



European
Commission

Implementation of the 'Transparency Regulation' by the Commission

**EFSA SOUNDING BOARD
23 MARCH 2020, BRUSSELS**

DG SANTE

'Transparency' Regulation

- Publication: **6 September 2019**
- Entry into application: 27 March 2021
 - **Exception:** *New EFSA MB and appointment of experts in panels: **as of 1 July 2022***
- **Transitional measures:** *The new rules **will not** apply to requests for scientific output submitted to EFSA **before its entry into application***

What is next by COM ? (1)

- Align 9 existing COM implementing acts in sectoral legislation to the new rules, **by 27 March 2021**:
 - i. Commission Implementing Regulation (EU) No 307/2012 on the implementation of Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods [PAFF GFL]
 - ii. Commission Regulation (EC) No 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006 [PAFF – Novel food and Toxicological safety]
 - iii. Commission Regulation (EC) No 450/2009 on active and intelligent materials and articles intended to come into contact with food [PAFF – Novel food and Toxicological safety]
 - iv. Commission Regulation (EU) No 234/2011 implementing Regulation (EC) No 1331/2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings [PAFF – Novel food and Toxicological safety]
 - v. Commission Regulation (EU) No 257/2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 on food additives [PAFF – Novel food and Toxicological safety]

- vi. Commission Implementing Regulation (EU) 2017/2469 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 on novel foods [PAFF – Novel food and Toxicological safety]
- vii. Commission Implementing Regulation (EU) 2017/2468 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 [PAFF – Novel food and Toxicological safety]
- viii. Commission Implementing Regulation (EU) No 844/2012 of setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market [PAFF – Phytopharmaceuticals]
- ix. Commission Implementing Regulation (EU) amending Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives [PAFF – Animal nutrition]

What is next by COM ? (2)

- Align existing COM guidance in sectoral legislation to the new rules – this alignment needs to be coordinated with the alignment of EFSA guidances: **By 27 March 2021**
- To ensure IT infrastructure to accommodate new requirements in close cooperation with EFSA/MS (e-submission system for the transparency/confidentiality provisions): **By 27 March 2021**
- To carry out the fact-finding missions to laboratories for checking compliance with applicable standards when carrying out studies supporting EFSA's risk assessment (**2021-2025**)– findings to be presented in an overview report

What is next by COM ? (3)

- To adopt the general plan on risk communication (IA) – not subject to a deadline
- To adopt standard data formats for applications (IA) – not subject to a deadline
- Contribute to ensure a smooth transition to the new EFSA governance model (MB) – New EFSA MB will consist of representatives of 27 MS, COM, EP and representatives of civil society and food chain interests – **to take office as of 1 July 2022**



Further information:

https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en

Email: SANTE-SCIENCE-TRANSPARENCY@ec.europa.eu

Thank you for your attention!