

Agenda

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



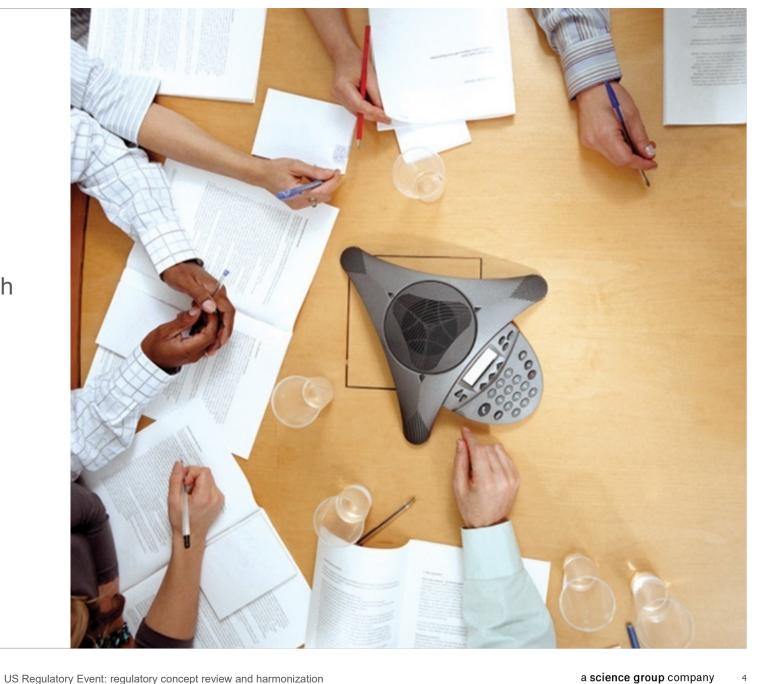
Background

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

Established the principle of risk analysis with three components:

- 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

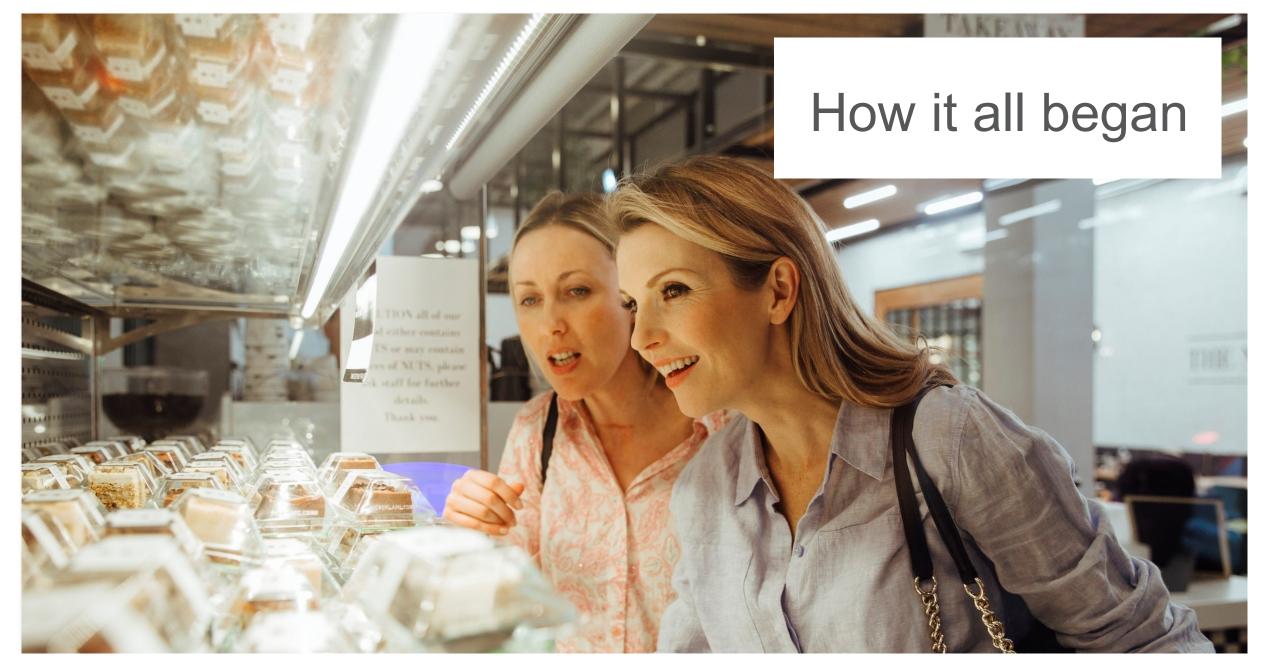
Traceability

Transparency

Emergency

Prevention

Cooperation



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

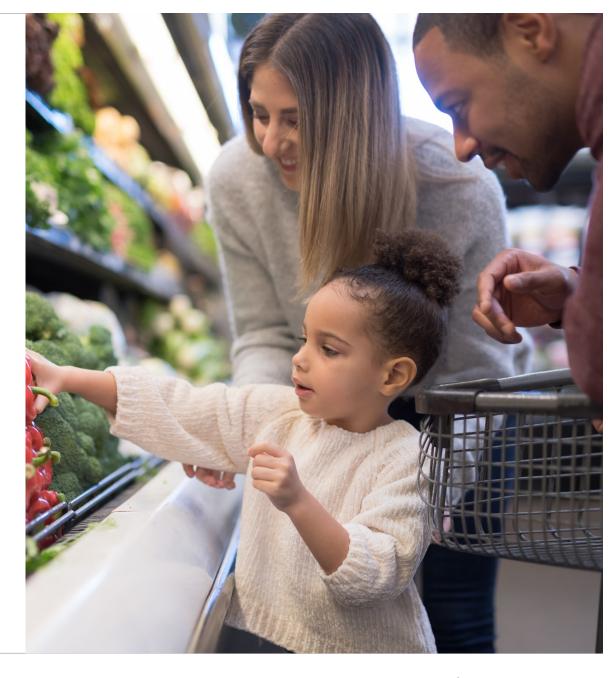




Submitted 06/10/2017



Answered 12/12/2017



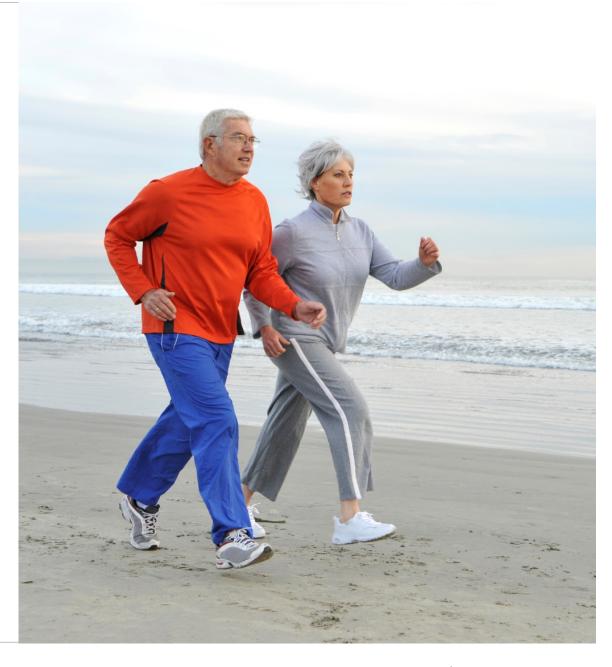
Fitness check of the General Food Regulation

The system was found to work well

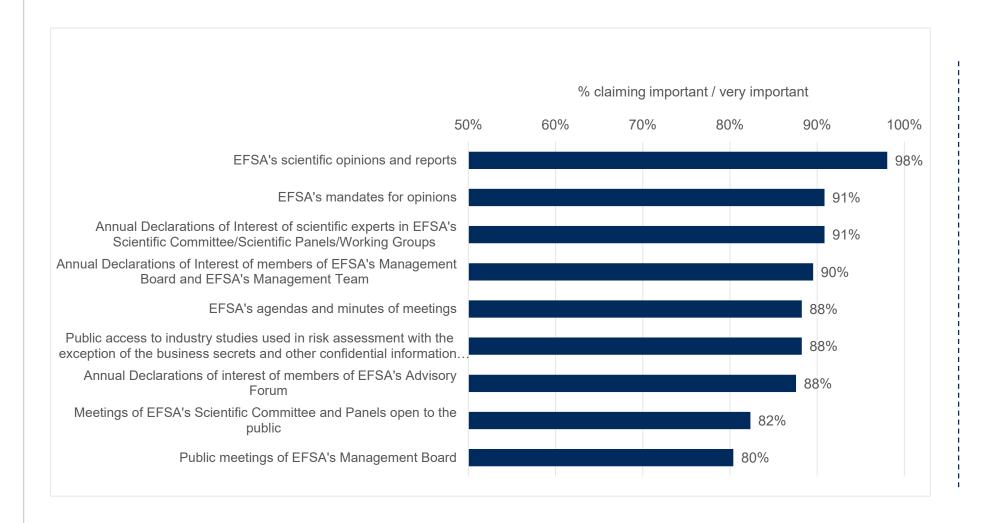
- No systematic failures
- EFSA improved the scientific basis of EU measures

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

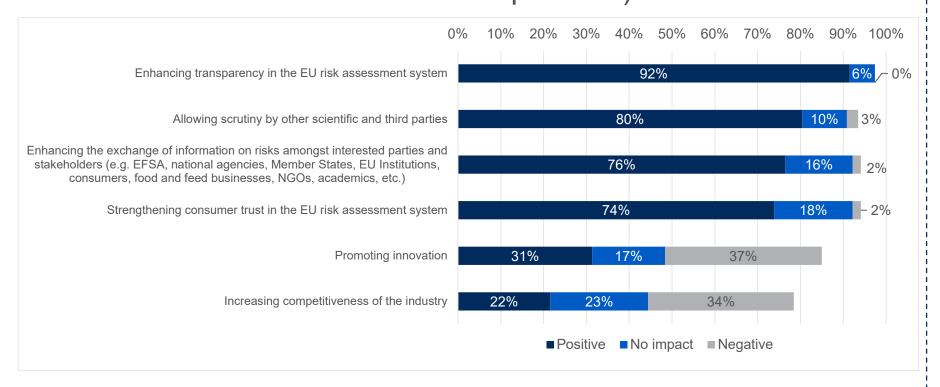


Response options
Not at all important
Not very important
Important
Very important
Very important
No opinion/don't
know

N = 153

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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)



Response options

Very negative
Negative
No impact
Positive
Very positive
No opinion/Don't
know

N = 153

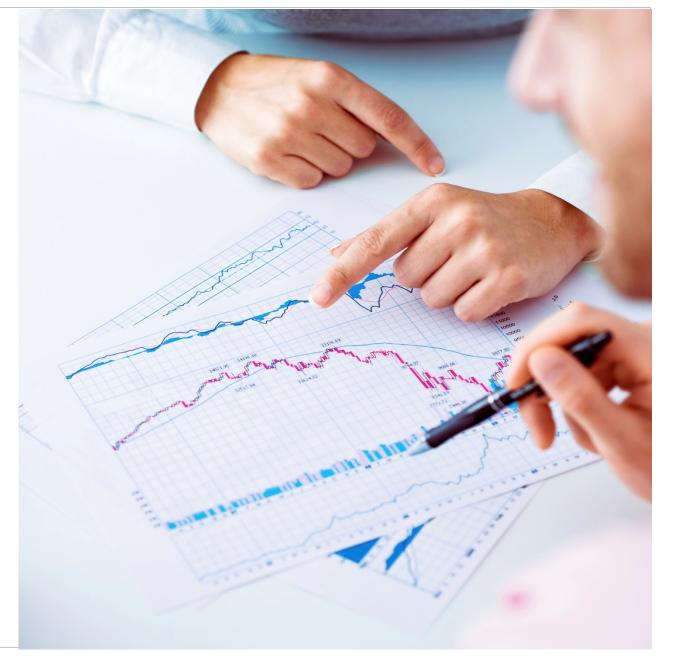
Four pillars

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



US Regulatory Event: regulatory concept review and harmonization

Risk communication (RC)

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

Key factors to be taken into account

Appropriate mechanism for open dialogue amongst interested parties

Types and levels of RC and the appropriate tools and channels

Appropriate mechanisms of coordination & cooperation amongst risk assessors & managers

Other elements

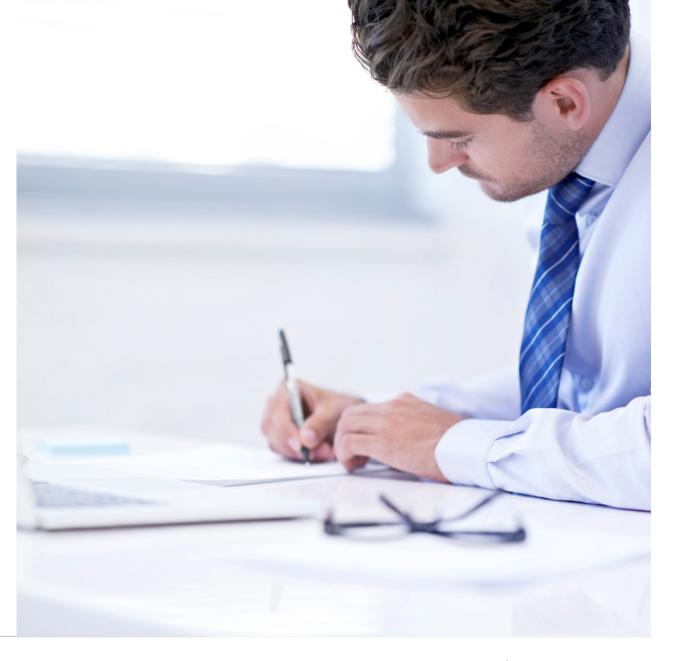
Transitional measures

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'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)

What's next?

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

By EFSA

Setting up practical arrangements/ infrastructure for presubmission advice, public consultations of planned and submitted studies

Drawing up draft standard data formats for further adoption by the Commission (IA) Developing new and/or align existing guidance in conformity to the new transparency rules (IA)

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 standard data formats for applications (IA)

Adopting the general plan on risk communication

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

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Thanks for listening!

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Questions

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