



EXPERT GROUP ON GENERAL FOOD LAW STATE OF PLAY ON THE IMPLEMENTATION OF THE TRANSPARENCY REGULATION

MINUTES OF THE MEETING

16 NOVEMBER 2020, 9H30-15H30

1. INTRODUCTION BY THE COMMISSION

DG SANTE opened the meeting and informed the Member States' (MS) experts about the different agenda items that would be presented.

DG SANTE provided an update on the adaptation and timeline of seven [COM implementing acts](#) that need to be aligned to the new provisions of the Transparency Regulation.

2. DRAFT PRACTICAL ARRANGEMENTS

DG SANTE informed the MS experts that all questions that had previously posed on the three sets of the draft EFSA Practical Arrangements would be answered during the meeting. At the request of some MS experts, DG SANTE provided an extended deadline for the submission of additional comments **by 20 November 2020, noon**. DG SANTE asked the MS experts to limit their additional comments to any major issues as the Practical Arrangements are to be adopted at the latest by end of 2020. As regards the draft EFSA Practical Arrangements on confidentiality in accordance with Articles 7 and 16 of the Plant Protection Products Regulation, DG SANTE asked Member States to address their questions and comments through the relevant channel, i.e. the plant protection products section of PAFF (Standing committee of Plants, Animals, Food and Feed - SCoPAFF).

EFSA presented the three sets of its draft Practical Arrangements and addressed specific questions from the MS experts:

- **DRAFT PRACTICAL ARRANGEMENTS ON TRANSPARENCY AND CONFIDENTIALITY (ARTICLES 38 AND 39-39E OF THE TR)**

Prior to EFSA's presentation on the [Practical Arrangements](#), the Commission recalled the consultation process. Under the new provisions of the Transparency Regulation, this set of Practical Arrangements was subject to a formal consultation of the Commission only.

- **DRAFT PRACTICAL ARRANGEMENTS ON CONFIDENTIALITY IN ACCORDANCE WITH ARTICLES 7 AND 16 OF REGULATION (EC) No 1107/2009**

EFSA presented the [Practical Arrangements \(PAs\) concerning confidentiality in accordance with articles 7 and 16 of the Plant Protection Products \(PPP\) Regulation as an information point](#).

Under the new provisions of the Transparency Regulation, this set of Practical Arrangements was subject to a formal consultation of the Member States only.

Accordingly, the main formal consultation of the Member States to this set of draft Practical Arrangements was taking place in the context of the plant protection products section of the PAFF (SCOPAFF). EFSA informed the MS experts of the timeframe of this formal consultation, as follows:

- Presentation to SCOPAFF on 22 October 2020. Deadline for submission of written comments by 9 November 2020.
- Comments had been submitted by NL and SE.
- EFSA would provide feedback in the next SCOPAFF meeting (PPP section) early December 2020.
- Following the December SCOPAFF meeting, EFSA would finalise the set of PAs.

- **DRAFT EFSA'S PRACTICAL ARRANGEMENTS ON PRE-SUBMISSION PHASE AND PUBLIC CONSULTATIONS (NEW ARTICLES 32A, 32B AND 32C OF GFL)**

EFSA presented the [draft Practical Arrangements on pre-submission phase and public consultations](#). Under the new provisions of the Transparency Regulation, this set of PAs, relevant to the updating of certain sectoral Commission implementing acts, is not subject to any formal consultation (neither of the Commission, nor the Member States).

3. UPDATE ON EFSA'S GUIDANCES

EFSA presented an update of its [guidances](#) that need to be aligned to the new provisions of the Transparency Regulation. A total of 27 EFSA guidances would need to be updated by 27 March 2021: 12 administrative guidances and 15 scientific guidances.

4. PRESENTATION OF NOTIFICATION OF STUDIES DATABASE

EFSA provided a [presentation of the notification of studies database](#) for the new Article 32b of the General Food Law (notification of commissioned studies) and Article 32c(1) of the General Food Law (notification of intended studies in the case of renewals).

5. PRESENTATIONS OF E-SUBMISSION SYSTEMS FSCAP AND IUCLID

- **FSCAP:** DG SANTE presented progress on the [electronic submission system FSCAP](#) that will be offered for all authorisation processes with the exception of plant protection products (PPP and maximum residue limits (MRLs) in pesticides. DG SANTE underlined the need to have contact points identified in all Member States for the purposes of ensuring the smooth operation of the FSCAP tool.
- **IUCLID:** EFSA presented progress of the [IUCLID electronic submission system](#) to be used for all applications in the areas of PPP and MRLs.

6. AOB

DG SANTE informed the MS experts that as regards stakeholders' engagement, an ad-hoc working group meeting of the [Advisory Group on the food chain and animal and plant health](#) on the Transparency Regulation implementation would take place on 18 November 2020 to address the stakeholders' questions and comments on the Practical Arrangements.

Should there be a need, DG SANTE may organise another meeting of the Expert Group on GFL before the legal deadline of 27 March 2021.

Note after the meeting: On 23 December 2020, EFSA adopted the relevant 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 Practical Arrangements are available on the EFSA website at <https://www.efsa.europa.eu/en/corporate/pub/tr-practical-arrangements>.