EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Directorate E – Food and Feed Safety, Innovation

EXPERT GROUP ON GENERAL FOOD LAW
STATE OF PLAY ON THE IMPLEMENTATION OF TRANSPARENCY REGULATION AND FARM TO FORK STRATEGY

MINUTES OF THE MEETING

3 MARCH 2020, 10-18H00

1. INTRODUCTION TO THE TRANSPARENCY REGULATION ([1])

The Commission opened the meeting and explained that SANTE and EFSA are closely cooperating on the implementation of the Transparency Regulation, such as the updating of Implementing Acts and different guidance notes. The Commission added that they work towards having the necessary systems in place before the legal deadline to be able to inform stakeholders (Member States, industry and SMEs) in due time of the changes.

2. STATE OF PLAY ON THE IMPLEMENTATION OF THE TRANSPARENCY REGULATION BY EFSA

2a. EFSA's Practical Arrangements for implementing the Access-to-documents Regulation and the Aarhus Regulation (new article 41 of GFL) – Presentation

EFSA informed that these practical arrangements are to be adopted at the EFSA Management Board meeting on 18-19 March 2020 and will then be made publicly available. The Practical Arrangements would implement the Access-to-documents Regulation ([2]) and articles 6 and 7 of the Aarhus Regulation ([3]) ensuring as wide access

[1] Regulation (EU) No 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency of the EU risk assessment in the food chain and amending Regulations (EU) No 178/2002, (EC) No 1829/2003, No 1831/2003, (EC) No 2068/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283, and Directive 2001/18/EC, (OJ L 231, 6.9.2019, p. 1).

[2] REGULATION (EC) No 1049/2001 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 May 2001 regarding public access to European Parliament, Council and Commission documents

[3] Regulation (EC) No 1367/2006 of the European Parliament and of the Council of 6 September 2006 on the application of the provisions of the Aarhus Convention on Access to Information, Public

as possible to documents in EFSA's possession. EFSA informed that after the adoption of the Practical Arrangements by the EFSA Management Board, EFSA would produce a user guidance for future requestors in order to tackle issues that are not necessarily covered in the practical arrangements.

POST-MEETING UPDATE: In view of the measures put in place in Italy for the containment of the spread of COVID-19, the EFSA Management Board meeting of 18-19 March 2020 has been cancelled. The EFSA Management Board will comment and adopt the practical arrangements by written procedure.

2b. EFSA's Practical Arrangements on transparency/confidentiality (new articles 38 and 39 to 39e of GFL) – Discussion

Prior to the meeting, the Commission shared an EFSA staff working paper summarising the key concepts of the Practical Arrangements to facilitate the presentation and discussion. EFSA stressed that the working paper is a first collection of thoughts and does not represent EFSA's final position. EFSA explained that they decided to combine Practical Arrangements on transparency and Practical Arrangements on confidentiality into one set of Practical Arrangements. EFSA highlighted the change in confidentiality assessment from COM to EFSA (for most food domains except for pesticides approval of new active substances and for GMO Directive) and explained that these Practical Arrangements explain how EFSA will implement this decision-making.

https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200303_efsa.pdf

2c. Discussion with Members States

- A Member State asked for clarification about the Aarhus Regulation and the publication of environmental data. EFSA explained that Art. 2 and 4 of the Aarhus Regulation have very strong provisions on transparency. EFSA's assessment will be a case-by-case assessment with the default understanding that environmental information is to be made public without prejudice to personal data protection.

- A Member State asked whether the shared EFSA working document will be discussed with stakeholders and whether Member States will be allowed to send written comments. The Commission and EFSA confirmed that the document will be presented to stakeholders in EFSA and SANTE fora (i.e. EFSA Sounding Board and SANTE Advisory Group on the food chain and animal and plant health). The Commission invited Member States to send their written comments **by 16 March**. At the request of a Member State, EFSA gave some words of explanation on the Sounding Board and informed the participants about an EFSA public stakeholder event in October in Brussels where EFSA will present its practical arrangements.

- On the minimum content of confidentiality requests (section 8.2c and 8.2f of EFSA working paper), EFSA indicated that "*explanation or evidence demonstrating to the satisfaction of the Authority that the harm that may be caused is of a significance corresponding at least to 5% of their total turnover for legal persons, or earnings for natural persons. If the harm is quantified as not reaching this percentage, the person shall provide a specific reason on why they considered that any public disclosure would potentially harm their interests to a significant degree*" and "*the confirmation that the document, information or data for which confidentiality status is requested has not been finalised more than five years prior to the submission of the confidentiality request. If the document, information or data deemed to be awarded confidential status is older than five years, the applicant shall provide a specific reason on why public disclosure of that information would still potentially harm its interests to a significant degree*." A Member State stated that these two criteria, i.e. 5% and 5 years, will be subject to discussion. Another Member State indicated that the topic of discussion will be more the criteria rather than the percentage level. The Commission agreed that the first aim should be to agree on a similar approach before discussion on the percentage itself should take place. EFSA also clarified to one Member States that the criteria of "document older than five years" was taken after a legal case[4].

- A Member State referred to a recent publication of a call for data for the risk assessment of heat-treated products containing chia seeds and the application by EFSA of Art. 38 and 39 to data that will be submitted by parties other than the applicant. EFSA replied that until the date of applicability of the Transparency Regulation it keeps complying with Articles 38 and 39 of the GFL as currently applicable, and that it has no intention to apply the new provisions of the Transparency Regulation before its entry into force. EFSA refers to the current regulation.

- A Member State asked whether EFSA intends to consult the national risk assessment bodies on the practical arrangements. EFSA replied that in the area of plant protection product (PPP) discussions are taking place in the Pesticides Steering Network but for other sectors there is no legal mechanism to harmonise. The Commission added that too many parallel consultation channels should be avoided.

- A Member State asked for clarification on the withdrawal of applications. EFSA explained the any applicants can withdraw at any time (before or after adoption of confidentiality decision) but this withdrawal has different implications at different moment in time.

[4] Case C-162/15 P, Evonik Degussa v Commission [2017], ECLI:EU:C:2017:205, paras. 64-67

3. STATE OF PLAY ON THE IMPLEMENTATION OF THE TRANSPARENCY REGULATION BY THE COMMISSION

3a. Fact-finding missions and international aspects

The Commission presented the state of play on the fact-finding missions in testing facilities.
https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200303_sante.pdf

The Commission explained the legal basis, scope and the different options being explored.

The Commission stressed that, as regards the regulation of Good Laboratory Practice (GLP) the fact-finding missions do not replace the activities of the GLP monitoring authorities in Member States.

The Commission concluded that elements are still being discussed: resources, inspection models to adopted, identification of critical studies and facilities, the existence and development of agreements/arrangements with third countries and need to cover studies across all regulated products areas.

Discussion with Member States

- A Member State stated that the question on fact-finding missions in third countries could be a critical issue as applicants are going more and more to third countries given that EU labs are reaching their full capacity. There could be major difference in GLP inspection systems between EU and third countries. The Commission replied that discussions on international aspects related to fact-finding missions are still at an early stage. The Commission reminded that there is no obligation for facilities in third countries (or in Member State, for that matter) to accept Commission fact-finding missions.

- A Member State asked whether the Commission was already in contact with the US and China. The Commission replied that no contacts have been made so far. The Commission explained that it is still reflecting on this question as the Transparency Regulation mentions an agreement with third countries or an arrangement. In any case, either option would imply reciprocity (i.e. the right of the third country to 'inspect' facilities in the Member States. Furthermore, the Commission added that arrangement is more likely to bear fruit than an agreement as these tend to take a long time to be reached. The Commission also added that there are already moves to allow EFSA to be deemed as a receiving authority for OECD and therefore in a position to directly ask GLP monitoring authorities in third countries to audit testing facilities and studies where necessary.

- A Member State asked how and when the decision on the different options explored by the Commission will be taken. The Commission replied that as fact-finding missions are to be undertaken as of April 2021, it is important that decisions are made in the interim term on how the fact-finding missions are to be conducted, both in GLP-compliant facilities and those applying other relevant 'standards' (e.g. EFSA guidance documents or OECD test protocols). In the interim period, the Commission's intends to participate as observer in more GLP

inspections in the EU and also explore ways in which non-GLP facilities may be subject to fact-finding missions.

3b. Update on IT-related aspects of the Transparency Regulation

The Commission followed up to the previous meeting of 21 January 2020 where Member States were asked to provide information on whether they have national IT systems in place for the e-submission of applications for authorisations. The Commission presented the results of the replies they have received so far from Member States. https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200303_fscap.pdf

The Commission asked the Member States who have not replied to the questionnaire yet to do so.

The Commission explained that during the next phase of the process, they will contact countries with existing IT systems for the e-submission of applications for authorisations individually to explore how to ensure interoperability between the national system and FSCAP.

4. Farm to Fork Strategy

4a. Introduction

The Chair started the meeting by presenting the objectives of the meeting and the Farm to Fork strategy timeline, which led to the following questions and comments:

A Member State enquired whether Member States would have the possibility to provide feedback on the Communication, on the roadmap and on the action plan.

Another Member State asked whether other consultations with Member States and stakeholders would be organised before the publication of the Farm to Fork Communication. They also wondered what would be the next steps once the strategy is adopted, and if the replies on the public consultation currently being organised and their written contribution sent to the Commission would be made public.

The Commission replied that the Farm to Fork Communication would expose its objectives and the long-term vision of the EU as regards sustainable food systems. It will also comprise an action plan that will list all the main actions necessary to achieve the given objectives. In that respect, some proposals will be made on the regulatory and non-regulatory side. The Commission added that once work would start on individual legislative measures, it would be done according to the Better Regulation rules. Consequently, there will be a possibility for Member States to comment on individual initiatives of the strategy at an early stage. The Commission also said that the adoption of the Communication would launch a public debate including the organization of public events, dialogues, visits to the Member states on the strategy. The Commission shared with Member States that an event is planned to be organized in October on the Farm to Fork strategy. Therefore, there will be plenty of possibilities to react to the Farm to Fork strategy.

The Commission reminded Member States that the roadmap had been published on 17 February and that there was a possibility to comment and react on it until 16 March through the feedback mechanism, a specific public consultation process working through a dedicated page with no confidentiality rules or restrictions (https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12183-Farm-to-Fork-Strategy). The Commission also said that another meeting with stakeholders would take place on 13 March in the context of the Advisory group on the food chain.

POST-MEETING UPDATE: the 13 March meeting in the context of the Advisory group on the food chain was cancelled due to the COVID-19 pandemic.

4b. The Farm to Fork strategy objectives and implementation

The Commission provided a presentation to Member States on the current state of play of the Farm to Fork strategy, insisting on its main features and objectives, as well as on its roadmap.

Subsequently, the Chair gave the floor to Member States, which raised the following questions and comments:

A Member State congratulated the Commission for the ambitious strategy, in line with the UN Sustainable Development Goals (SDGs), and insisted on the need for all Directorate-Generals (DGs) to work closely with each other, especially DG SANTE, AGRI, MARE and RTD. This Member State outlined the difficulty to implement the Farm to Fork strategy, especially on the necessity to find a balance between all different aspects of sustainability (notably the economic aspect) and to work horizontally with stakeholders at the national level. They praised the inclusion of nutrition issues in the Farm to Fork strategy, but insisted on the importance to be science-based. Therefore, they called for an extension of EFSA's mandate to nutrition issues. This Member State finally insisted on the importance of communication surrounding the Farm to Fork strategy.

Another Member State welcomed the Farm to Fork Strategy and expressed their support to the Green deal and the political orientations assigned to the Farm to Fork strategy in order to link better food, environment and public health policies all along the food supply chain. They thanked the Commission for organising this consultation and the one held on 31 January.

They summarised their position on the Farm to Fork strategy which should:

- Improve the fight against food fraud by creating a control task force ;
- Set up quantified targets to reduce the use of chemical pesticides at EU level (50% by 2025) and ban the substances of greatest concern. Hence, they support both a quantitative and qualitative objective;
- Ensure a decrease of antimicrobial resistance (AMR);
- Strengthen food information to consumer as regards origin, nutrition aspects and means of production;
- Impose a strong ambition for the EU primary sector as regards sustainability while preserving its competitiveness compared with third countries. In particular, the strategy should ensure that, as stated in the Green Deal, imported food that does not comply with EU environmental standards is not allowed on EU markets.

Finally, this Member State reminded that it was favourable to the strengthening of the CAP's environmental ambition, and that it must be used as a primary tool to support the environmental transition of farms.

The Commission replied that the objectives of the Farm to Fork strategy are ambitious and encompass a great vision for sustainable food systems combining the health of the planet, people, animals and plants and ensuring access to safe and affordable food for all. The Green Deal necessitates a change of paradigm as regards EU food policies. The Commission stressed the importance of the implementation of the strategy through horizontal enablers to help those who will be impacted by the transition through R&I and financial support. To this end, DG SANTE is working closely with DG RTD in order to develop Food 2030 under Horizon Europe and take into account the Farm to Fork objectives.

The Commission said that it would not be possible under the current General Food Law to expand EFSA's mandate to include nutrition issues. There would be a need to adapt the structures and methodologies to achieve the desired objectives.

The Commission insisted on the necessity to communicate properly on the Farm to Fork strategy to get all the involved actors adhere to the project, clarified that all relevant Directorates-General were collaborating closely in a co-construction process and encouraged Member states to do the same to address the objectives of the Farm to Fork strategy. The Commission clarified that the new Common Agricultural Policy (CAP) proposal should fully reflect the ambitions of the Green Deal.

A Member State also expressed their support to the Farm to Fork strategy, including the ambition to reduce the use of pesticides and AMR. However, they asked that particular attention be given to the situation in their own country, where, due to climate change, new pests might emerge. The same might apply to other Member States. This necessitates the use of control agents or a comprehensive biologic pest reduction strategy. To control AMR, other options might be favoured than just reducing antimicrobials.

The Commission answered that these aspects would be covered by the Farm to Fork strategy, and its elaboration. Consequently, no other strategies would be needed.

A Member State asked what would be the balance between regulatory and non-regulatory approaches in the strategy. They wondered whether the GFL would be re-opened to also include aspects around sustainability and also pointed at nutrient profiles and food safety issues related to the recycling of plastic, on which EFSA is preparing an opinion. They called for better collaboration between the DGs of the Commission, as well as between agencies (e.g. between EFSA and ECHA).

The Commission acknowledged that policy coherence requires good collaboration and a clear policy framework.