

Implementation of the 'Transparency Regulation'

EXPERT GROUP ON GENERAL FOOD LAW 21 JANUARY 2020, BRUSSELS

DG SANTE, Food chain science and stakeholder relations





'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? (1)

- Considerable budget increase proposed in the MFF proposal:
 - EUR 62.5 million; and,
 - 106 additional posts
- Budget negotiations still ongoing!





What is next? (2)

By COM:

- To ensure IT infrastructure to accommodate new requirements in close cooperation with EFSA/MS
- Align existing COM guidance/implementing acts in sectoral legislation to the new rules – this alignment needs to be coordinated with the alignment of EFSA guidances: By end of March 2021
- To adopt the general plan on risk communication (IA) not subject to a deadline
- To adopt standard data formats for applications (IA)
- To carry out the fact-finding missions (within 4 years following entry into application) – findings to be presented in an overview report
- Contribute to ensure a smooth transition to the new EFSA governance model (MB)

Food Safety



What is next? (3)

By EFSA:

- To ensure IT infrastructure to accommodate new requirements in close cooperation with SANTE/MS
- Draw up draft standard data formats for further adoption by the Commission (IA)
- Develop new and/or align existing guidance in conformity to the new transparency rules (esp. in sectoral legislation)
- Prepare a smooth transition to the new EFSA governance model (MB) and selection process for experts in Panels





IT infrastructure – implementation elements (1)

- New Articles 38, 39-39g of the GFL (transparency/confidentiality):
 - Proactive public disclosure of all scientific studies in a readable and searchable e-format
 - Processing of confidentiality requests mainly by EFSA
 - Information systems fully auditable and at the highest standards of security





IT infrastructure – implementation elements (2)

- New Article 32b of the GFL notification of commissioned studies)
- New Article 32c of the GFL public consultations of studies
 - In the case of renewals, notification of intended studies, public consultation and provision of tailor-made advice (Article 32c(1) of the GFL)
 - Public consultation of all submitted studies (Article 32c(2) of the GFL)



Thank you for your attention!