Expert Group on GFL meeting on the Implementation of the Transparency Regulation

Revision of certain Implementing Acts – State of play

26 June 2020

DG SANTE

Revision of certain Implementing Acts

- By 27 March 2021: 7 implementing acts (IAs) have been identified for revision:
  - To remove outdated provisions
  - To ensure alignment with the Transparency Regulation new provisions

List of Implementing acts to be revised (1)

- Novel Foods:
  - Commission Implementing Regulation 2017/2468 concerning traditional foods from third countries (amend)
  - Commission Implementing Regulation 2017/2469 for applications referred to in Article 10 on novel foods (amend)
- Food additives:
  - Commission Regulation 234/2011 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (amend)
  - Commission Regulation 257/2010 for the re-evaluation of approved food additives (amend)

List of Implementing acts to be revised (2)

- Feed additives:
  - Commission Implementing Regulation 429/2008 on the assessment and the authorisation of feed additives (amend)
- PPP
  - Commission Implementing Regulation 844/2012 for the implementation of the renewal procedure for active substances (repeal/replacement)
- Addition of vitamins and minerals to foods (Regulation 1925/2006):
  - Draft amending Commission Implementing Regulation 307/2012 for the application of Article 8 on the addition of vitamins and minerals and of certain other substances to foods (amend)

COM IA revision – preliminary planning 2020

- June-July — Inter-Service Consultation (ISC)
- July-September — Presentation/Discussion with the Member States
- July-September — Feedback mechanism (consultation of 4 weeks): To be rolled up for each IA, after the ISC
- September-October — Vote in the appropriate PAFF Committee sections
- October-November — Adoption by the Commission

IT – E-submission system

- IT infrastructure to be ensured for new TR requirements on public disclosure of documents: “downloadable, printed and electronically searchable”
- **E-submission system** for the transparency/confidentiality provisions developed in close cooperation with EFSA:
  - **FSCAP** for all food sectors except PPP

    FSCAP in use for novel foods, demo video of current FSCAP version: https://ec.europa.eu/food/sites/food/files/safety/docs/gfl_expg_20200121_demo.mp4
  - **IUCLID** for Plant Protection Products (PPP) (active substances, basic substances)/ Maximum Residue Levels (MRL)
    - EFSA-ECHA Technical Group on IUCLID
  - Information system to store data, including confidential and personal data, to be fully auditable and comply with the highest standards of security appropriate to the security risks at stake (new Article 39f of the General Food Law)

Novel foods: Commission Implementing Regulation 2017/2468 concerning traditional foods from third countries and Commission Implementing Regulation 2017/2469 for applications referred to in Article 10 on novel foods (amend)

- Both acts concern the content, drafting and presentation of the notifications/applications, the arrangements for verifying the validity of notifications/applications and the type of information to be included in the EFSA opinion
- Key points considered for the adaptation of these 2 Regulations include:
  - Removal of any outdated provisions
  - References to the e-submission system (FSCAP)
  - Where necessary, references to the applicable provisions of Regulation (EC) No 178/2002 (General Food Law) as amended by the Transparency Regulation
  - Amendment to allow verifying that the requirement of notification of commissioned studies is complied with (new Article 32b of General Food Law)

Food additives: Commission Regulation 234/2011 establishing a common authorisation procedure for food additives, food enzymes and food flavourings (amend)

- This act concerns the content, drafting and presentation of the applications, the arrangements for verifying the validity of applications and the type of information to be included in the EFSA opinion
- Key points considered for the adaptation of this Regulation include:
  - Removal of any outdated provisions
  - References to the e-submission system (FSCAP)
  - Where necessary, references to the applicable provisions of Regulation (EC) No 178/2002 (General Food Law) as amended by the Transparency Regulation
  - Amendment to allow verifying that the requirement of notification of commissioned studies is complied with (new Article 32b of General Food Law)

Food additives: Commission Regulation 257/2010 for the re-evaluation of approved food additives (amend)

- This act concerns the re-evaluation programme for food additives permitted on the EU market before 20 January 2009. While the re-evaluation exercise is due to end in December 2020, it is likely that this will not be the case.
- Key points considered for the adaptation of this Regulation include:
  - Removal of any outdated provisions and alignment with those laid down in the Transparency Regulation (e.g. confidentiality provisions)
  - References to the e-submission system (FSCAP)

Feed additives: Commission Implementing Regulation 429/2008 on the assessment and the authorisation of feed additives

This act concerns the procedure for the authorisation of feed additives under Regulation (EC) No 1831/2003, including rules for the preparation and the presentation of the applications and for the assessment and the authorisation of such additives

Key points considered for the adaptation of the Implementing Regulation include:

- Removal of any outdated provisions (e.g. confidentiality)
- References to the e-submission system (FSCAP)
- Where necessary, references to the new provisions of Regulation (EC) No 178/2002 (General Food Law) especially as regards pre-submission phase and the specific case of renewals

Plant Protection Products: Commission Implementing Regulation 844/2012 for the implementation of the **renewal procedure for active substances** (repeal and replace)

- This act sets out the provisions necessary for the implementation of the renewal procedure, including, where relevant, the implementation of a work programme, as provided in Article 18 of Regulation 1107/2009 (PPP Regulation)
- Key points considered for the adaptation of this Regulation include:
  - Removal of any outdated provisions
  - Alignment with those laid down in the Transparency Regulation taking into account the role of rapporteur(s) Member State(s) especially regarding pre-submission phase:
    - general pre-submission advice
    - renewal pre-submission advice following notification of intended studies for renewals and public consultation
    - notification of commissioned studies
  - References to the e-submission system (IUCLID)

Addition of vitamins and minerals and of certain other substances to foods: Commission Implementing Regulation 307/2012 for the application of Article 8 of Regulation 1925/2006

- This act sets out the provisions necessary for the implementation of the procedure of Article 8 of Regulation 1925/2006 as regards the prohibition, restriction or placing under Union scrutiny a substance other than a vitamins or minerals or an ingredient containing such a substance that is added to foods/used in the manufacture of foods
- Key points considered for the adaptation of this Regulation include:
  - Removal of any outdated provisions and alignment with those laid down in the Transparency Regulation (e.g. confidentiality provisions)
  - References to the e-submission system (FSCAP)

Thank you

European Commission