: stakeholder and international relations* with the participation of DG SANTE Unit D1: *Science, stakeholders, enforcement*, Unit E1: *Food information and composition, food waste*, Unit E4: *Pesticides and biocides*, the DG SANTE Directorate F responsible for *health and food audits and analysis* (via video) and EFSA.

2. Topics discussed

COM gave an overview of the initiative on the transparency in scientific assessment and decision-making, quality and independence of scientific studies and the governance of EFSA. The initiative is based on the findings of the Fitness Check of General Food Law (GFL) Regulation and addressing the Commission's reply to the European Citizens' Initiative (ECI) "Ban glyphosate".
COM explained that the objectives are targeted and include:

- the improvement and further clarification of the existing rules on transparency (especially with respect to the scientific studies supporting risk assessment (RA), and the rules on increased reliability, objectivity and independence of studies used by EFSA in its RA (mainly authorisation dossiers),
- changes to the governance and scientific cooperation structures in EFSA and further involvement of MSs in EFSA's work (EFSA Board structure to follow other agencies model, presently there are no MSs in the Management Board, MSs not participating in the appointment of experts),
- addressing the limitations affecting the long term scientific capacity of EFSA and its ability to maintain a high level of scientific expertise,
- developing a more effective and transparent risk communication (RC) with public, in collaboration with MSs.

COM informed participants of the very tight timetable for the proposal, to be tabled latest in May 2018 in order to meet the target for adoption in the mandate of the current COM as well as on the planned consultation activities. COM proposed a number of questions to the Group to guide the discussions in the Group.

General questions and comments raised:

BEUC asked why COM decided to address only these specific points, in its view scope of the initiative was very narrow although the Fitness Check of the GFL Regulation includes other concerns. It also asked about transparency of RM decisions.

COM replied that the Fitness Check exercise concluded that the system generally works well and is still fit for purpose. However, certain areas have been identified which require further fine-tuning and therefore the proposal concentrates on these issues. Furthermore, similar issues were also highlighted by the ECI "Ban glyphosate". COM reminded participants that the proposal will be submitted to the Council and the European Parliament, who are the co-legislators. On transparency of RM decisions COM stated that it adopted a proposal on comitology which is currently under discussion in Council and Parliament.

CEO suggested broadening the last question *How can Member States be further involved in the risk assessment system to ensure its sustainability, including support to Expertise needed by EFSA?* to include how EU institutions can contribute to sustainability.

FEDIOL asked whether the ordinary legislative procedure is envisaged and touched upon the issues of implementation at national level and lack of harmonization.

COM confirmed that the proposal will be adopted by means of the ordinary legislative procedure. It acknowledged that there are issues relating to lack of harmonization, but these will not be addressed in the proposal.

The discussion further focused on the following questions:

Question 1: How should the transparency of the risk assessment process of regulated products be increased without compromising confidential data?

Questions and comments raised:

GREENPEACE clarified that it is not the transparency of the process that the ECI challenged, the ECI called for full publication of studies underlying RA. GREENPEACE acknowledged that the RA process is fairly transparent in EFSA. Its request is to ensure that all studies used to back up regulatory approval of pesticides are published. GREENPEACE asked to what extent this request requires changes in legislation since Art 38 in the GFL provides for it.

PAN EUROPE stressed that studies are carried out by laboratories contracted by the industry and then used for public health evaluation. According to the Aarhus convention, access to such information should be granted to the public. So there is no need to make changes in the law. PAN EUROPE called for using independent laboratories and for

access to data so that other experts can assess them in order to increase transparency and public trust.

ECCA stressed that used contract laboratories are independent Good Laboratory Practice (GLP) accredited laboratories, audited by national bodies. Although they are paid by industry there is no interest to cheat on data. They work for any entity that wants to contract services. Their independence relies on their reliability and they are not dependent on industry. When it comes to the auditing system of GLP laboratories, it is functioning well and there is no need to change it.

FEFANA supported efforts to increase transparency but stressed that such efforts should not compromise confidential data and challenge the competitiveness of the industry. In the feed ingredients sector, where both safety and efficacy are assessed, disclosing such information might compromise efforts to bring innovation in the EU market and provide unfair competitive advantages to companies outside EU.

COCERAL asked whether, since there was no impact assessment, there would be an extended time for the evaluation process.

ECPA pointed at the willingness of pesticide industry to disclose their studies used for registration of pesticides through a self-regulatory approach and asked whether a change in legislation is after all needed.

FoEE expressed regret over the insufficient period provided for feedback on the relevant roadmap for this initiative as it coincided with the Christmas period as well as over the shorter period provided for the open public consultation (8 weeks). FoEE stated that to rush for a May deadline is not an appropriate way of transparency. FoEE further stated that the Fitness Check of the GFL pointed at weaknesses on all three components of the risk analysis principle, namely RA, risk management (RM) and RC, so transparency should touch upon all three of them.

GREENPEACE stated that its main concern is confidentiality claims e.g. in the glyphosate case EFSA in its view granted unjustified confidentiality to applicants. Confidentiality claims should be reviewed properly and only the ones that are justified should be accepted. GREENPEACE stressed that publication of studies is key and publications should be available to public in machine-readable format without an obligation of signing in and giving personal data. It stated that granting access under access-to-documents rules is not enough.

FOODDRINK EUROPE highlighted that EFSA has made a lot of effort to increase transparency so maybe opening the GFL regulation was not necessary. It stressed that transparency of RA needs to go together with competitiveness. In particular, it is important that applicants know in advance that their studies are suitable.

ECPA clarified that the pesticide industry is not talking about making information public but disclosing the relevant studies, which means under certain control standards, i.e. not to be used for commercial purposes or challenge competitiveness.

CEO commented that when trying to obtain studies from EFSA which were used in its RA on glyphosate, it received large unclear tables and that experts could not review, quote or publish them. According to CEO, EFSA has not used all options allowing in particular data to be reused and to have a proper scientific debate.

COM provided the following replies to the points raised above:

- COM explained that there are different structures in different pieces of sectorial legislation resulting in an inconsistent approach regarding the disclosure of studies. There is a need therefore to change approach in the GFL Regulation and in the sectorial legislation to ensure consistency. According to the existing legislative framework, EFSA is often obliged not to disclose information.
- COM acknowledged that efficacy aspects should be considered confidential in certain sectorial legislation (e.g. feed additives and health claims).
- COM reminded participants that according to the Treaty duly justified confidential data must be protected.
- Regarding the three aspects of risk analysis mentioned by FoEE, RM problems highlighted in the Fitness Check will be actually addressed through the revised RC provisions to be included in the proposal.

Chair commented that there was a very little criticism on EFSA in the feedback received on the roadmap. Regarding the disclosure of data, EFSA has to work within the law, as it is currently framed. Obviously, the main issue is the disclosure of studies, when and how these are to be disclosed since timing of disclosure has to be looked at very closely as well. Chair stressed that competitiveness and length of authorizations must be taken into account but cannot be at the expense of food and feed safety.

Question 2: How should, if at all, public authorities/agencies, like MSs, EFSA, Commission, get more involved in the process of deciding which studies are needed?

ECCA stressed that during the REFIT of Regulation (EC) No. 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, industry asked for a system of data calling for renewals. It is important that applicants are told what is needed to be renewed. It is positive to see this question here since it has not been covered in the mentioned REFIT.

PAN EUROPE commented that for pesticides authorization, there is clarity on the studies required and EFSA systematically reviews it. It is important that MSs rapporteur is sure that all studies are collected and part of the RA. The structure in MSs is already there for them. PAN EUROPE asked where the problem with the system is.

BEELIFE stressed that the request should be done also to field practitioners. The beekeeping sector has a system in place to screen when the system fails, e.g. in the area of environmental safety. BEELIFE commented that for certain pieces of law the contextualization of potential threats that are coming to the market is needed.

ECPA commented that the industry does not decide which studies to perform today. It suggested to sit together with MSs authorities, COM, stakeholders etc. to decide ahead of

time what is really needed to be performed as studies and involve as well the public via public consultation.

GREENPEACE highlighted that safety studies should not be directly commissioned by industry/applicants but by public authorities to independent laboratories and asked why their suggestion has not been taken on board by COM in the context of this proposal. Such studies should be paid by the industry.

FoEE commented that the problem is not only limited to the studies but there is a gap in implementation by EFSA of high scientific standard. FoEE challenged EFSA's rules that apply internally in RA to reject some scientific information. It stressed that EFSA rules on independence are stricter than in MSs. According to FoEE EFSA does not listen to other scientists challenging the EFSA model.

PAN EUROPE underlined the need to focus on properly trained independent experts in MSs since decision on what studies are needed is already in legislation and guidelines.

UECBV gave the example of Denmark where there is a close collaboration between national authorities, the industry, academia and stakeholders on which studies must be carried out. UECBV acknowledged that lack of published data leads to lack of trust and advocated for peer-review papers to be published.

ECPA clarified that regarding pesticides, GLP laboratories selected to carry out studies can be located anywhere in the world.

AVEC mentioned the upcoming trend of consumers' distrust in scientists and pointed at the fact that some associations are good at talking to citizens' emotions. It underlined the common responsibility towards science.

CEO expressed concern on the increasing distrust in science possibly caused by a trend in research policies, where universities are asked to work together with industry on industry priorities. CEO countered that media manipulation and using the emotions of public are practiced by the industry through its advertising campaigns.

In relation to the question of GREENPEACE as regards its suggestion for the studies to be commissioned by the public authorities, COM pointed out the difficulties encountered to apply this proposal as it is difficult to ensure the appropriate way of choosing a laboratory for performing such studies. For example, should that be on the basis of a call of tender for every study? How offers should be compared? On what basis the choice should be made, without jeopardizing the impartiality and independence of the process? In addition, such an option would have a considerable impact on increasing the length of the authorization procedures. COM said it would be difficult to move to such operational model, which is quite radical.

GREENPEACE agreed that it would be a radical departure from the current system, nevertheless it is worth discussing, and would be willing to discuss the details in a separate meeting. GREENPEACE stated that practical considerations should not prevent introduction of any needed changes. GREENPEACE gave an example on the genotoxicity

of glyphosate where most industry studies did not report adverse effects, whereas most literature studies did.

CEO mentioned that the GLP accreditation provides transparency in the standards of laboratories but does not ensure quality/reliability. CEO stressed the importance of compliance of industry to GLP and public authorities' audit; nevertheless GLP should never be used as a prerequisite to be admissible evidence to RA.

COM concluded that current issues that are more acute in certain very specific sectors do not necessarily justify such a radical approach to be applied horizontally.

Question 3: What could be done further to enhance the auditing system of laboratories' compliance with GLP principles?

Chair stated that while the system works well it is necessary to look at strengthening its effectiveness to ensure the credibility of studies.

PAN EUROPE commented that independent laboratories contracting studies have different certificates. Studies that are not GLP certified should be taken into account as well. GLP can be audited but the question is how often raw data of GLP studies are verified by COM or national authorities.

ECCA commented that EFSA is working on the guidance on weight of evidence approach and EFSA currently accepts not only GLP certified studies but other studies as well. Via GLP, it can be verified whether somebody is an expert or not.

CEO is of an opinion that the problem is not about industry conducting the studies. The problem is that the industry controls the publication and does not publish the studies with non-desirable results. Declaration of study should be done from the beginning. CEO pointed at differences in GLP depending on where in the world the study is done.

FOODDRINK EUROPE commented that there had been a long discussion on GLP and EFSA looked at it. It is positive that this question is raised in the public consultation questionnaire. There are also other tools available in EFSA but FOODDRINK EUROPE agreed that GLP auditing is needed.

Chair stated that EFSA looks at the full remit of scientific evidence available and takes into account also non-GLP data. He acknowledged that GLP auditing system can be reinforced.

EFSA complemented that it has been working on GLP audits already for years to improve transparency and a lot of information is available to public on the website. EFSA has access to raw data of GLP studies and it uses all relevant evidence (700 studies considered for glyphosate). EFSA has a project ongoing to improve reproducible data and thus also in transparency. EFSA stated that further publication would have financial and resource implications.

SAFE argued that in the case of glyphosate not only citizens or NGOs but also MSs (e.g. Italy) did not trust the EFSA RA and that is a serious issue.

Chair replied that the glyphosate case was taken very seriously and this planned initiative is a proof of it. To clarify what was said by SAFE, Chair explained that RA process was endorsed by all MS risk assessors (except Sweden) but the issue of difference of opinions was at RM level. Chair highlighted that the challenge is broader and includes in particular issues such as the sustainability of current agri-food production and citizens' demands beyond safety.

Question 4: How can the commissioning of ad hoc studies, that could be foreseen in case of serious controversies and widely used substances, be organised?

BEELIFE commented that it must be clearly defined whether it should be pre or post authorization since the approach is then different. If it is pre-authorization, the system is already established. If it is for post-authorization it is to support RM and there might be research or other tools in the framework of the GFL Regulation available.

PAN EUROPE said that from experience on pesticides the RA does not take into account the formulations. PAN EUROPE considered that the formulation issue should be studied by endocrinologists/experts with a wider background. PAN EUROPE stressed that conflict of interest (CoI) checking is critical.

COCERAL challenged the wording in the question since serious controversies would imply the distrust in work of EFSA. COCERAL asked why to distinguish between widely used substances and others since all substances have to be safe. It should also be clearly determined why and when to commission ad hoc studies, in order not to undermine trust in EFSA's work.

Chair stated that even if substances are considered safe, and RA is OK, there might still be a need to provide further reassurance to citizens or MSs with an additional ad hoc study. For example, the US has in place a toxicology programme where all aspects of chemicals are considered.

CEO mentioned the importance of resources since EFSA might cut activities due to lack of resources. CEO therefore proposed to establish funds for regulatory studies to which industry should contribute. For commissioning some ad hoc studies, EFSA should be provided with more resources. There should be more money available for food safety in general.

Chair explained that the decision on the financing of EFSA implies EP and Council. He emphasized the importance of research – Framework Programme (FP)9 - as an instrument to facilitate R&I via networks, to the benefit of society.

ELO brought up the issue of alternatives for farmers and stressed that when substances that are used in agriculture are banned alternatives should be listed for farmers. It expressed concern that in some areas there are simply no more alternatives.

GREENPEACE stated that the main problem is that industry has an interest in a certain outcome of the regulatory studies. It questioned whether EFSA would run additional

studies where it is certain of its conclusion. It thinks that industry proving the safety of its own products is a CoI.

Chair clarified that it will be the risk managers (i.e. MSs and COM) that would be commissioning the studies.

BEELIFE asked what is done by the responsible authorities to implement controls to ensure the safety of food and whether controllers are getting enough resources.

Question 5: How can Member States be further involved in the risk assessment system to ensure its sustainability, including support to Expertise needed by EFSA?

CEO expressed concern that EFSA relies too much on applicant's resources. CEO thinks that it might be better to have MSs in EFSA Management Board instead of industry representatives as it is in other agencies. As long as COM and MS are forcing cuts in food safety capacity, the quality of the system goes down. Resources are the key issue.

PAN EUROPE insisted on the need for the right balance of expertise not only in EFSA Panels but in the COM meetings of MS experts as well.

BEUC believes that MSs should share data with EFSA on e.g. review of food additives that are presently re-evaluated by EFSA. A Directorate F report shows that MSs do not enforce law properly on monitoring of data linked to exposure to additives. EFSA's lack of data leads to non-conclusive opinion. On certain issues opinions from MSs bodies differ from EFSA ones, which confuses citizens. RC must be improved so it is clear whether the questions asked are not the same or indeed the conclusions differ.

UECBV stressed that in many areas of food chain there is very good collaboration and good experts available. It is important to develop ways of working together also in the pesticides area; we should not let the glyphosate case contaminate discussion across the food chain. UECBV agreed that more transparency through control and disclosure of data would be useful.

Chair stressed that EFSA is providing an important service to MSs by carrying-out RA. He acknowledged that it is challenging for EFSA to find excellent experts for its Scientific Panels due to constrains of CoI. He stressed that the ways must be found in order for EFSA to have a large pool of scientific experts with wide range of expertise and MSs should be more involved in the process e.g. by encouraging experts to put themselves forward and in nominating these experts. Chair agreed that MSs should make scientific data available to EFSA and COM will look at this issue closely.

COPA and COGECA highlighted the good job performed by EFSA and stressed that the discussion on how to strengthen EFSA role must be pragmatic and professional. It needs to be ensured that data are credible. COPA and COGECA raised the issue of a need for a toolbox with alternatives for farmers and regulatory framework has to allow new products and substances to come to market.

Chair acknowledged difficulties for farmers in doing their job and the need of ensuring available and viable alternatives. Chair concluded that EFSA has a high international credibility.

CEO suggested that EFSA should implement the concept of hearing experts who would reply to questions when their specific expertise is needed, but would not have any capacity in the drafting of opinion or voting. According to CEO, more hearing experts would require funding. CEO also mentioned that the revised independence policy of EFSA was still not fully satisfactory.

EFSA stated that the survey to MSs showed there is willingness to send MSs' experts but indeed there must be a financial compensation. EFSA also clarified that its revised independence policy meets all the demands of EP and most of CEO ones.

COM concluded by providing an overview of further steps in the process to be followed. COM encouraged stakeholders to reply to the public consultation questionnaire as soon as possible. COM informed participants about upcoming meeting of EFSA Advisory Forum in February and meeting with MSs in March where a discussion on the initiative will take place. The adoption of a proposal is foreseen for April 2018.

Chair thanked all stakeholders for their active participation and closed the meeting.

3. List of participating stakeholders

Members of the Advisory Group

Organisation	*Registered in TR as*
AESGP **Association of the European Self-Medication Industry**	**TBA**
AnimalhealthEurope **(formerly known as IFAH-Europe)**	**TBA**
AVEC **Association de l'Aviculture, de l'Industrie et du Commerce de Volailles dans les Pays de l'Union Européenne**	**TBA**
BEUC **Bureau européen des unions de consommateurs**	**NGO**
CEFIC **European Chemical Industry Council**	**TBA**
CELCAA **European Liaison Committee for the Agricultural and Agri-food Trade**	**TBA**
COCERAL **Comité du commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures de l'UE**	**TBA**
COPA and COGECA **European farmers** **European agri-cooperatives**	**TBA**
ECPA **European Crop protection Association**	**TBA**
ECSLA **European Cold Storage and Logistics Association**	**TBA**
EHPM **European Federation of Associations of Health Product Manufacturers**	**TBA**
ELO **European Landowners' Organization**	**NGO**
EUROCOMMERCE	**TBA**

EUROGROUP FOR ANIMALS **Eurogroup for animal welfare**	**NGO**
EU Specialty Food Ingredients **Federation of European Specialty Food Ingredients Industries (previously known as ELC)**	**TBA**
FEAP **Federation of European Aquaculture Producers**	**TU and PA**
FEFAC **Fédération Européenne des Fabricants d'Aliments Composés**	**TBA**
FEFANA **EU Association of Specialty Feed Ingredients and their Mixtures**	**TBA**
FoEE **Friends of the Earth Europe**	**NGO**
FOODDRINKEUROPE	**TBA**
FVE **Federation of Veterinarians of Europe**	**TU and PA**
INDEPENDENT RETAIL EUROPE	**TBA**
IFOAM-EU GROUP **International Federation of Organic Agriculture Movements EU Regional Group**	**OTHER**
IPIFF **International Platform of Insects for Food & Feed Association**	**TBA**
PAN EUROPE **Pesticide Action Network Europe**	**NGO**
PFP **Primary Food Processors**	**TBA**
SLOW FOOD	**NGO**
SNE **Specialised Nutrition Europe**	**TBA**
UEAPME **Union européenne de l'Artisanat et des petites et moyennes entreprises**	**TBA**
UECBV	**TBA**

Union européenne du commerce du bétail et de la viande	

Permanent Observers in the Advisory Group

ECCA **European Crop Care Association**	**TBA**
EDA **European Dairy Association**	**TBA**
EUROPABIO	**TBA**
FACEnetwork **Farmhouse and Artisan Cheese & Dairy Producers European Network**	**TBA**
FOODSUPPLEMENTS EUROPE	**TBA**

Additional stakeholders

BEELIFE **European Beekeeping Coordination**	**NGO**
CAOBISCO **Association of Chocolate, Biscuit and Confectionery Industries of Europe**	**TBA**
CEO **Corporate Europe Observatory**	**NGO**
ClientEarth	**NGO**
EAZA **European Association of Zoos and Aquaria**	**NGO**
EFFA **European Flavour Association**	**TBA**
ESSNA **European Specialist Sports Nutrition Alliance**	**TBA**
EUCOPE **European Confederation of Pharmaceutical Entrepreneurs**	**TBA**
EVU **European Vegetarian Union**	**NGO**
FEDIOL **Federation of the European Vegetable Oil and Proteinmeal Industry in Europe**	**TBA**
Greenpeace European Unit	**NGO**
IPA **International Probiotics Association**	**TU and PA**
ISA **International Sweeteners Association**	**TBA**
SAFE **Safe Food Advocacy Europe**	**NGO**
SERVING EUROPE **Branded Food and Beverage Service Chains Association**	**TBA**
SIPA **Seafood Importers and Processors Alliance**	**TBA**

UNESDA **European association** **of the European soft drinks industry**	**TBA**