Revision of EU General Food Law: potential effects on Innovation, Transparency and Risk Assessment (food and plant protection)

Agenda

1 What is the EU Transparency Regulation?

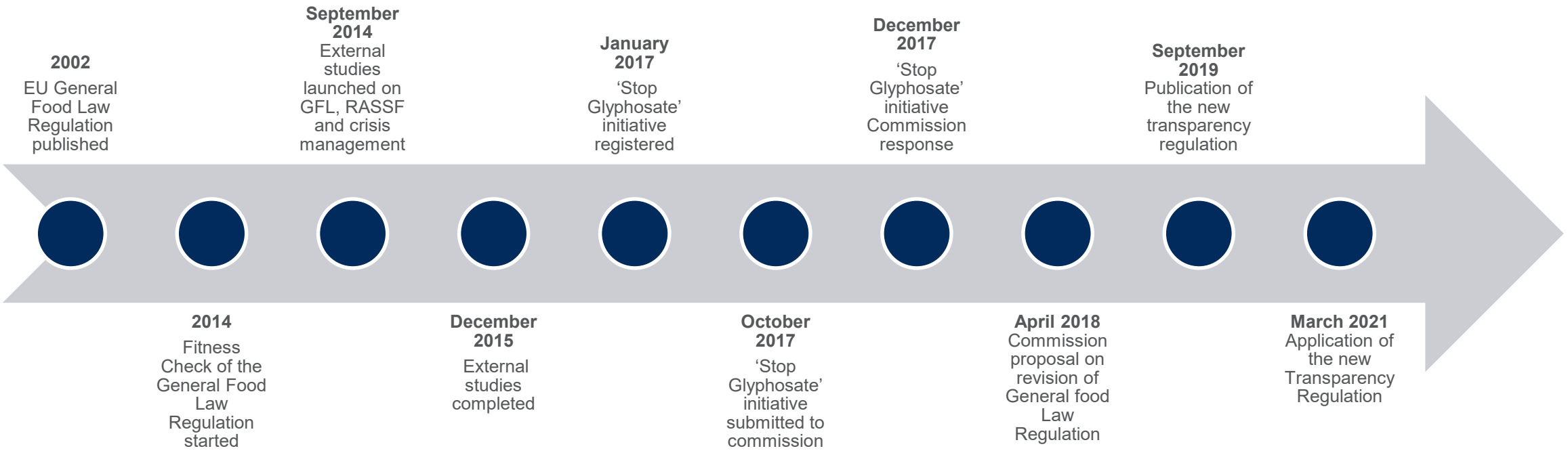
2 Changes to General Food Law and other frameworks

3 Dealing with Confidential Information

4 Challenges and Opportunities for Industry

What is the EU Transparency Regulation?

General Food Law Evolution Timeline



Background

The new Regulation is a direct response to the European Citizens initiative “Stop Glyphosate” and builds on the findings of “Fitness check of the General Food Law Regulation”.

- No systematic failures
- EFSA improved the scientific basis of EU measures
- Civil society perceived a certain lack of transparency and independence
- Risk communication was not always effective enough

Background

Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain was published on 6 September 2019 and applies on 27 March 2021

The main aims of the Regulation are:

- Increasing the transparency of EU risk assessments
- Closer ties between member states and EFSA
- Improving communication to stakeholders and the public

Changes to General Food Law and other frameworks

Amendments

Regulation (EU) 2019/1381 amends several EU Regulatory Frameworks.

Stakeholders working with any of these, particularly in the approval space, will be affected by the changes.

- (EC) 178/2002 – General Food Law
- (EC) 1829/2003 – GM Food and Feed
- (EC) 1831/2003 – Feed Additives
- (EC) 2065/2003 – Smoke Flavourings
- (EC) 1935/2004 – Food Contact Materials
- (EC)1331/2008 – Food Improvement Agents
- (EC) 1107/2009 – Plant Protection
- (EU) 2015/2283 – Novel Foods

Transparency

- Citizens will have automatic access to all studies and information submitted by industry when an application is validated
- Citizens and Stakeholders will be consulted on submitted studies for new applications and renewals

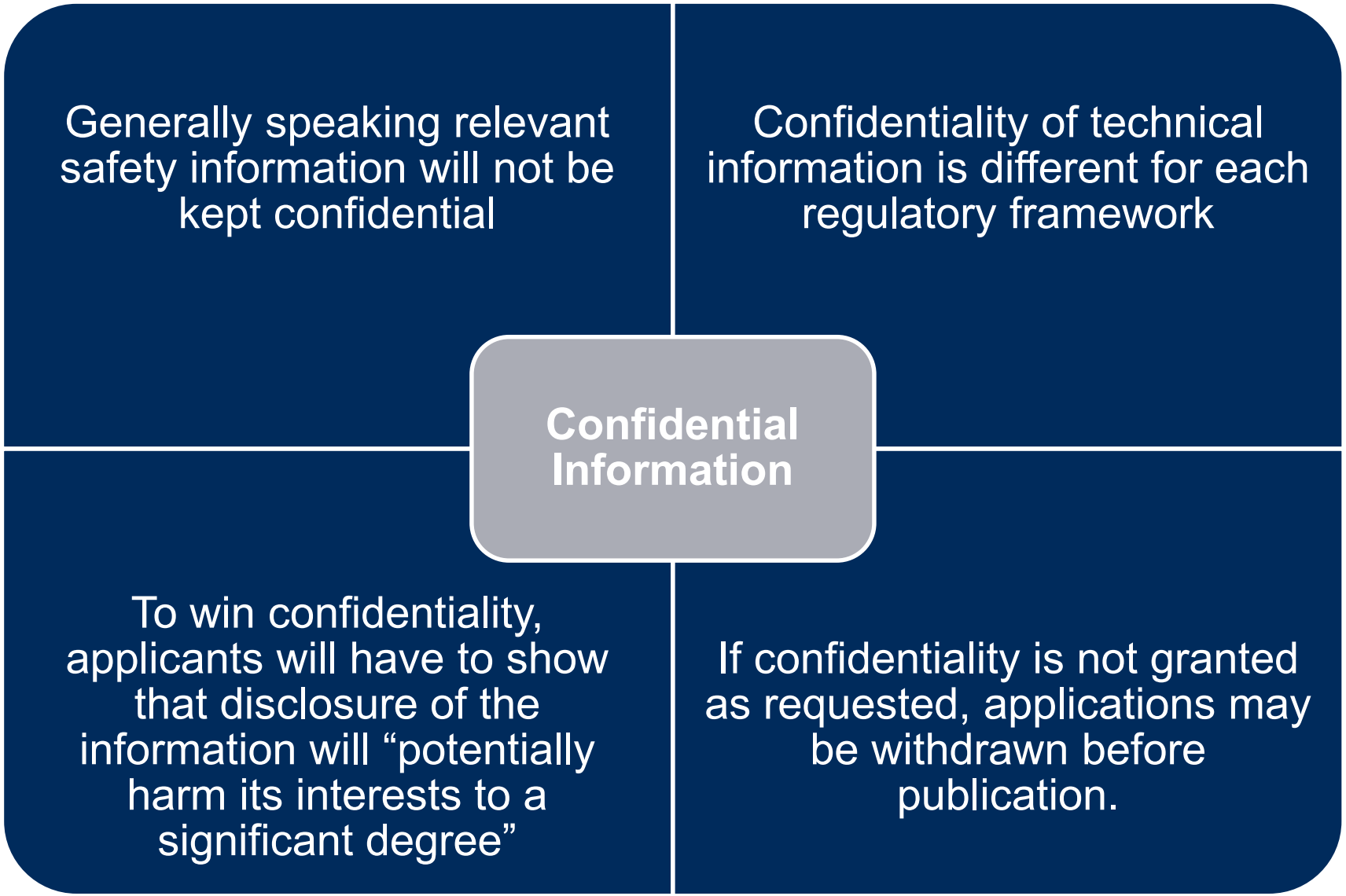
Confidential Information

- IP and data will be protected in accordance with existing legislation
- Applicants may apply to retain certain confidential information
- The confidential information must meet certain criteria
- Ultimately EFSA decides what is confidential and what is not

Independence of Studies

- EFSA will be notified when scientific studies are commissioned
- A new database of studies will be created
- Pre-submission advice is now available
- EFSA can commission its own studies in exceptional circumstances
- Fact finding missions by the commission to enforce standards

Dealing with Confidential Information



Confidentiality and Trade Secrets

Applicants may request to keep the following information confidential

- The manufacturing or production process, including the method and innovative aspects thereof….except relevant safety information
- Commercial links between a producer or importer and the applicant or authorisation holder
- Commercial Information revealing sourcing, market shares or business strategy
- Quantitative composition of the subject matter …except relevant safety information

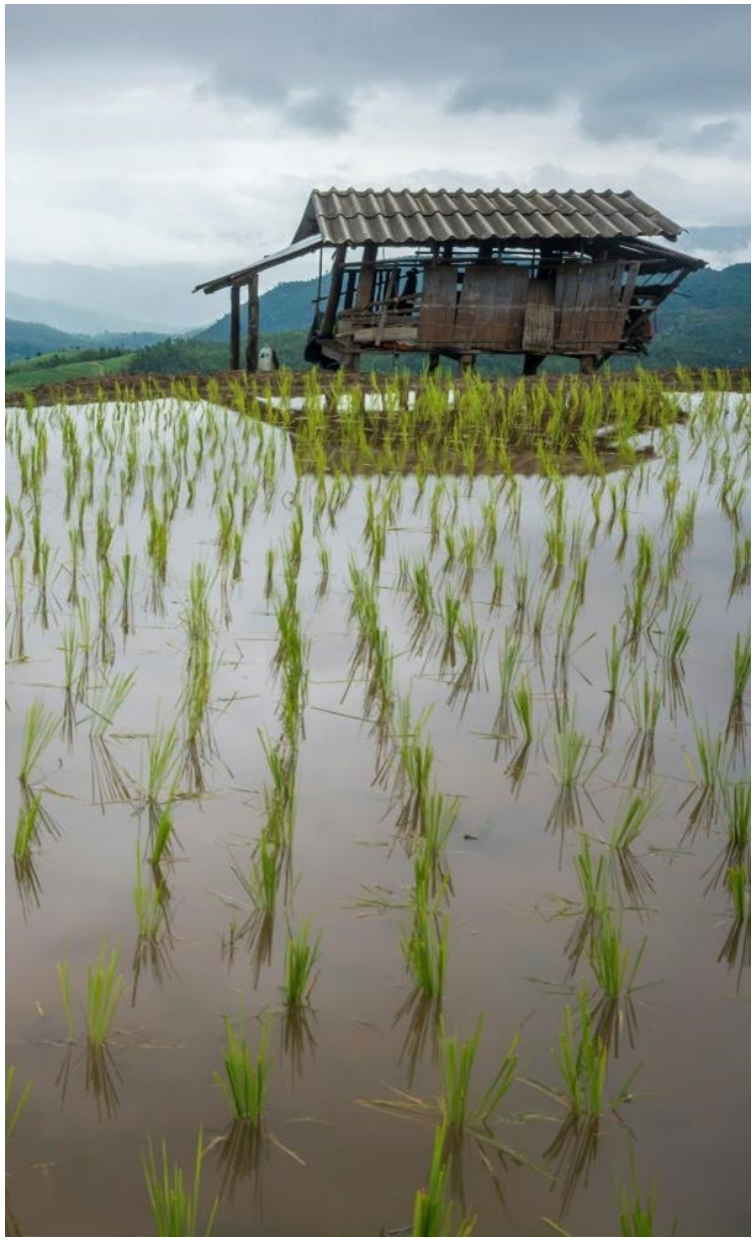
Confidentiality and Trade Secrets

Applicants may request to keep the following information confidential

Under GMO Framework: DNA sequence information (except those used for detection, identification etc) ,breeding patterns & strategies.

Under Feed additive Framework: Study plans for those studies demonstrating efficacy of a feed additive.

Under Feed additive Framework: specifications of the impurities of the active substance and the relevant methods of analysis developed internally by the applicant, except for impurities that may have adverse effects on animal health, human health, or the environment.



Confidentiality and Trade Secrets

Applicants may request to keep the following information confidential

Food Contact Materials Framework: information provided in detailed descriptions of starting substances and mixtures used to manufacture the substance subject to the authorisation, the composition of mixtures, materials or articles in which the applicant intends to use that substance, the manufacturing methods of those mixtures, materials or articles, impurities, and migration testing results, except when relevant to safety.

Food Contact Materials Framework: the trademark under which the substance shall be marketed as well as the tradename of the mixtures, material or articles in which it shall be used.

Confidentiality and Trade Secrets

Applicants may request to keep the following information confidential

Food Improvement Agents: detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information relevant to the assessment of safety.

Food Improvement Agents: Information provided in detailed descriptions of starting substances and starting preparations and on how they are used to manufacture the substance subject to the authorisation, and detailed information on the nature and composition of the materials or products in which the applicant intends to use the substance subject to the authorisation, except for information relevant to the assessment of safety.

Confidentiality and Trade Secrets

Applicants may request to keep the following information confidential

Novel Foods: detailed analytical information on the variability and stability of individual production batches, except for information relevant to the assessment of safety.

Novel Foods: Information provided in detailed descriptions of starting substances and starting preparations
and on how they are used to manufacture the novel food subject to the authorisation, and detailed information on the nature and composition of the specific foods or food categories in which the applicant intends to use the novel food, except for information relevant to the assessment of safety.

Challenges and Opportunities for Industry

Innovation Challenges

If scientific studies will be made public at their onset ‘without delay’ this could give advantages to stakeholders and competitors outside the EU.

Will the risks of disclosing confidential business information as part of an application mean companies are more reluctant to seek approval in the EU?

How does a notifier demonstrate the disclosure of confidential information will potentially harm its interests to a “significant degree” when this is untested in the courts?

Opportunities?

1. Pre-application advice from EFSA in theory will help streamline approval process

2. Increased consumer trust in the process

Thanks for listening!

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Questions