



EXPERT GROUP ON GENERAL FOOD LAW

IT IMPLEMENTATION OF TRANSPARENCY REGULATION

MINUTES OF THE MEETING

21 JANUARY 2020, 10-13H

1. INTRODUCTION TO THE TRANSPARENCY REGULATION¹

The Commission opened the meeting and explained that this meeting was the first in a series of meetings with Member States (MSs) on the implementation of the Transparency Regulation. They highlighted that the Transparency Regulation had been published on 6 September 2019 and would enter into application on 27 March 2021 (with the exception of the provisions for the new Management Board and the expert panels, which would be applicable as of 1 July 2022). The Commission, in close cooperation with EFSA and Member States, informed the Member States that a proper IT infrastructure to accommodate the new requirements would need to be in place on time. The Commission and EFSA envisaged setting up the required new IT systems (at least at testing phase) by the third quarter of 2020.

The aim of the meeting was to have a first introduction to the Member States of the Commission and EFSA's proposals for the implementation of IT related aspects of the Transparency Regulation. The Commission stressed that any new IT system should not go contrary to any existing IT systems in Member States. The Commission explained that this first meeting would focus in particular on the transparency and confidentiality IT-related aspects and on the implementation of notification of studies database, and that all IT systems would have to be interlinked and interconnected.

The Commission provided an introductory presentation to the Transparency Regulation (https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_transparency_20200121_eg_pr es01.pdf).

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. IMPLEMENTATION OF IT-RELATED ASPECTS OF TRANSPARENCY REGULATION

2a. Transparency- and confidentiality-related provisions (new Articles 38 to Article 39h of the GFL Regulation, as amended by the Transparency Regulation) – Presentation on FSCAP e-submission system

The Commission explained that the Transparency Regulation requires the dissemination of non-confidential data in searchable and readable format and contains increased confidentiality processing requirements. The possibility of electronic submission of applications would be a precondition to meet these requirements.

The Commission and EFSA proposed the Food System Common Authorisation Procedure (FSCAP) e-submission system as an adequate IT solution for the electronic submission of applications in the context of the Transparency Regulation. The Commission in close collaboration with EFSA explained it intended to extend FSCAP (operational for Novel Foods since January 2018) to all food-related sectors, and be the main and single entry point for applicants, Member States, Commission and EFSA. In case Member States already had IT systems in place, the Commission wished to explore how these could be linked to FSCAP, especially in sectors where MSs play an important role in the process..

The Commission highlighted, however, that for the Plant Protection Products (PPP) sector, an EFSA-ECHA pilot project on the feasibility of extending IUCLID for pesticides was ongoing in parallel and that a decision on using FSCAP or IUCLID for the PPP sector would be taken depending on the outcome of the pilot in the following weeks. The Commission mentioned they would keep the Member States updated on the developments.

The Commission presented the FSCAP e-submission system (https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_transparency_20200121_eg_pr es02.pdf) and provided a ‘live’ demonstration of the system (https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_transparency_20200121_eg_fsc ap-demo.mp4).

The Commission and EFSA explained that it had started analysing the needs for each food sector, application structure and workflow specificity for the following types of applications:

- Applications submitted to the MS CAs, which are then forwarded without delay to EFSA (GM food and feed (new), smoke flavourings, health claims and FCM);
- Applications submitted to the MS CAs and for which CAs are more involved in the process (GMO Directive and PPP);
- Applications submitted to EC (Food improvement agents, novel/traditional foods feed additives, GM food and feed (renewals) etc.).

The Commission asked for initial Member States’ feedback on FSCAP and proposed to go into more detail on FSCAP in further meetings.

Presentation on the database of notification studies

EFSA presented their proposal for the development of the database for notification of studies (new Articles 32b and 32c of the GFL Regulation, as amended by the Transparency Regulation) (https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_transparency_20200121_eg_pr es03.pdf).

2b. Fact-finding on IT systems in use by Member States where they receive applications, in the context of GMO Directive, GM Food and Feed, Smoke flavourings, Food Contact Materials, Plant Protection Products, Health Claims

The Commission asked Member States to reflect how they could participate in the development of FSCAP also in view of linking it to any existing IT systems in Member States. The Commission asked specific input from Member States for the food sectors on GM Food and Feed, smoke flavourings, Health Claims, and FCM (for which applications are submitted to the MS CAs) and on the cultivation of GMOs and Plant Protection Products (PPP) (for which applications submitted to the MS CAs and for which CAs are more involved in the process).

In order to gather input from the Member States on the IT systems being used, the Commission invited Member States to fill in a questionnaire ‘Transparency Regulation implementation – IT aspects’ for each of these food sectors. Member States were asked to send their input to: Sante-science-transparency@ec.europa.eu by 7 February 2020.

3. DISCUSSION WITH MEMBER STATES

- A MS asked about the use of future standard data formats in FSCAP. The Commission clarified that standard data formats would be developed at a later stage and would afterwards be adopted through a set of implementing acts. Once the Implementing Acts are adopted, the Commission would ensure that the IT infrastructure is adapted to support them.
- A MS asked for further information on the GMO Directive and how the Commission envisaged linkages to current systems on national assessments. The Commission clarified that this would require more specific discussions with Member States on how to link their national system to FSCAP and urged Member States to fill in the questionnaire.
- A MS asked about training and user support on FSCAP. The Commission replied that they would provide ‘contextual help’ in FSCAP and practical user manuals. Feedback sessions would be organised with early users (representatives industry, MS, EFSA, COM) to build and improve training materials. In addition, there would be a helpdesk.

4. ANY OTHER BUSINESS

The next meeting of the Expert Group on GFL will be held on 3 March 2020.

The Commission has published a webpage on the implementation of the Transparency Regulation: https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en