EUROPEAN COMMISSION
Health and Food Safety Directorate-General

Food information and composition, food waste
Science, stakeholders, enforcement

Minutes of the Expert Group on the General Food Law

5 March 2018
Brussels, CCAB -2A

1. Nature of the meeting

The purpose of the meeting was to consult Member States 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 co-chaired by the Head of Unit of DG SANTE D1: *Science, stakeholders, enforcement* and the Head of Unit of DG SANTE E1: *Food information and composition, food waste* with the participation of DG SANTE Unit D1 and Unit E1, the DG SANTE Directorate D responsible for *Food chain: stakeholder and international relations,* the DG SANTE Directorate E responsible for *Food and feed safety, innovation* (via webstreaming), Secretariat-General Unit E1: C*itizens and Security* 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.

General questions and comments raised:

DE welcomed the initiative and the work towards a strengthened role of EFSA and a more transparent and better risk communication. DE as well as FR, BE, ES and DK highlighted that the system works well in many sectors and that COM needs to be measured when it comes to this initiative. Authorisation procedures should not be more bureaucratic and longer otherwise that would slow down the whole system and endanger the innovation and competitiveness, especially for smaller companies.

COM replied that since the creation of EFSA, 15 years ago, the situation has evolved and that some aspects may need to be adjusted. COM agreed that procedures should not be impacted and been looked at with EFSA. COM carefully analyses the impact on budget and staffing to ensure continuity. The initiative will address targeted key issues without creating more complication to the current situation.

FR welcomed the initiative and believes the system works well. However, the glyphosate case showed its limits. FR stressed that the following should be addressed: the independence of studies and EFSA's opinions, the conflict of interests of experts, the plurality of the scientific advice/divergences, EFSA's code of conduct – are internal rules going far enough? Moreover, there is a need to verify on a case-by-case basis the quality and reliability of studies submitted by the applicants. For the pesticides area, adequate financing is needed, i.e. funds that are not linked to applicants to maintain neutrality. As for transparency, FR considered that there should be a balance between data protection and intellectual property rights and that the quality of studies should be verified to guarantee the safety of the products.

BE highlighted the political character of the initiative – political reaction to public perception - and considered that more elements needed to be discussed to take a position. BE underlined that the system works well and should not be endanger because of the outcomes of some substances were unsatisfactory to some. The result of this review should be an improvement of the weaknesses of the current system. BE noted that the measures are targeted to the pesticides area as other areas should be included.
BE suggested that other issues impacting directly or indirectly the transparency should be considered, e.g. the transparency of the RM, the role of science, the independence of the system and the increasingly strict criteria for which no political debate has taken place, the policy of independence in MSs and the lack of harmonisation, the variability of quality of dossiers by applicants and the system of selection of MS rapporteur.

COM replied that the risk perception has escalated in recent years to the point that an efficient system becomes inefficient because of blockages in RM. The initiative will remain loyal to the findings of the Fitness Check and touch upon weaknesses identified.
As for the transparency of RM, COM replied that much of it will be addressed by enhanced risk communication. COM clarified a line cannot be drawn between risk communication of RA and RM. COM also reminded that risk communication is not limited to the public and that it concerns all actors in the process.

FI considered EFSA scientific work rather transparent and that criticisms raised in certain areas are a matter of trust. FI suggested that transparency of RM should be looked at. FI highlighted the importance of risk communication practices.

SE welcomed the initiative in general but stressed that the principle of transparency should be implemented to the extent possible. SE asked for more information on the increased financial needs.

ES praised EFSA system and stressed that the initiative should improve its weaknesses. ES agreed with most of the points of the analysis of COM but is concerned that this may challenge the efficiency of the process in EFSA and could politicise the scientific work. ES highlighted that as for conflict of interests, good scientists often have links with industry. ES believed that EFSA needs more financing and that it should benefit the scientific cooperation with MSs. Finally, changes should be done at a global level in order not to lose competitiveness.

COM replied that public funding in research should be looked at but that in the area of new substances it would be challenging.

DK aligned with DE and will send written comments.

IE highlighted that the aim of this initiative was to address public negative perception and that it will be challenging to change. IE considered that EFSA system was working well and that the main issue was the conflict of interests and the difficulty for EFSA to attract enough scientists. IE stressed that the publication of studies used in RA will not address the issue of perception unless the confidential data are published. IE asked whether EFSA could hire scientists on a permanent basis and underlined that MSs have capabilities that could be used. As for risk communication, IE considered that EFSA improved in that area. Nevertheless, if COM would come forward with principles of communication, IE believes it would be a challenge to have them agreed by all MSs.

COM replied that hiring scientists on a permanent basis would significantly increase EFSA's budget.

NL agreed that EFSA RA process works well in EU. NL asked the extent of EFSA's financial needs and the areas that will be concerned. Collaboration with MSs is a good way to get support but procedures for collaboration with MSs should be put in place. As for risk communication, NL believes there should not be shared risk communication between RA and RM.

PT welcomed the initiative and will send written comments. PT asked for clarification on the timing of the initiative i.e. May 2018 and 11 April 2018.

COM clarified that the proposal had to be tabled in May 2018 at the latest but that the target date for adoption is 11 April 2018.

EL worried about the short timetable and the absence of IA. EL considered that all options presented would have an impact on MSs or COM or EFSA budget and that more time to address particular issues should be needed.

The discussion further focused on the following subjects:

Transparency of studies

BE warned that since there will still be confidential parts in industry studies, this might not change public perception and therefore could worsen the situation.
BE also asked whether the rules on transparency would be applicable to studies provided by MSs.

COM replied that the scope of what is considered confidential will be as narrow as possible. Only in PPP there is a closed positive list and this is the model to follow.
As for the application of the rules, COM reassured that the primary focus is the industry studies but that any thoughts from MSs on this would be welcomed.

SE expressed doubts on the link of the listing with Article 4 in Regulation (EC) 1049/2001. New articles should not challenge the rules of Regulation (EC) 1049/2011.

COM reassured that they look closely at the interpretation to access to documents requests.

FR asked about the retroactivity of confidentiality in case of studies used for renewals.

COM replied that the rule should apply from the moment it enters into application. As regards renewals, it will depend on the way the final text is framed.

Choice of studies

DE expressed concerns on new procedures in particular public consultations creating delays.

COM replied that this will be challenging for new substances but the information will be limited. For renewals it should be easier.

EL,SE, BE, FR asked for clarifications on whether the register of commissioned studies will be open to the public, on the extent of the clarifications that EFSA can provide at pre-submission stage on planned studies and on how the public consultation will function (who responds, what is the follow up).

Good Laboratory Practice (GLP)

ES, EL and IE recalled that there were already national systems of inspections of labs in MSs.

BE considered that the problem to address was how to check labs in third countries.

COM reassured that a change of the system – MS authorities auditing the labs – is not envisaged.

Ad hoc studies for verification purposes

BE considered it was an excellent tool since it could help in particular to settle differences between non-GLP and GLP studies.

SE stressed that this should not impact on the principle that the burden of proof is for industry and considered that the scope of exceptions should be limited.

FR considered that MSs or EFSA could also ask for additional studies and asked how it will be funded. FR believes that all applicants should fund this tool.

COM informed that EFSA Scientific Committee advised this tool could be used in case of divergence between EFSA and MSs.
COM also reassured that the burden of proof will remain industry.
As for the funding of this tool, fees are excluded and the only sustainable solution is a public financing by EU budget.

Governance: MS in EFSA's Management Board (MB)

FR, SE welcomed the proposal.

DE welcomed but stressed the need to avoid the risk of politicising EFSA (issue of MB appointing EFSA scientific experts in EFSA's Panels/Committee).

IE, NL, BE highlighted the need to ensure MS in EFSA MB is of added value and not detrimental.

ES considered that a change of the current system in EFSA's MB should imply to review the functions of the Advisory Forum with a more scientific advice role.

COM explained that the presence of MSs in EFSA's MB would help ensure more involvement and accountability of MSs in EFSA. COM informed about an interinstitutional agreement on the representation of MSs in agencies MBs and about the similar system in ECDC (clear rules avoiding same people in both MB and Forum) and the different roles of both organs.

Governance: MS nominate experts for EFSA's Panels

DE is in favour but the rules to designate experts should be such as avoiding political influence.

FR is in favour and mentioned the ECHA possibility to appoint experts from other MSs.

ES, BE, DK, IE, EL considered that this will not support sustainability but complicate the system: more conflict of interests. They stressed that keys for sustainability are: financial incentives for MSs institutions/organisations (i.e. up to 20% of expert time dedicated to EFSA), more cooperation with MSs via Art. 36 (Grants), supporting experts better with training in risk assessment and to ensure better scientific recognition of experts by publishing EFSA outputs in peer reviewed journals .

FR advised to provide more support to EFSA Panels via EFSA own staff and cooperation with MS Agencies (e.g. preparatory work).

LU and EL highlighted the difficulty to find expertise in some MSs.

COM replied that the Fitness Check findings identified the need to provide sustainability and that the issue of incentives will be addressed not only financial but beyond, e.g. training.

COM stressed that the involvement of MSs is crucial to maintain the sustainability of the system in the long-term.

Risk Communication

ES and BE welcomed the initiative as a way to move risk communication 'outside silos'.

Conclusions

COM kindly requested MSs to send their written comments by the end of this week, i.e. 9 March.

Some MSs expressed the difficulty to meet this deadline.

BE asked whether the COM targeted modifications could be challenged and changed during the interinstitutional process.

COM replied that given the political context and the interinstitutional agreement, significant amendments would need to be argued.

Co-Chair thanked all MSs for their active participation and closed the meeting.