

Annex

to the minutes of the EG on GFL 26 June 2020

Transparency Regulation – Summary of DG SANTE-EFSA replies to questions raised by MSs on the EFSA staff working document, dated 26.02.2020

During the Expert Group (EG) meeting on the GFL Regulation on 3 March 2020, EFSA presented a staff working document (non-paper – version 26.02.2020 –) on the EFSA Practical Arrangements for Articles 38(1) and 39d(5) of the GFL Regulation¹.

This non-paper outlined the key concepts of the forthcoming Practical arrangements with the aim of gathering input and comments from Member States' experts. It set out the position of EFSA's services on 18.02.2020 and should not be interpreted as representing EFSA's final position.

In the meeting of 26 June 2020, DG SANTE and EFSA provisionally replied to the questions raised by Member States on the basis of that non paper, taking into account that the Commission Inter-service Consultation on the Commission's opinion on the draft EFSA Practical Arrangements for Articles 38(1) and 39d(5) of the GFL Regulation had not yet been formally completed.

SUMMARY OF PROVISIONAL REPLIES

1. GENERAL ON THE LEGAL BASIS FOR EFSA TO ADOPT PAS RELATING ON CONFIDENTIALITY

- The new TR provisions and most specifically the new Article 39d(5) specifically require EFSA to develop practical arrangements (i.e. binding implementing rules) to implement, amongst others, the confidentiality rules (laid down in Articles 39, 39a, 39b, 39d and 39e, including arrangements concerning the submission and treatment of confidentiality requests. The scope of this legal basis is quite broad to address all relevant aspects pertaining to confidentiality when EFSA is entrusted with this task according to the applicable sectoral legal provisions.

¹ Link to the EFSA working document: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200303_efs_a.pdf)

2. SECTION 3 OF THE EFSA SWD- Proactive disclosure and IT standards

Intellectual Property Rights (IPRs)

- DG SANTE clarified that under the Transparency Regulation, EFSA would not be an enforcer of IPRs. The TR clearly indicates that the Union institutions shall not be responsible for the use of the disclosed information by third parties (new Article 38(1a) (last subparagraph)). Tracing of who has access to data would be an enforcement action of IPRs and therefore outside the scope of EFSA's competence.
- In addition, any implementation action of this provision needs to ensure that it would not reproduce a 'request for access' mechanism: TR sets out a proactive public disclosure principle.
- On the basis of these 2 confirmations, a simple message clarifying unambiguously, and asking confirmation of the understanding, that the person who accesses the data has no right to exploitation would suffice.

Timing – Risk of delays in the RA process due to confidentiality assessment

DG SANTE clarified that the risk of delays in the risk assessment process due to confidentiality assessment processes has been addressed in the Transparency Regulation, which provides for an exceptional 'stop-the-clock' of seven weeks of the risk assessment period in duly justified cases where there is a risk that the results of the public consultation foreseen under Art. 32c(2) on the basis of the final non-confidential version of the submitted applications cannot be given proper consideration.

3. SECTION 5 OF EFSA SWD - Scope of Practical Arrangements for confidentiality decision making

Confidentiality requests/assessment under the GMO Directive

- The confidentiality assessment under the GMO Directive remains with the Member States.
- The new Article 25 of the GMO Directive, read also in conjunction with Article 28(4) of the same Directive, as amended by the Transparency Regulation, explicitly mentions this and provides for certain procedural steps.
- In that respect, this means that only the transparency provisions of EFSA's PAs on transparency/confidentiality (new articles 38 and 39 to 39e of GFL) would be applicable to data or information submitted by applicants under this Directive and received by EFSA where the Authority is consulted pursuant to article 28(4) of the GMO Directive.
- In summary:
 - o Confidentiality assessment remains with the MS and therefore it would be respected by EFSA, the Commission and Union Member States (as provided explicitly by the new Articles 25(8) and 28(4) of the Directive);

- The supporting studies of a GMO notification would be made public - except for the duly justified confidential information as assessed by the relevant MS - only when EFSA is consulted pursuant to Article 28(4) of the GMO Directive. Where EFSA is not consulted in a given procedure, no public disclosure will take place and any documents would be accessible through the "Access-to-Documents" legal framework set out in Union or Member States' law.

Confidentiality assessment in GMO-related areas

- Requests for confidentiality under the GMO Directive are handled differently compared to similar requests under Regulation 1829/2003, as far as the procedure is concerned, the actors involved and the level of proactive disclosure:
 - In the case of the GMO Directive:
 - Confidentiality requests would be assessed by the MS who receives the GMO notification;
 - Assessment would be carried out in accordance with the (simplified) procedure of Article 25 of the Directive;
 - Proactive disclosure would take place, only when EFSA is involved under Article 28(4) of the Directive.
 - In the case of Regulation 1829/2003:
 - Confidentiality requests would be assessed by EFSA;
 - Assessment would be carried out in accordance with Articles 39 to 39e read in conjunction with EFSA's practical arrangements on confidentiality;
 - Proactive disclosure of all applications submitted under the Regulation.
- Nevertheless, the grounds on the basis of which confidentiality would be given are the same in both legal regimes (positive lists) and the same legal requirements apply (potential harm to a significant degree, accompanied by verifiable justification).
- In any event, the competent Member State or EFSA are required to perform individual assessments of each confidentiality request.

4. SECTION 7 OF EFSA SWD - Submission of confidentiality requests

No payment of fees

- The TR does not delegate to EFSA to set up a cost recovery system for the processing of confidentiality requests.
- No step of the procedure aimed at assessing or handling confidentiality requests may be subject to a fee.

5. SECTION 8 - Minimum content of confidentiality requests

Introductory remarks

- The Transparency Regulation establishes the principle of proactive public disclosure as all scientific data supporting requests for scientific output addressed to EFSA, including authorisation requests. As such, confidentiality is the exception to the proactive public disclosure and must be applied strictly.
- The positive lists of information items that may qualify for confidential treatment are set out in the GFL Regulation (new Article 39(2) of the GFL) but also in sectoral legislation (see cross-reference of Article 39(3) of the GFL). They are binding and they do not need to be explicitly mentioned in the EFSA PAs.
- While EFSA is required to perform an individual assessment of each confidentiality requests received from applicants, EFSA has tried to provide indications how 'potential harm to a significant degree' could be substantiated so as to achieve higher consistency, reduce margin of discretion and ultimately increase the predictability and transparency of EFSA's confidentiality decision making. The Commission considers this as being within the remit of EFSA's empowerment as regards the assessment of confidentiality to be performed by EFSA. This set of PAs are not applicable in the cases where confidentiality is assessed by the Member States or by the Commission pursuant to the applicable legal provisions.
- By "specific reasons" EFSA meant the obligation for an applicant to provide discursive justification why in the concrete case of that confidentiality request on that piece of information or document, it is not possible for the applicant to quantify the potential damage in case of disclosure, or the reason why the potential damage would still comply with the damage to a "significant degree" requirement.
 - o **Point (a): The document, information or data for which confidentiality status is requested is not publicly available or is known only to a limited number of persons**
 - This condition is logical especially when confidentiality is an exception to public disclosure and 'potential harm to significant degree' needs to be proven. If the document is already publicly available and known to a large number of persons, the threshold of 'significant harm' cannot be considered to be met.²
 - o **Point (c): Possible quantification of "significant harm"**
 - 'Potential harm to a significant degree' can be both qualitative and quantitative.
 - EFSA has introduced a rebuttable presumption. Rebuttable presumptions have been accepted by the EU courts especially in the context of access to the file in the area of EU competition law.

² A similar point of view is reflected in the Commission notice for access to the file in the context of the EU competition law. See for instance formulation in the Commission Notice on the rules for access to the Commission file in cases pursuant to Articles 81 and 82 of the EC Treaty, Articles 53, 54 and 57 of the EEA Agreement and Council Regulation (EC) No 139/2004, OJ C 325, 22.12.2005, p. 7–15, point 23: "*Information relating to an undertaking but which is already known outside the undertaking (in case of a group, outside the group), or outside the association to which it has been communicated by that undertaking, will not normally be considered confidential. [...].*"

- According to EFSA, there is case law identifying 5% of the turnover of the applicant as being a “negligible” or anyway “not serious” harm to the applicant.³ By translating the fact that impacts between 0% and 5% are considered as “negligible harm”, taking that figure as the lowest impact compatible with the concept of harm, and foreseeing the possibility for applicants to justify why in their case the damage would still be considered “potentially harming them to a significant degree”, EFSA proposed 5% as an indicative threshold (rebuttable presumption) mainly aimed at excluding from the award of confidential status items whose disclosure is not likely to cause a sufficient degree of harm from a quantitative perspective.
 - EFSA acknowledged the figure is not set out in stone and could be subject revision based on experience gained by EFSA in the processing of confidentiality requests. However, this percentage can be considered a proportionate way to ensure that the core tasks of EFSA are not disrupted by processing high numbers of small value confidentiality requests. Crucially, the current proposal does contemplate a high degree of flexibility insofar as it allows applicants to submit confidentiality requests also for items not complying with this figure, upon justification of the reason why the disclosure of the item would prove to be harmful to their interests to a significant degree.
 - EFSA further indicated that the reference to turnover should be better specified in the draft PAs.
- **Point (f): Novelty of the document**
 - This is a rebuttable presumption. A rebuttable presumption that information older than 5 years is not confidential has been used in Union law in the context of the EU competition law (access to the file) for refusing a sufficient degree of harm.⁴
 - EFSA committed to review the starting point for calculating the five years period.
 - **Point (e): Environmental information**
 - The definition of “environmental information” in the Aarhus Regulation is set out in Article 2(1) point d of this regulation.
 - The applicant would need to explain why the Aarhus Regulation is not applicable to the items for which they submit a confidentiality request;

³ ORDER OF THE PRESIDENT OF THE GENERAL COURT 15 November 2011 in Case T 269/11 R, Xeda International SA, para. 21 making reference to C-474/00.

⁴ See for instance formulation in **the Commission Notice on the rules for access to the Commission file** in cases pursuant to Articles 81 and 82 of the EC Treaty, Articles 53, 54 and 57 of the EEA Agreement and Council Regulation (EC) No 139/2004, OJ C 325, 22.12.2005, p. 7–15, point 23: “[...] *Information that **has lost its commercial importance**, for instance **due to the passage of time, can no longer be regarded as confidential**. As a general rule, the Commission presumes that **information pertaining to the parties' turnover, sales, market-share data and similar information which is more than 5 years old is no longer confidential**.*” This rebuttable presumption concerning the age of the information was upheld by the Court of Justice in its judgment of 14 March 2017 in C-162/15 P *Evonik Degussa v Commission*, ECLI:EU:C:2017:205, paragraph 64. “Those considerations, which give rise to a rebuttable presumption, are valid both in the context of requests for confidential treatment in respect of parties intervening in actions before the EU Courts and in the context of requests for confidentiality with a view to the publication by the Commission of a decision finding an infringement of competition law.”

- EFSA would then be assessing this request and whether it is substantiated; a decision would be taken on the basis of an individual assessment considering all specificities of each request.

6. SECTION 9 OF EFSA SWD– Working languages

- Currently the IT tools are being developed in English only.
- EFSA will be revisiting the applicable rules regarding the applicable linguistic regime.

7. SECTION 12 OF EFSA SWD - EFSA decisions on confirmatory applications

- EFSA provided additional clarifications on the scope of confirmatory applications; its intention was to ensure that the original confidentiality requests submitted are solid enough and avoid abuse of confirmatory applications to delay the relevant processes.
- EFSA will be revisiting its proposed text to clarify better the scope of confirmatory applications.