Chemical Watch

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The impact of the recent Commission's "*Proposal on the transparency and sustainability of the EU risk assessment model in the food chain*" on FCM Regulation and the functioning of EFSA

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Overview

- Context of the Proposal
- Next Steps – Adoption process
- Proposed EFSA Structure
- Study Controls and Verification studies
- Transparency and Register of Studies
- Rules on Confidentiality
- Impact on FCM Regulation

Context of the Proposal

- **Fitness check of the General Food Law** (GFL) – 15 January 2018
  Identified Shortcomings
  - Transparency of risk analysis remains an important issue in terms of perception
    - Assessment based on industry studies + strict confidentiality rules

    → Lack of transparency and perceived lack of independence of EFSA's scientific work
    - Ineffective risk communication
  - Capacity of EFSA to maintain a high level of scientific expertise
- **European Citizens' Initiative** "*Ban glyphosate and protect people and the environment from toxic pesticides*"
  - Commission Communication on legislative proposal covering
    - Transparency in scientific assessment
    - Quality and independence of scientific studies
    - Governance of EFSA
- **Public consultation**: 23 January - 20 March 2018 – 471 replies
  - Proposal: only 56 days after public consultation
  - No Impact Assessment – Justification by Commission: "*not expected to have significant socio-economic and environmental impact*"

Scope of the Proposal

- In addition to the GFL, eight of the existing EU sectoral legislation covering the food chain will be impacted

  - Regulation 178/2002; General Food Law (GFL)
  - Directive 2001/18/EC; on the deliberate release into the environment of genetically modified organisms (GMOs)
  - Regulation 1829/2003; on GM food and feed,
  - Regulation 1831/2003; on feed additives,
  - Regulation 2065/2003; on smoke flavourings,
  - Regulation 1935/2004; on food contact materials,
  - Regulation 1331/2008; on food additives, food enzymes and food flavourings,
  - Regulation 1107/2009; on plant protection products, and
  - Regulation 2015/2283; on novel foods.

Adoption procedure – Next Steps

- Same as for the adoption of the GFL and amended legislation - Co-decision procedure
  - Normally: lengthy; 2-3 years needed for negotiation between Parliament and Council
  - Proposal: potentially short as adoption process needs to completed before the current European Parliament's term of office expires in May 2019
    - Political support by the Council: push from Germany and France
    - Topic potentially highly debated by the Parliament

- If adopted, it will apply after transitory measures
  - Transitory measures: 18 months after entry into force
  - Regulation → entirely and directly applicable in all Member States

Proposed Changes

EFSA Structure

- Transformation of the **Management Board**
  - Today: 14 Member State nominees
  - Proposal: 34 sitting members from a wider range of backgrounds:
    - 27 members nominated by Member States (plus alternatives when necessary);
    - 2 members from the Commission (plus alternatives when necessary);
    - 1 from the European Parliament; and
    - 4 representing civil society and food chain interests (1 from consumers organisations, 1 from environmental NGOs, 1 from farmers organisations and one from industry organisations).

- Transformation of the **Scientific Panels**
  - Today: composed of independent scientific experts with varying numbers
    - CEF Panel 21 members
  - Proposal: Each Member State would nominate at least 12 scientific experts and each panel would be allowed to have up to 21 members
    - More risk assessors?

Study controls and Verification studies

- Introduction of Article 32d and 32e of the GFL
  - Today: no such controls and verifications
  - Proposed rule:
    1) Article 32d: Controls by European Commission experts of testing facilities
    2) Article 32e:

    "*… the Commission, in exceptional circumstances, may request the Authority to commission scientific studies with the objective of verifying evidence used in its risk assessment process. The studies commissioned may have a wider scope than the evidence subject to verification.*"

Rules on Transparency

- Amendment to Article 38 of the GFL – Transparency
  - Today: make public agendas, minutes; opinions; information on which opinions are based; results of scientific studies; annual reports (Article 38(1)(a)-(g) GFL)
  - Amendment:

    1) Addition to Article 38(c)

    "***scientific data***, *studies and other information supporting applications for authorisation under Union food law, including supplementary information supplied by applicants, as well as other scientific data and information supporting requests from the European Parliament, the Commission and the Member States for a scientific output, including a scientific opinion, taking into account protection of confidential information and protection of personal data in accordance with Articles 39 to 39f*". (emphasis added)

    2) Addition of Article 39(b)

    Disclosure to the public is without prejudice:

    (a) to any intellectual property right; and,

    (b) data exclusivity rules.

    Disclosure should not be considered as an explicit or implicit permission or license
- Disclosure of all and full studies?
- Implications for expert judgment of EFSA?

Union Register of Studies / Consultation

- Inclusion of Article 32b into the GFL – Union Register of Studies
  - Today: No register of studies
  - Inclusion:

    "*Business operators shall notify, without delay, to the Authority the subject matter of any study commissioned to support a future application for an authorisation under Union food law. The register shall be managed by the Authority.*"

    The notification obligation also applies to Union laboratories carrying out those studies.

  - Publication of notified information if and after application of authorisation has been received by EFSA
    - Which studies? All the studies performed on the substance?
    - Study undertaken for which purpose? Only for the authorization in specific area?
    - Compliance with above rules – EFSA rules to be developed
- Inclusion of Article 32c(2) into the GFL – Consultation of third parties
  - Today: No consultation of third parties
  - Inclusion: public consultation to identify whether other relevant scientific data or studies are available on the subject matter

Rules on Confidentiality - GFL

- Replacement to Article 39 of the GFL - Confidentiality
  - Today: protection of confidential information if requested by applicant and justified
    - Exception: conclusions relating to "*foreseeable health effects*"
  - Proposed rule: Article 39 – Exception from Article 38
    1) List of information for which confidential treatment could be claimed, "*disclosure of which may be deemed, upon verifiable justification, to significantly harm the interests concerned*"
       - Method and other technical and industrial specification used for manufacture and production
       - Commercial links between producer/importer and applicant
       - Commercial information about market
       - Quantitative composition
  - **Unclear** from where the "*significantly harm*" threshold comes from
    - The requirement in Regulation 1049/2001 on access to documents requirement: disclosure would undermine the protection of commercial interests (Article 4(2))
    - Other EU chemical legislation, for example, the REACH Regulation: similar to Regulation 1049/2001: disclosure deems to undermine the commercial interests (Article 118(2))
  - **Unclear** how "*verifiable justification*" will have to be construed

Procedural Rules on Confidentiality - GFL

- Replacement to Article 39 of the GFL - Confidentiality
  - Today in GFL: protection of confidential information if requested and justified
  - Today in FCM: EFSA Administrative Guidance (for plastic FCM): Appendix C (Justification for confidential information)

  - Proposed rule: Article 39a – 39g
    - Submission to EFSA along with an application for authorisation.
    - EFSA informs the applicant of its intention to disclose information and the reasons for it, giving opportunity for disagreeing or for withdrawing its application within two weeks.
    - Final decision on the confidentiality request, within ten weeks from the date of receipt of the request - potentially be challengeable before the Court of Justice of the European Union.
    - Non-confidential information is made public.

→ Clear rules on procedure are welcomed!!!

→ The real commercial impact of disclosure of information is likely to be felt outside the EU, where national data protection and confidentiality regimes (in so far as they exist) are not bound by EU law.

Rules on Confidentiality – FCM Regulation

- Amendment of Article 9 of Regulation 1935/2004 (FR)
  - Today: Application and supplementary information is made available to MS and Commission only (Article 9(c) of the Framework Regulation)
  - Amendment: Article 9: introduction of c(ii)
    - public access to the application, relevant supporting information and any supplementary information supplied by the applicant
- Replacement of Article 20 of Regulation 1935/2004
  - Today: The applicant may indicate which information is to be treated as confidential on the ground that its disclosure "*might significantly harm its competitive position*". Verifiable justification must be provided. (Article 20(1) of FR)
  - Replacement: 20: Addition to list of information included in Article 39 of GFL

    - detailed descriptions of starting substances and preparations,
    - the composition of preparations,
    - materials or articles in which the applicant intends to use this substance,
    - the manufacturing methods of these preparations, materials or articles,
    - impurities,
    - migration testing results AND
    - *"any other information deemed confidential"*

Impact on FCM Regulation

- **No significant "game-changing" proposals for FCMs**
  - Threshold for confidentiality claims very similar to current ones: "significant harm" + "verifiable justification"
  - List of information to be treated as confidential on the ground that its disclosure "*might significantly harm its competitive position*" as compared to no list
  - Publication of scientific data and all supporting information
  - Other Transparency requirements: no real impact as listing of a substance on the Union List is not proprietary

- **Changes to be monitored**
  - Existence of Register of Studies and its potential correlation with REACH registration dossiers
  - Pre-submission meetings
  - New members in the EFSA Scientific Panels

Questions?

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