Annex

to the minutes of the Expert Group on General Food Law meeting held on 16 November 2020

Transparency Regulation – Summary of replies provided by DG SANTE and EFSA to questions raised by Member States (MSs) on the draft Practical Arrangements on:

- **Transparency and confidentiality (Articles 38 and 39-39e of the Transparency Regulation)**
- **Confidentiality (Articles 7 and 16 of Regulation (EC) No1107/2009)**
- **Pre-submission phase and public consultations (Articles 32a, 32b and 32c of the Transparency Regulation)**

Prior to the Expert Group meeting on 16 November 2020, the three sets of draft EFSA Practical Arrangements were shared with the Member States (MS) experts for any comments and questions.

In the meeting of 16 November 2020, DG SANTE and EFSA addressed all questions that had been raised by the MS experts in previous meetings (i.e. 26 June 2020) as well as any new additional questions on the three sets of draft EFSA Practical Arrangements (PAs).

SUMMARY OF PROVISIONAL REPLIES

DRAFT PRACTICAL ARRANGEMENTS ON TRANSPARENCY AND CONFIDENTIALITY (ARTICLES 38 AND 39-39E OF THE GENERAL FOOD LAW, AS AMENDED BY TR)

1. HEALTH CLAIMS

DG SANTE clarified that the Transparency Regulation amends mainly the General Food Law Regulation and as far as transparency/confidentiality provisions are concerned, eight other sectoral acts. As such, the new provisions of the Transparency Regulation are not only relevant and applicable to the eight sectoral acts that were amended, but their impact is far greater; the new provisions of the General Food Law apply horizontally across all sectors covered by the latter, including for example the area of Health Claims. The Transparency Regulation did not amend the Health Claims Regulation (Regulation 1924/2006) per se, as it did not contain any specific confidentiality provisions that required alignment. Therefore, there is no need to explicitly refer to Regulation 1924/2006 in the Practical Arrangements (PA), as it is covered by the application of the General Food Law provisions.

2. **SECTION 8 - MINIMUM CONTENT OF CONFIDENTIALITY REQUESTS**
    - **Point (c): Criteria set for confidentiality**

DG SANTE indicated that in the Commission's view – as depicted in its formal opinion to the draft EFSA PAs on Art. 38/39 – this draft provision did not go beyond the Transparency Regulation. In fact, it could provide some legal certainty and assist applicants in substantiating their confidentiality claims for confidentiality treatment.

As regards the quantification of harm, EFSA highlighted that the wording had been refined, giving the applicant the possibility to justify the reason why it is impossible to quantify the harm in a specific case.

EFSA added that, based on collected experience on the implementation of this criteria, further refinement could be done.

The draft PAs would also foresee a timeline for review, i.e. 5 years, which is the latest possibility of review.

3. **ANNEX – ITEMS FOR WHICH CONFIDENTIALITY REQUESTS MAY BE SUBMITTED – REFERENCE TO IMPURITIES**

EFSA clarified that the annex to the draft EFSA PAs on 38/39 reflected the text of the provisions listing the items of the closed positive lists (provided in the GFL Regulation and the eight other sectoral acts, as amended by the TR). EFSA concluded that it would not be appropriate to include a specific example in the annex and would only mention impurities in the recitals.

4. **EFSA DECISIONS ON CONFIRMATORY APPLICATIONS**

EFSA clarified that the draft PAs would not prevent applicants from submitting additional factual elements in the context of confirmatory applications. The only constraint for applicants would be that no new confidentiality requests could be introduced at the level of confirmatory applications.

5. **POSSIBILITIES FOR APPLICANT TO CONTEST THE CONFIDENTIALITY DECISION BEFORE DISCLOSURE**

DG SANTE explained that applicant would have a number of occasions to contest EFSA's draft decision on confidentiality.

- At a very early stage, when EFSA drafts its first decision on intention to disclose, EFSA would send this draft decision to the applicant and the applicant would have the opportunity to make comments or withdraw its application, prior to the formal adoption of that EFSA decision.
- With the adoption of the EFSA confidentiality decision, the applicant would still have 2 weeks to react during which timeframe no public disclosure would take place.
- If the applicant disagrees with the decision, it can still decide to submit a confirmatory application.
- Until EFSA notifies the applicant about the adoption of the formal final confidentiality decision, no public disclosure will take place.
- If the applicant still disagrees with the final decision by EFSA, it can go to the European Court of Justice to ask for interim measures to block the public disclosure.

6. COMMON LIST OF DEFINITIONS

Concept of 'applicant'
DG SANTE explained that the concept of applicant in the draft EFSA PAs on Articles 38 and 39 of the General Food Law is broader than the concept of applicants in the draft EFSA PAs on Articles 32a, 32b and 32c of the same Regulation.

This is because Article 38 foresees that EFSA will disclose studies - not only those that support a request to EFSA for a scientific output by stakeholders in the context of authorisations - but also when there are requests to EFSA for a scientific output by Member States, the Commission or the European Parliament. Although the Member States or the Parliament cannot claim confidentiality per se, this request may be accompanied by a study done by another party, e.g. NGO or a food business operator and there may be a need to ask for confidentiality treatment. Therefore, a broader definition of applicant for the purposes of Articles 38 and 39 would be needed in that context.

As regards the draft EFSA PAs on Articles 32a, 32b and 32c of the General Food Law, DG SANTE clarified that the concept of potential applicants is only limited to *stricto sensu* authorisation processes of regulated products.

Other definitions

The definitions set out in the General Food Law apply as well as the definitions set out in the other relevant sectoral legislations. Therefore, the draft EFSA PAs contain only the definitions that were absolutely needed for the relevant rules in place.

EFSA added that as regards the confidentiality decision on PPP, there is a very specific set of PAs relying entirely on Regulation 1107/2009, therefore it is very difficult to have a different set of definitions applicable to that set of PAs.

7. TRANSITIONAL MEASURES

EFSA clarified that it was not legally empowered to lay down transitional measures in the PAs.

DRAFT PRACTICAL ARRANGEMENTS ON CONFIDENTIALITY - (ARTICLES 7 AND 16 OF REGULATION (EC) NO 1107/2009, AS AMENDED BY THE TR)

1. ARTICLE 7.5 – DISCLOSURE OF CONFIDENTIALITY ITEMS

EFSA confirmed that it is the responsibility of the Rapporteur Member State (RMS) involved in the peer review process to ensure that the information items for which confidentiality treatment has been granted are not disclosed.

EFSA further explained that the PAs apply without prejudice to the Aarhus Regulation. In that respect, EFSA indicated that any information falling under the definition of environmental information set out in the Aarhus Regulation would not be granted confidentiality treatment, to ensure compliance with the Aarhus Regulation.

2. ARTICLE 4 - CONFIDENTIALITY OF INFORMATION SUBMITTED FOR THE RENEWAL OF APPROVAL OF AN ACTIVE SUBSTANCE

DG SANTE explained that according to good legal practice, provisions that are already laid down in the Transparency Regulation are not repeated in the PAs.

3. ARTICLE 7 - ASSESSMENT OF THE CONFIDENTIALITY REQUESTS AND DECISIONS BY THE RAPPORTEUR MEMBER STATE UNDER ARTICLE 7.3 OF REGULATION 1107/2009

DG SANTE indicated that, when Member States assess confidentiality under article 7.3 of Regulation 1107/2009, they need to abide by the provisions of the Transparency Regulation (i.e. compliance with the positive list of confidentiality items and demonstration by the applicant that disclosure of the relevant information would potentially harm its interests to a significant degree).

DG SANTE further clarified that, under the new provisions, Member States would assess confidentiality requests for new approvals while EFSA would assess confidentiality requests for renewals.

DG SANTE reminded that the purpose of the specific empowerment to EFSA to adopt PAs as regards the confidentiality assessment of new approvals/renewals in the area of the plant protection products was to ensure the consistency of the confidentiality assessments.

The use of rebuttable presumptions would help both the applicants in substantiating their confidentiality requests but also the Member States in their assessment of such requests.

As regards the requirement on 5% of total gross annual turnover, DG SANTE confirmed that this rebuttable criterion, like in the PAs on transparency and confidentiality (Articles 38 and 39), had been revised by EFSA. EFSA further explained that it would be for the RMS to assess the soundness of the reasoning proposed by the applicant, relying on the statements provided by the applicant.

4. FEES/TAXES

EFSA mentioned that it is aware that RMS already demand fees for the performance of the peer review process that may cover the confidentiality assessment process. EFSA confirmed that it is not empowered by legislators to levy any fees.

5. TIMELINES FOR THE ASSESSMENT OF AND DECISION MAKING ON CONFIDENTIALITY REQUESTS

EFSA explained that the very stringent timelines foreseen for the RMS decision-making process reflect the timelines granted for EFSA. EFSA further explained that the reasoning behind is that prolonged confidentiality assessment could potentially delay public consultation and therefore could in turn delay the peer review process.

6. SIX-MONTH REVIEW AFTER IMPLEMENTATION

EFSA agreed on the need for review but does not foresee any review before at least one year of application. DG SANTE supported the need to see the full effect of the application before a review.

DRAFT PRACTICAL ARRANGEMENTS ON PRE-SUBMISSION PHASE AND PUBLIC CONSULTATIONS (ARTICLES 32A, 32B AND 32C OF THE GENERAL FOOD LAW, AS AMENDED BY THE TR)

1. INFORMATION TO BE NOTIFIED - INTENDED STUDIES AND COMMISSIONED STUDIES (ARTICLES 32C(1) AND 32B OF THE GEENRAL FOOD LAW)

DG SANTE clarified that the notification requirements set out in Article 32c(1) - for renewals - and Article 32b of the General Food Law - applicable to both new approvals and renewals - have different objectives, timelines and procedural consequences.

- As regards Article 32c(1) (notification of **intended** studies for renewals): DG SANTE explained that this notification requirement is meant for intended studies (before they are commissioned). Information on the intended studies is needed for EFSA to perform a meaningful public consultation in order to deliver a tailor-made presubmission advice to the potential applicants in the case of renewals. This advice is not committal neither to EFSA, nor to the applicants.
- As regards 32b (notification of commissioned studies): DG SANTE further explained that the notification of commissioned studies under Article 32b has a different objective, namely to ensure that EFSA is aware of all studies being commissioned or carried out and to provide assurances to that there are no hidden studies. In this context, procedural consequences in case of non-compliance are foreseen in the General Food Law, as amended by the TR.

EFSA indicated that only for Article 32c(1) the field "study guideline" or "study design description" shall be provided to describe the design of the study. The field "authorisation of the ethical committee" is no longer present in the NoS-DB. The field "study international certification", remains a mandatory information only in relation to a notification of study under Article 32b. The certification is essential to characterise the essential aspect of the quality of the study and to retrieve and match correctly between information previously notified in the database at pre-submission level and the studies included (or not) in the application.

2. INFORMATION PROVIDED DURING PRE-SUBMISSION PHASE

DG SANTE stressed that it is essential for applicants that Member States ensure not to disclose this information during pre-submission phase. DG SANTE added that there is time for transparency later on in the process. Therefore, EFSA added it would prefer to keep the text as it is.

3. NOTIFICATION OBLIGATION (ART. 32B OF THE GFL) IN RELATION TO ADDITIONAL STUDIES REQUESTED AT VALIDITY, ADMISSIBILITY AND RISK ASSESSMENT PHASE

EFSA explained that when applicants submit additional information requested in the context of the assessment of the validity and admissibility stage or later on, during the risk assessment, they will be reminded that also in this context the

notification obligation of commissioned studies would apply provided that the studies are carried out after 27 March 2021.

4. ACTORS INVOLVED IN THE VERIFICATION OF THE COMPLIANCE WITH NOTIFICATION OBLIGATION OF COMMISSIONED STUDIES (ART. 32B OF THE GFL)

EFSA reminded the four authorisation sectors for which Member States retain full responsibility in the assessment of admissibility of the application including verification of compliance against the notification of studies obligations: GMO Directive, PPP regulation, MRL Regulation and Health Claims.

Since the EFSA Practical Arrangements are binding rules and are meant to be future-proof, EFSA would not indicate for which sectors the assessment of the compliance with the notification obligations is performed by EFSA or the Member States and mentioned that it would be more appropriate to clarify this in a Q&A document.

5. PUBLIC CONSULTATION – RENEWALS (ARTICLE 32C OF THE GFL)

DG SANTE explained that in the context of renewals, there are two public consultations: at presubmission phase (Article 32c(1)of the General Food Law) and the public consultation on the non-confidential version of the application including submitted studies (Article 32c(2) of the same Regulation) - without prejudice to any additional public consultations provided for in sectoral legislation during the RA. DG SANTE confirmed that there is no public consultation at presubmission phase for new substances.

6. ARTICLE 43 OF PPP REGULATION 'RENEWAL OF AUTHORISATION' – NOTIFICATION OF INTENDED/COMMISSIONED STUDIES

DG SANTE explained that at presubmission phase for renewals, the general provisions of Article 32a (general presubmission advice), Article 32b (notification of study) and Article 32c are applicable. The PAs need to be read together with the relevant implementing acts and in the area of PPP with the implementing act on renewals (Regulation 2020/1740). DG SANTE further explained that the rules are complementary and do not repeat each other.

As regards the authorisation at national level of plant protection products pursuant to PPP Regulation, Article 32a (general presubmission advice), Article 32b (notification of study) and Article 32c are not applicable since EFSA is not involved in such procedures.

7. GENERAL PRESUBMISSION ADVICE - RENEWALS

EFSA clarified that Article 32a of the GFL also covers renewals; therefore applicants may request EFSA's presubmission advice also for renewal applications (in addition to the specific tailor-made presubmission advice of Art. 32c(1) of the GFL which is systematically provided by EFSA when the potential applicant envisages to perform new studies).

8. ANIMAL TESTING

DG SANTE clarified that the Transparency Regulation requires to make sure that the Directive on animal testing is taken into account. When EFSA provides a pre-submission advice to applicants, EFSA will take into account that studies performed on animals should not be repeated.

9. AUTHORISATIONS UNDER PPP REGULATION

Authorisations of products under PPP Regulation are only granted by Member States. There is no involvement of EFSA or the Commission. Therefore, Article 32a (general presubmission advice), Article 32b (notification of study) and Article 32c are not applicable in this context (see also point 6).

10. "PRESUBMISSION ADVICE" TIMELINES

EFSA clarified that Article 32a of the GFL only regulates the provision of general presubmission advice by EFSA; therefore the relevant PAs only cover the relevant requests to, and provision of advice by EFSA under that provision.

As regards the timelines for requesting general presubmission advice to EFSA under Article 32a of the GFL, EFSA indicated that the recommendation of asking advice minimum 6 months before the planned date of submission of the application is based on EFSA's experience. Requesting advice too late in the process could be disruptive since it could take too much time for the potential applicant to adapt its application to the advice provided by EFSA. Requesting advice too early might result in applicants posing too generic questions. However, EFSA indicated that this is only a recommendation and not a mandatory timeline.

11. DESIGN OF STUDIES

DG SANTE clarified that EFSA may provide (non committal) presubmission advice on the specific design of studies only in the context of the presubmission advice for renewals under the specific conditions of Article 32c(1) of the GFL. EFSA will not give advice on the design of studies in the context of Article 32a of the GFL except where the design of studies has been developed in generic EFSA guidances, which are publicly available. Anyway, in the latter case, the advice provided under Article 32a of the GFL would remain general and never result in tailored made advice on study design.

The design of studies falls within the responsibility of the applicants.

12. ADVICE PROVIDED BY THE RAPPORTEUR MEMBER STATE (RMS)

RMS may provide presubmission advice if the request is addressed to the RMS. If the advice is requested to EFSA – in case of decentralised system– EFSA will inform the RMS and provide advice in full collaboration with the RMS.

13. PROVISION OF GENERAL PRE-SUBMISSION ADVICE IN THE PPP AND MRLS AREAS

EFSA will clarify the text on the applicable timelines of the administrative check in relation to general presubmission advice provided by EFSA in the areas of PPP and

MRLs. The intention is to apply the same timeline as for the default option, i.e. 10 working days.

14. GENERAL PRESUBMISSION ADVICE – TIMELINE FOR ADMINISTRATIVE CHECK IN THE AREA OF PPP/MRL

EFSA clarified that it would not be appropriate to have [considerable] discrepancies between PPP/MRLs and other sectors. The timeline of 20 working days for the provision of the advice was identified as appropriate for that reason. EFSA explained that the 20-day timeline will allow exchange with National Competent Authorities to ensure they can provide the advice in a certain limited period of time to applicants. EFSA will re-discuss this timeline in line of comments received.

15. INFORMATION TO EFSA ON ADMISSIBILITY OF APPLICATION BY NATIONAL COMPETENT AUTHORITIES

EFSA clarified that even in sectors with a decentralised system, it has a role to play and relevant responsibilities both at presubmission phase and later on during the peer review/risk assessment processes, as regards the dissemination and public disclosure of certain information. In between those phases, there are the submission of the application and the work done by the national authorities to assess the application. EFSA highlighted that it is important to have provisions requiring that, once the admissibility is decided by the RMS, the latter will promptly inform EFSA so that EFSA can proceed with the relevant dissemination of information as required by law and the carrying out of public consultation(s).

16. ADMINISTRATIVE CHECK IN THE CONTEXT OF PUBLIC CONSULTATION

EFSA indicated that – when there is the possibility for EFSA to ask further information to applicants during the administrative check in the context of public consultations – there is no specific deadline indicated in the Practical Arrangements for the applicants to submit the requested information. The deadline will be on a case-by-case basis, depending on the type of information asked.

17. PRESUBMISSION ADVICE – DESIGN OF STUDIES

EFSA indicated that in the context of the renewal presubmission advice, the Practical Arrangements would allow EFSA to ask the support of external experts to advise on design of studies due to the specificity and scientifically complexity in some cases. EFSA indicated that this possibility only applies in relation to the renewal presubmission advice pursuant to Article 32c(1) of the GFL.

18. CONSULTATION OF THIRD PARTIES ON INTENDED STUDIES FOR RENEWAL

DG SANTE reminded that EFSA's renewal presubmission advice that will be given on the basis of results of the public consultation is non-committal, i.e. studies submitted in a related application can be rejected at a later stage or more studies can be requested at the RA phase.

19. FAILURE TO MEET THE DEADLINE OF DOSSIER SUBMISSION FOR RENEWAL

DG SANTE indicated that in case of missed deadline, the existing application will expire without being renewed. DG SANTE further explained that applicants will

have to submit a new application and withdraw the product from the market before a new authorisation is approved.

20.ADMISSIBILITY CHECK / VALIDITY CHECK

DG SANTE explained – as indicated previously in the discussion - that in some sectors admissibility/validity checks are to be done by Member States and not by EFSA/COM. DG SANTE further clarified that sectoral PPP legislation refers to admissibility check but that all other sectors refer to validity checks. EFSA will provide to Member States information regarding study notification, strictly on a need-to-know basis, to allow them to perform the relevant validity/admissibility checks of submitted applications/notifications.

21.SUBMISSION OF STUDIES IN FULL

DG SANTE explained that in the area of PPP, it is for the Member States to assess whether the study is submitted in full. This is addressed in the new Implementing Act on renewals for active substances (Regulation (EU) 2020/1740)[1].

22.ANNEX II – STUDY DESIGN

DG SANTE explained that Annex II to the relevant PAs is about Article 32c(1) of the GFL.

The study design is excluded from the list of information that can be requested in the context of Article 32b, as it goes beyond the scope of that article.

23.COMPLIANCE WITH ARTICLE 32C(1) AND ARTICLE 32B FOR RENEWALS IN THE AREA OF FEED ADDITIVES AS OF 27 MARCH 2021

DG SANTE explained that Article 32c(1) will only apply as of 27 March 2021, where a potential applicant still intends to carry out a new study in support of a future renewal. If a study has been commissioned/is ongoing, there is therefore no obligation to notify it as an intended study.

Both Article 32c(1) and Article 32b will only apply if actions have to be taken by applicants after 27 March 2021.

DG SANTE recognised that for a period of time, there may be a simultaneous process of parallel application of Article 32c(1) and Article 32b. DG SANTE stressed that non-compliance with Article 32b will have procedural consequences.

[1] Commission Implementing Regulation (EU) 2020/1740 of 20 November 2020 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012 (Text with EEA relevance) https://eur-lex.europa.eu/legal-content/EN/TXT/?toc=OJ:L:2020:392:TOC&uri=uriserv:OJ.L_.2020.392.01.0020.01.ENG#:~:text=Commission Implementing Regulation (EU) 2020/1740 of 20 November, Regulation (EU) No 844/2012 (Text with EEA relevance)

Note after the meeting: On 23 December 2020, EFSA adopted its Practical arrangements on (a) Transparency and Confidentiality; (b) Confidentiality in accordance with the Plant Protection Products Regulation; and (c) Pre-submission phase and public consultations. The EFSA Practical Arrangements are available on the EFSA website at https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements.