



**AD HOC MEETING OF THE ADVISORY GROUP ON THE IMPLEMENTATION OF THE TRANSPARENCY
REGULATION**

5 JUNE 2020, 10H00-13H10

Summary Record

**1. WELCOME AND OPENING BY MS SABINE JÜLICHER, DIRECTOR, SANTE, FOOD AND
FEED SAFETY, INNOVATION**

SANTE Director Sabine Jülicher opened the virtual meeting and welcomed the participants and EFSA representatives. The Chair explained that SANTE and EFSA are closely cooperating on the implementation of the Transparency Regulation and conveyed key messages concerning e.g. the principles and framework for stakeholder engagement. She further elaborated on the focus/purpose of the meeting and concluded by introducing the first item on the agenda, namely an update on the EFSA Practical Arrangements.

2. UPDATE ON EFSA PRACTICAL ARRANGEMENTS

EFSA presented an [update on EFSA's Practical Arrangements](#) (PAs):

- ✓ Practical Arrangements on access to documents and the Aarhus Regulation
- ✓ Practical Arrangements on transparency/confidentiality (Articles 38/39 of the GFL)
- ✓ Practical Arrangements on the Pre-submission phase (Articles 32a/32b/32c of the GFL)
- ✓ Practical arrangements on PPPs

EFSA presented the progress on each of these Practical Arrangements. but emphasised that this is still work in progress. EFSA also reminded participants that Practical Arrangements are binding and that they generate rights and obligations.

The Chair thanked EFSA for the presentation and asked stakeholders to hold back with questions until the dedicated questions and answers session. Due to a prior engagement, the Chair had to leave the meeting. She excused herself and handed the Chair over to SANTE Head of Unit Péter Bokor (Food chain science and stakeholder relations – SANTE Unit D1).

3. STATE OF PLAY OF COM IMPLEMENTING ACTS

COM presented a [state of play on the ongoing revision of certain implementing acts](#). In fact, COM has identified seven implementing acts for revision to ensure alignment with the new provisions of the Transparency Regulation including the removal of

any outdated provisions. These implementing acts are in the areas of novel foods, food additives, feed additives, Plant Protection Products, and foods with added vitamins, minerals and other substances.

COM further presented a short overview of the expected timeline for adoption.

COM also gave a brief update on the IT-related aspects, more specifically the FSCAP (Food System Common Authorization Process) e-submission system for transparency/confidentiality provisions, developed in collaboration with EFSA. FSCAP would be used for all food sectors except for PPPs and MRLs, for which the International Uniform Chemical Information Database (IUCLID) would be used. A specific Technical Group on IUCLID has been created by EFSA.

4. QUESTIONS AND ANSWERS

COM gave a brief introduction and explained the structure of the questions and answers session. It underlined that stakeholders should focus on application-related questions in the following areas:

- ✓ Transparency (Article 38 and PAs)
- ✓ Confidentiality (Art. 39etc and PAs)
- ✓ Pre-submission phase

COM consequently opened the floor for questions.

Questions and comments raised

Transparency

ECCA enquired about the process under comitology for establishing Practical arrangements. According to ECCA, since Practical arrangements have a legally binding effect, EFSA would be drafting law.

EFSA replied that it creates a legally binding framework in order to implement the Transparency Regulation.

COM reiterated that Practical Arrangements are not comparable with comitology acts. COM reminded participants that Practical arrangements are not a new concept but are already included in article 41 of the GFL. The Transparency Regulation specifically provides for Practical Arrangements, which have the effect of legally binding rules.

ECPA asked to elaborate on the mechanisms for disclosure. ECPA enquired if the person accessing information would be informed and if so, how would this be done, e.g. by disclaimer. Furthermore, ECPA asked if it would be done via a normal website. Finally, ECPA asked if COM/EFSA would be gathering information on who accesses information and if access would be by information, study or full dossier.

As regards dissemination, EFSA replied that the website would be a combination of different tools, namely Data portal, EFSA Journal, etc.

Regarding the different types of documents, EFSA explained that EFSA journal would be used for disclosure of outputs and its Data portal would be used for the proactive disclosure of underlying background documents.

Concerning accessibility of the documents, EFSA explained that the Transparency Regulation requires a system to be put in place where users have to confirm acceptance of certain terms of references.

As regards access study-by-study, COM replied that it would come back to that question in September.

FSE enquired whether a consultation on the Practical Arrangements is foreseen.

EFSA replied that it envisages further stakeholder engagement, but that a written consultation on core documents is not foreseen – further feedback would be solicited on concepts.

Europabio asked if the e-submission system FSCAP is separate of the database of notification of studies. It further asked if – in light of the automation of PAD process – the submission of the confidentiality request would also be done electronically. Finally, Europabio asked to clarify if the IT systems would operate separately or if there would be synergies between the systems.

COM replied that it is premature to answer these questions, since the IT systems are still in development. COM would come back to this in September.

EU Specialty Food Ingredients asked EFSA to confirm that the new measures do not interfere with Risk Assessment (RA) deadlines and whether EFSA can continue compliance during 9 months for RA for food additives or novel food ingredients.

EFSA replied that confidentiality provisions would not impact deadlines and confirmed that it would comply with RA deadlines, unless specific provisions are foreseen, e.g. Article 32c(2).

COM explained that the provisions in the Transparency Regulation have been designed to not have impact on RA and that confidentiality assessment would run in parallel with RA. Article 32c(2) provides a potential stop-the-clock of seven weeks when the results of public consultation (due to delay in the process) cannot be given due consideration in the risk assessment.

COM said that for food additives - for which the public consultation is scheduled to take place halfway of the nine-month risk assessment period - it might not be necessary to trigger the stop-the-clock. Nevertheless, this provision could be used in other areas with shorter timeframes.

FEFANA commented that the legislative procedure was very fast. Its role is to pass information to their members and therefore it is important to receive information at the earliest convenience. FEFANA participated in the EFSA Technical Group on notification of studies. Meetings are ongoing, however, minutes of these exchanges are not available to the members. According to FEFANA, this unavailability of minutes constitutes a lack of transparency. FEFANA consequently invited EFSA to look into this issue and ensure the production of minutes. FEFANA supported FSE's comment regarding a consultation on the Practical Arrangements. FEFANA referred to the EFSA explanation that PAs are binding and similar to IAs and that they would like some form of stakeholder consultation. It stressed the importance of contributions by stakeholders, since they would have to implement the Practical Arrangements.

EFSA replied that stakeholder engagement modalities have been put in place and referred to the creation of the Sounding Board and Technical Groups, which have been established in an inclusive and transparent manner. EFSA emphasised that all material is publicly available on the website, including meeting reports. EFSA stressed that implementing rule are not required to be co-created with stakeholders. Nevertheless, EFSA has done the maximum to ensure transparency and engagement on all matters and is committed to engage with stakeholders as much as possible.

COM commented that it does not agree that it is not sufficiently transparent. In the context of EG on GFL, a discussion on PA 38/39 has taken place and the relevant working documents have been made public through the SANTE website. The input received from Member States has been taken into account both by EFSA and the Commission; however, the draft PAs are still under formal consultation by COM. COM stressed that it shared with stakeholders the maximum that it could share at present. In addition, COM reminded participants of its commitment to deliver 3-4 months in advance of the formal implementation deadline. It assured stakeholders that it does its utmost to deliver on time and be as transparent and inclusive as possible. All input received from stakeholders has been and would continue to be considered while it would be published on the website. As soon as draft documents are mature enough, they could be shared with stakeholders in order to keep the flow of information going. COM further informed stakeholders that it would organise a follow-up Ad hoc meeting of the Advisory Group in September (tbc) and EFSA would organise a meeting to inform stakeholders about the implementation of the Transparency Regulation in autumn 2020. Finally, COM reminded participants that the legal rules have already been set out in the Transparency Regulation and that the purpose of the PAs is to look at the modalities of implementing these rules.

The Chair reiterated that there is no legal obligation to perform a co-creation process, but that the final responsibility to establish the rules lies with EFSA in close cooperation with COM and the MS. Stakeholders have been given the opportunity to give feedback and to express concerns

FOODDRINKEUROPE also stressed their need to be consulted on the Practical Arrangements. It referred to the PA on articles 38/39 and a working document dated from February (prepared for the purpose of the meeting of the Expert Group on the GFL, which took place on 3 March 2020 and published on SANTE website). FOODDRINKEUROPE would like to see the text of the PAs.

ECPA stated that it fully appreciates the opportunity to engage and that preparations of submissions of comments are underway. As an example, it referred to the data format of pesticides, which would be applicable from 27 March 2021. Companies would need to convert their dossiers. One modality is to have a viable product with guidance in October. However, this would not allow companies sufficient time. In addition, Covid-19 caused even further delays. In view of the fact that IUCLID is not obligatory by 2021, ECPA asked about the possibility to put transitional measures in place.

COM replied that it is looking into putting transitional measures in place, but that this is still under discussion. Nevertheless, COM emphasised that the new rules apply to all submissions to dossiers/studies commissioned as from 27 March 2021.

As regards standard data formats, COM clarified that this means a harmonised way of data submission in a structured format. However, except for existing standard data formats this would not be introduced for all sectors by March 2021. EFSA requires documents to have a certain format, in order to ensure that they can be published. They need to be electronically searchable, printable and downloadable.

EFSA replied that the standards OHT/GHSTS are EFSA's way of managing the obligation they have to implement the Transparency Regulation by 27 March 2021. EFSA reiterated that they are not using standard data formats, but a type of standard dossier. EFSA would provide more information after the summer break.

FSE stressed the importance of the application process for novel foods. In the PA for confidentiality, there would be requirements to have documents printable, searchable, etc.

FEDIOL asked whether EFSA intends to address the data provided by the industry under the current data collection framework and whether EFSA envisages the establishment of a specific Technical Group to deal with this question.

As regards confidentiality, EFSA replied that it would also extend the possibility to file confidentiality requests to questions from the European Parliament and MSs.

The discussion on calls for data is ongoing and EFSA would have a final reply in the coming weeks.

COM replied that DG SANTE is currently considering how to address the issue from a legal perspective and stressed that it does not want to discourage companies from submitting data voluntarily. COM took note of FEDIOL's position and said that a reply would be provided at a later stage.

As regards SMEs and submissions, the Chair added that in view of the limited timeframe, COM and EFSA opted for simple solutions. The databases and systems that are being set up build to the maximum on existing systems and are easy and applicable for SMEs.

Confidentiality

COM commented that certain questions were already addressed by EFSA in the presentation on PAs.

On the question whether old studies in renewals can qualify for confidentiality/transparency, COM explained that this is part of the PAs. As regards, renewals, COM said that if the IA requires that previously submitted studies should be resubmitted, they qualify for transparency and confidentiality. The scope would depend on the IAs.

COM further underlined that the significant harm concept is not new and is introduced in all sectors except in novel food and plant protection products. There are two differences now:

- ✓ The premise has changed. Everything is in the public domain, except what is duly justified as confidential.
- ✓ The creation of a positive list (which already exists in the area of PPP).

FEFANA commented that significant harm for feed additives was not used in the past. It stressed that there are a large number of SMEs for which the quantitative estimation of the degree of significant harm proposed by the EFSA would be quite costly, if feasible at all.

COM replied that there has not been a change and that this is included already in the existing article 18 of the Regulation on feed additives. The only two exceptions to the concept of 'significant harm are in the areas of novel foods and plant protection products. In the area of feed additives, the only change is the introduction of the positive list.

EFSA commented that these concepts are not new and that COM/EFSA worked with existing case law to apply these concepts.

EU Specialty Food Ingredients commented that the assessment of confidentiality requests was done by COM before (in most sectors) and would now be (mainly) managed by EFSA. EU Specialty Food Ingredients asked if there are any novelties in EFSA approach regarding the proposed criteria for the determination of the confidentiality test compared to what is applied by COM so far. It referred to the non-paper (working document) with numerical targets presented to the MS in the context of the Expert Group on the GFL meeting on 3 March 2020 (and which has been made public in the SANTE website). According to the EU Specialty Food Ingredients, these targets would be very difficult to comply with, and expressed concern that some of the numbers are not workable. EU Specialty Food Ingredients further raised concern that – when developing a new substance – the need to justify a confidentiality request already exists and is known by applicants, but the EFSA set of criteria are new. If this is based on case law, EU Specialty Food Ingredients requested to see the specific case law in order to determine if the criteria are applicable.

FEFANA expressed concern about the application of the criteria in the non-paper.

EFSA reiterated that these concepts were not invented by EFSA, but refer to case law in the field of e.g. competition. It remains to be seen if it works in this area as well. EFSA stated that it does its utmost best to produce helpful and predictable criteria that are also recognised in EU case law and that fall within EFSA's remit.

COM once again underlined that the working document shared with the MS for the purpose of the Expert Group on the GFL meeting that took place on 3 March 2020 has been made public and that stakeholders had taken the initiative to send their comments both to EFSA and to COM, which has been welcome. Those comments have been taken into account. This demonstrates the high level of transparency that SANTE and EFSA are committed to provide, taking however into account certain limitations (namely that these documents are still work in progress).

As regards the targets, COM underlined, as EFSA has previously explained that the said targets are rebuttable presumptions and as such future applicants can still provide valid justifications for the purpose of confidentiality even when these targets are not met. EU case law has endorsed rebuttable presumptions of that sort in the area of EU competition law as well as in the area of access to documents in relation to confidentiality aspects. COM explained that the reason to have certain rebuttable presumptions is to adopt a more systematic approach and provide guidance to applicants.

The Chair acknowledged and expressed understanding for the stakeholders' points of view. He explained that the goal is to make it easy for applicants to introduce a claim whilst facilitating the assessments for EFSA.

Pre-submission phase

Before opening the floor to stakeholder questions, EFSA made some preliminary remarks. EFSA clarified that – according to article 32b - studies that have been completed by 27 March 2021, would not have to be notified. The same goes for studies that are ongoing by 27 March 2021. EFSA explained that the scope of the article only applies to studies that have been commissioned after 27 March 2021.

As regards the notion of studies, EFSA explained that the relevant PAs would ensure a definition that is sufficiently clear. Nevertheless, the notion of study would remain a broad notion. At present, EFSA cannot yet share a final definition.

ECCA enquired about the notification of studies and the transitional measures. Regarding applications for pesticides renewals, ECCA asked what would happen if an application is submitted before the deadline, but submission of the supplementary dossier follows later and includes studies commissioned after 27 March 2021. ECCA would like to know if its understanding that – in this case – these studies do not have to be registered in the database, is correct.

COM replied that it cannot comment on this at present, but that transitional matters would be addressed in IA on PPP and that stakeholders can comment via the feedback mechanism.

EU Specialty Food Ingredients commented that on the EFSA Register of questions, there are a number of recent mandates related to guidances and asked if these are new guidances or updates of existing guidances intended to reflect the new provisions of the Transparency Regulation.

COM replied that SANTE/EFSA would update existing COM and EFSA guidance documents in close collaboration with each other to ensure alignment with the new requirements. Any updates would take into account the new Transparency Regulation framework. COM/EFSA's aim is to have these updated guidance documents ready by the end of 2020.

EFSA said that it was currently updating administrative guidance documents in each area as well as the catalogue of services.

5. WRAP UP AND CLOSURE

The Chair invited participants to give feedback and informed participants that all presentations had been shared via email earlier that day.

The Chair also reiterated that this was only the first of further exchanges. The Chair stressed that COM/EFSA's aim is to keep stakeholders informed about the progress. He underlined once more that the goal is to make the system as simple as possible and that COM/EFSA aim to share the necessary information ahead of the deadline.

EFSA had no further remarks.

COM reminded participants that there are dedicated websites¹ for the publication of the stakeholder feedback received and instructed stakeholders to clearly indicate, when making contributions, whether they give their permission for their feedback to be made public.

The Chair thanked all speakers and participants for their constructive contributions and closed the meeting.

¹ https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en
<http://www.efsa.europa.eu/en/stakeholders/transparency-regulation-implementation>