EU General Food Law - possible impact on the food industry
Agenda

1. What is General Food Law (GFL)?
2. How it all began
3. What will change
What is General Food Law (GFL)?
Background

General Food Law Regulation (EU) No. 178/2002 as amended

Established the principle of risk analysis with three components:
1. Risk assessment
2. Risk management
3. Risk communication

Established the European Food Safety Authority (EFSA), an independent body entrusted with risk assessment
Key obligations of Food Business Operators (FBO)

- Food Business Operations (FBO)
- Safety
- Responsibility
- Traceability
- Transparency
- Emergency
- Prevention
- Cooperation
How it all began
European Citizen’s Initiative “Ban glyphosate”

“Ban glyphosate and protect people and the environment from toxic pesticides”

- Concerns raised:
  - Transparency of the EU risk assessment
  - Quality and independence of scientific studies

- Commission’s commitment (Dec 2017) to introduce a legislative proposal in spring 2018

**Timeline**

- Registered: 25/01/2017
- Submitted: 06/10/2017
- Answered: 12/12/2017
Fitness check of the General Food Regulation

The system was found to work well

• No systematic failures
• EFSA improved the scientific basis of EU measures

Opportunities for improvements

• Civil society perceived a certain lack of transparency and independence
• Risk communication was not always effective enough
Importance of public access to EFSA’s sources to ensure trust in the EU food safety risk assessment

### Response options
- Not at all important
- Not very important
- Important
- Very important
- No opinion/don't know

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<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>EFSA's scientific opinions and reports</td>
<td>98%</td>
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<td>EFSA's mandates for opinions</td>
<td>91%</td>
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<td>Annual Declarations of Interest of scientific experts in EFSA's Scientific Committee/Scientific Panels/Working Groups</td>
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<td>Annual Declarations of Interest of members of EFSA's Management Board and EFSA's Management Team</td>
<td>90%</td>
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<td>EFSA's agendas and minutes of meetings</td>
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<td>Public access to industry studies used in risk assessment with the exception of the business secrets and other confidential information…</td>
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<tr>
<td>Annual Declarations of interest of members of EFSA's Advisory Forum</td>
<td>88%</td>
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<td>Meetings of EFSA's Scientific Committee and Panels open to the public</td>
<td>82%</td>
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<td>Public meetings of EFSA's Management Board</td>
<td>80%</td>
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Impact on objectives of publication of industry studies (including raw/aggregated data) used in EU risk assessment, with the exception of business secrets or other confidential information (in particular information about undertakings, their business relations or their cost components)

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Response options

Enhancing transparency in the EU risk assessment system
- Very negative: 92%
- Negative: 6%
- No impact: 0%
- Positive: 2%
- Very positive: 0%
- No opinion/Don't know: 0%

Allowing scrutiny by other scientific and third parties
- Very negative: 80%
- Negative: 10%
- No impact: 3%
- Positive: 3%
- Very positive: 2%
- No opinion/Don't know: 0%

Enhancing the exchange of information on risks amongst interested parties and stakeholders (e.g. EFSA, national agencies, Member States, EU Institutions, consumers, food and feed businesses, NGOs, academics, etc.)
- Very negative: 76%
- Negative: 16%
- No impact: 2%
- Positive: 18%
- Very positive: 2%
- No opinion/Don't know: 0%

Strengthening consumer trust in the EU risk assessment system
- Very negative: 74%
- Negative: 18%
- No impact: 2%
- Positive: 16%
- Very positive: 2%
- No opinion/Don't know: 0%

Promoting innovation
- Very negative: 31%
- Negative: 17%
- No impact: 37%
- Positive: 10%
- Very positive: 2%
- No opinion/Don't know: 0%

Increasing competitiveness of the industry
- Very negative: 22%
- Negative: 23%
- No impact: 34%
- Positive: 10%
- Very positive: 2%
- No opinion/Don't know: 0%

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Four pillars

- Transparency of EU risk assessment
- Independence of studies
- Risk communication
- The governance and the scientific cooperation
More transparency

Better access to scientific studies

- Scientific studies will be made public proactively and automatically
- Confidential information will be respected
- Interested parties will have easy access to the studies
- Standard data formats for applications will be developed
Independence of studies

EFSA will have more access to relevant scientific evidence in request for authorization

- A register of all studies commissioned by the industry
- Consultation of stakeholders and the public
- For renewals, additional consultation on planned studies
- Controls, including audits, will be carried out on the compliance of lab/studies with standards
- Commission to ask EFSA to carry out own studies for verification purposes
Better governance of EFSA

The governance and the scientific cooperation

- Board will include MS representative
- Strict independence criteria will be maintained
- Panels will be made from nominations by MS
- Panels work will be better organized
Risk communication (RC)

Improve coordination between risk assessors and risk managers to ensure a better communication to stakeholders and the general public.
Other elements

Transitional measures

The new rules will not apply to applications under Union law and requests for scientific output submitted to EFSA before it enters into application March 2021

The new management board (MB) will take over as of 1 July 2022

Review clause

• Regular review of GFL Regulation
• Every 5 years there is a Commission review of EFSA’s performance
What will change
What’s next?

Publication in Official Journals on 6 Sept 2019

Entry into force 20 days after publication

Entry into application 18 months later (27 March 2021)
Preparatory work must be carried out both by EFSA and by the Commission

By EFSA

1. Setting up practical arrangements/infrastructure for pre-submission advice, public consultations of planned and submitted studies
2. Drawing up draft standard data formats for further adoption by the Commission (IA)
3. Developing new and/or align existing guidance in conformity to the new transparency rules (IA)
4. Preparing a smooth transition to the new EFSA governance model (MB) and selection process for experts in Panels
What’s next?

Preparatory work must be carried out both by EFSA and by the Commission

By the Commission

- Aligning existing guidance/IA in sectoral legislation to the new rules
- Adopting the general plan on risk communication
- Adopting standard data formats for applications (IA)
- Adopting standard data formats for applications (IA)
Summary

1 New General Food Law Regulation (EU) 2019/1381 was published 6 Sept 2019 and will be adopted in 18 month time

2 Main changes expected are:
   • Greater transparency in risk analysis
   • Improving the quality and reliability of scientific studies
   • Greater engagement of citizens in decision-making process, facilitated by digital innovation
   • Strengthens risk communication between the Commission, EFSA, the Member States, stakeholders and the general public
Thanks for listening!

Luke Murphy- Head of Regulatory (Commercial)

Luke.Murphy@LeatherheadFood.com
Questions