Steptoe

# EU's New Transparency Regime

May 26, 2021

# Topics

1. General architecture of the new transparency scheme and implementing rules

2. Pesticides and the transparency regulation: focus on active substance renewals

3. Transparency and crop protection solutions: an industry perspective

4. Transparency and specialty food ingredients: industry perspective and preparations

5. Legal rights and remedies

# Today's Speakers

Federica Bruno DG SANTE
Legal Officer, Pesticides & Biocides Unit,
European Commission

Alessio Ghiani,
IP & Legal Affairs Manager,
CropLife Europe

Maryse Hervé,
Secretary General,
EU Specialty Food Ingredients

# Darren Abrahams

***dabrahams@steptoe.com***

*"exceptional expertise on EU regulations on chemicals…and a great ability to understand the complexity of businesses."*
*"When it comes to things like REACH and chemical law, he is the best"*
***Chambers & Partners Europe, 2019 and 2020***

- **English barrister, *Avocat* at the Brussels Bar**, partner resident in Brussels.
- Darren enables clients throughout the chemicals and life sciences supply chain to **get and keep their products on the EU market**.
- He focuses on **defence of products** through strategic advice, **advocacy** before institutions and agencies, and **litigation** before EU and national courts and tribunals.
- He has a **wealth of experience with EU regulation** of biocidal products, plant protection products (agrochemicals), REACH, CLP, GM food and feed, cosmetics, and endocrine disruptors.
- Chambers & Partners **Europe-wide** Regulatory (2020): **Agro/Food and Environment** Legal Rankings: **top tier practitioner in both, and Steptoe listed as a band 1 firm.**

# Hannah Widemann

*hwidemann@steptoe.com*

- **Belgian-qualified associate**, ***Advocaat*** **at the Brussels Bar.**
- She advises clients on **EU regulatory compliance** questions in the areas of **chemical** and **product regulations**, including **REACH**, **CLP**, **biocides**, **plant protection products**, and **fertilizers**.
- Her work includes **product defense** and **litigation strategies** before the European Court of Justice and the Board of Appeal of the European Chemicals Agency (ECHA), as well as supporting clients with (data sharing**) negotiations**, **contracts**, and **potential disputes**.

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# General Architecture & Implementation - Topics

- How did we get here?
- Targeted sectors
- Wide Scope of disclosure
- Confidentiality Claims (burden of proof and standard)
- Notification of Studies

# How did we get here?

1. **A Commission response to the 2017 European Citizens' Initiative** "*Ban glyphosate and protect people and the environment from toxic pesticides*".

2. **Need for harmonization:** Complaint that transparency varies depending upon the different sectoral rules.

3. **Risk Assessment:** Commission conclusion that "*transparency and accountability of the studies EFSA uses to assess risks could not be achieved without opening up those studies and the data they use to the public*".

4. **Risk Communication** not considered effective enough.

# How did we get here?

**Fast-Track Adoption & Application:**

- April 2018 Commission Proposal on the transparency and sustainability of the EU risk assessment in the food chain".
- June 2019 Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain ("The Transparency Regulation").
- **Applicable from 27 March 2021**

**January 2021 EFSA:**

- Practical arrangements on pre-submission phase and public consultations
- Practical arrangements concerning transparency and confidentiality
- Practical arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009

**March 2021:**

- Q&A on the EFSA Practical Arrangements

# Targets: EU sectoral legislation in eight areas

As well as establishing a new horizontal regime for EFSA transparency under the General Food Law Regulation (EC) No. 178/2002, it makes related amendments to sector specific legislation in all of these areas:

1. the deliberate release into the environment of genetically modified organisms (GMOs)
2. GM food and feed
3. feed additives
4. smoke flavourings
5. food contact materials
6. food additives, food enzymes and food flavourings
7. plant protection products (agrochemicals)
8. novel foods

# Very Wide Range of Materials To Be Made Public

**Includes the following to be "made public without delay":**

- Applicant supplied scientific data, studies and other information supporting applications, including supplementary information, 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 * * * *
- a summary of the pre-submission advice provided to potential applicants pursuant to Articles 32a (pre-submission advice) and 32c (consultation with 3rd parties) * *
- EFSA's own scientific studies in accordance with Articles 32 (commissioned under old regime) and 32d (new regime "verification studies");
- the information on which EFSA's scientific outputs, including scientific opinions are based* *

If *, only made public once after an application has been considered valid or admissible.

If ***, assertion that ≠ granting IP rights or EU data exclusivity rights**

**If *, assertion that no explicit or implicit permission or license to use and clear undertakings or signed statements will be given be accessors to this effect**

**If * or red text, will be on dedicated section of EFSA website, for downloading, printing and in electronic searchable formats [ Art. 38(1) list]**

# Confidentiality Claims: new burden of proof (reversal)

**Confidential treatment may be claimed** by Applicant based on exhaustive list of information (a **"closed positive list"**):

- the manufacturing or production process, including the method and innovative aspects thereof, as well as other technical and industrial specifications inherent to that process or method, except for information which is relevant to the assessment of safety;
- commercial links between a producer or importer and the applicant or the authorisation holder, where applicable;
- commercial information revealing sourcing, market shares or business strategy of the applicant; and
- quantitative composition of the subject matter of the request, except for information which is relevant to the assessment of safety.

*PLUS sector specific additions (i.e. sector specific closed positive lists) granted by EFSA applying the same standard or proof (e.g. PPPR adds what was previously deemed to be CBI.)*

# Confidentiality Claims: standard of proof (highest in EU transparency regimes)

"verifiable justification" that "significantly harms the interests concerned"

"disclosure of such information is demonstrated by the applicant to potentially harm its interests to a significant degree"

Nothing in the Transparency Regulation to explain what this means in practice

# Confidentiality Claims: standard of proof (highest in EU transparency regimes)

**i. Substantive requirements (minimum content) for confidentiality requests, includes need to show <u>all</u>:**

**(i)** **Not publicly available** or is known only to a limited number of persons;

(ii) public disclosure may potentially harm the interests of the applicant to a significant degree;

(iii) the harm that may be caused corresponds to at least **to 5% of the gross annual turnover** for legal persons (or the gross annual earnings for natural persons) for the financial year preceding the calendar year of the submission of the confidentiality request. If the harm is quantified as not reaching this percentage, or the applicant is unable to calculate its impact on their turnover/earnings, the applicant shall provide a specific reason as to why they consider that any public disclosure would potentially harm their interests to a significant degree;

(iv) eligible for legal protection and has not been acquired in an unlawful manner;

(v) does, or does not, fall under the definition of "environmental information" (Aarhus Regulation);

(vi) has been finalised in the form in which it was submitted to the Authority **up to five (5) years prior** to the submission of the confidentiality request. If the document, information or data for which confidential status is requested is older than five (5) years, the applicant shall provide (a) specific reason(s) as to why public disclosure of that information would still potentially harm its interests to a significant degree.

# Notification of studies

New EFSA **Database of studies** "*commissioned or carried out by business operators to support an application or notification in relation to which Union law contains provisions for the Authority to provide a scientific output, including a scientific opinion*".

**System of double entry cross-verification:**

- **business operators** shall, without delay, notify the Authority of the title and the scope of any study commissioned or carried out by them to support an application or a notification, as well as the laboratory or testing facility carrying out that study, and its starting and planned completion dates.
- also **laboratories and other testing facilities located in the Union** shall also, without delay, notify the same info to EFSA, as well as the name of the business operator who commissioned such a study.

**Extra-territorial application for labs and other testing facilities** "located in third countries insofar as set out in relevant agreements and arrangements with those third countries…"

# Transparency Regulation Implementation
# The new renewal procedure for PPP Active Substances

**Steptoe webinar 26 May 2021**

*Federica Bruno*

*Unit E4 – Pesticides and Biocides*

*DG Health and Food Safety*

# Outline

- Transparency Regulation Implementation
- Implementation activities in the PPP area: the new “renewal regulation” – Regulation 2020/1740.

European Commission

# Transparency Regulation Implementation

- TR entered into application on 27 March 2021
- TR Celebratory event held on 30 March 2021
  Recordings: https://vimeo.com/531292900
- Risk communication – EFSA reports published
  https://www.efsa.europa.eu/en/news/efsa-reports-set-inspire-future-risk-communications-europe
- EFSA Q&A document on practical arrangements published
  https://www.efsa.europa.eu/en/corporate-pubs/questions-and-answers-efsa-practical-arrangements

European Commission

# Implementing Regulation (EU) 2020/1740 repealing Commission Implementing Regulation (EU) No 844/2012

- New renewal rules are required to implement the provisions of the Transparency Regulation
- Implementing Regulation (EU) 2020/1740 was adopted on 20 November 2020 and applies from 27 March 2021 (however, transitional measures apply)
- Key Changes:

  - ✓ Pre-submission phase – including notification
  - ✓ Single step – submission of a renewal application 3 years before expiry
  - ✓ Contents of the renewal dossier more comprehensive
  - ✓ Full dossier published
  - ✓ Public consultation on the dossier
  - ✓ New window for submission of information at the end of the peer review

# Planning phase before submission


Only in case of "renewals" (GM food and feed, Feed additives, pesticides), an additional procedure applies.

A pre-notification by a potential applicant of planned studies to EFSA is foreseen.

efsa

EFSA will then systematically launch a consultation on the planned studies and issue advice on the content of dossier.

European Commission

# Pre-submission phase

- ✓ Article 3 of the Implementing Regulation (EU) 2020/1740 - Notification of intended studies and advice on intended studies (only for renewals)
- ✓ Article 4 General pre-submission advice - any time before the submission of the application for renewal. EFSA shall inform the rapporteur Member State of the request and together they shall decide if the co-rapporteur Member State is required to participate in providing the general pre- submission advice.

# Content of the renewal application

- ✓ Article 6 of Regulation (EU) 2020/1740
- ✓ Expanded scope to ensure renewal includes all data, old and new

# Submission of the Application in IUCLID

**I**nternational **U**niform **C**hemica**L** **I**nformation **D**atabase

What is it used for?

- IUCLID is a software application to record, store, maintain and exchange data on

intrinsic and hazard properties of chemical substances in a structured format.

- In the EU it is used in the regulatory framework of the Biocidal Products Regulation,

CLP Regulation, REACH Regulation.

- IUCLID is now also used to support Plant Protection Products, active substances dossiers (Regulation (EC) No 1107/2009) and for MRL applications (Regulation (EC) No 396/2005).

European Commission

# Peer-review – key changes

- Article 10 - Public consultation (60 days) on the renewal application
  - Comments taken into account by the RMS in its assessment

(Article 12 – public consultation on the Renewal Assessment Report – remains as previous)

- Article 13(4) – new window for applicant's to submit comments and information

- Applicants can submit comments to EFSA on the draft Conclusion (2 weeks)

- Critical issues leading to no safe use – applicant could not foresee or had no opportunity to address during the stop the clock:
  - Applicant can submit data or information (2 weeks)
  - RMS, co-RMS and EFSA = 75 days

# When and to which substances will the new Regulation apply?

- See Article 2 and 17 of Regulation (EU) 2020/1740
- This new Regulation shall apply to the renewal of the approval of active substances **whose approval period ends on or after 27 March 2024**.
- It shall **not apply** to the renewal of the approval of the active substances for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

# What else?

- Adoption of the standard data format for new AS
- Guidance for Basic Substances
- MRLs – Administrative Guidance EFSA
- EFSA's Practical Arrangements
- **https://ec.europa.eu/food/safety/general_food_law/implementation-transparency-regulation_en**
- E-mail: SANTE-SCIENCE-TRANSPARENCY@ec.europa.eu

European Commission

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# Thank you



European Commission

# Transparency and crop protection solutions – an industry perspective

Alessio Ghiani, IP & Legal Affairs Manager

Steptoe Webinar - 26 May 2021

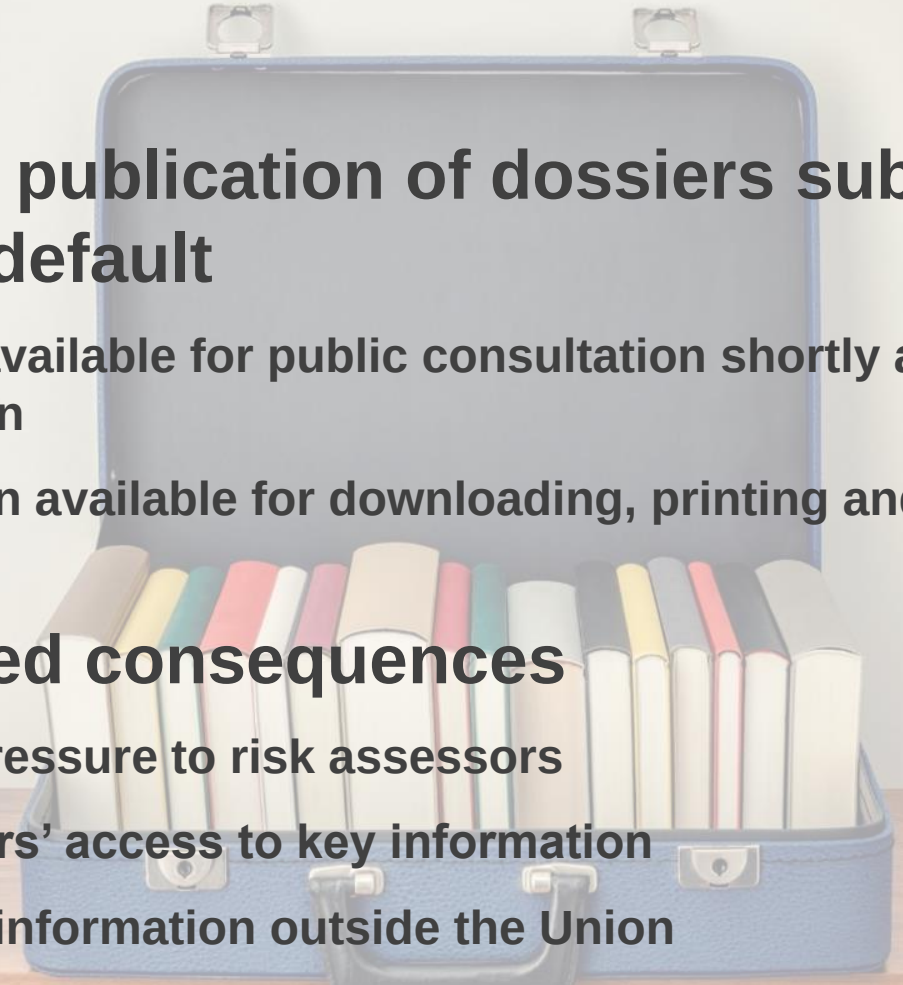
# Earning public trust

- CropLife Europe represents the world's leading developers of crop protection solutions
- The EU authorization process is the essential assurance that products meet the highest standards for safety and quality
- The new transparency regime can further enhance public confidence in the process

# The potential of the new regime

| | |
|---|---|
| **Risk Communication** | Provide clear and transparent information to interested parties<br>Increase understanding of decisions on PPPs |
| **More efficient submissions and evaluation** | Online submission and advanced preparation of dossiers<br>All data in the same place |
| **Pre-submission advice** | EFSA in cooperation with MS (in writing, where possible)<br>Made public along with the application |
| **Study notification** | All studies conducted or commissioned must be reported<br>Mismatches are possible but need to be documented and properly justified |

# Proactive dissemination of data



- **Proactive publication of dossiers submitted to EFSA by default**
  - Dossiers available for public consultation shortly after submission
  - Information available for downloading, printing and electronic searching
- **Unintended consequences**
  - Political pressure to risk assessors
  - Competitors' access to key information
  - Misuse of information outside the Union
  - Potential impact on applicants' global commercial interests

# Confidentiality of trade secrets

- **CBI protected only under provision of *verifiable justification that disclosure would potentially harm interests to a significant degree***
  - Manufacturing or production processes
  - Commercial links with producers/importers
  - Information revealing sourcing, market shares or business strategy
  - Quantitative composition of substance except for safety data
- **Reversal of burden for proving confidentiality**
- **Tailored claims for each piece of information must be made to, reviewed and approved by:**
  - EFSA (renewal of AS); or
  - Rapporteur Member State (new AS)

# Assessment of Confidentiality claims

- **Individual assessment of each claim**
- **Additional confidentiality criteria in EFSA's Practical Arrangements**
  - Information not publicly available
  - Information acquired legitimately
  - Novelty - information should not be older than five years
  - Negligible harm - disclosure should cause harm of at least 5% of turnover
  - Environmental information under the Aarhus Regulation
- **Non-confidential dossiers published "without delay"**
  - Other CBI previously redacted by applicants may be published following EFSA's confidentiality assessment
  - This decision is made under time pressure and may entail significant liability in case of inappropriate disclosure

# Conclusions

- The new regime will hopefully increase trust in the approval process of crop protection products
- Large workload for regulatory and legal experts
- Lack or reduced protection of regulatory information in certain non-EU countries
- Striking the right balance between utmost transparency and protection of food chain operators
- Future extension of the new regime to other highly regulated sectors?

# Transparency and specialty food ingredients

## An industry perspective and preparations

Steptoe webinar, 26 May 2021

## Content

- Introduction to EU Specialty Food Ingredients
- From the adoption of the Commission proposal...
- ... To the application of the Transparency Regulation
- What's next?

## Content

- **Introduction to EU Specialty Food Ingredients**
- From the adoption of the Commission proposal...
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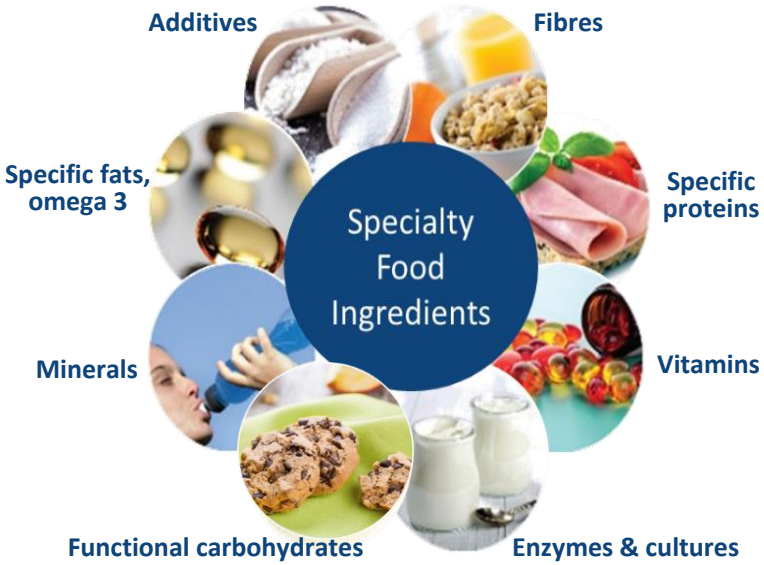
## Our Contribution




**Specialty food ingredients are present in almost all processed foodstuffs**, thus contributing to the competitiveness of the European food and drink industry → EU food and drinks industry annual turnover: **€ 1 trillion,** making it the largest manufacturing sector in the EU in terms of annual turnover.

**Specialty food ingredients have technological and/or functional benefits** that are essential in providing today's consumer with a wide range of tasty, safe, healthy, affordable, qualitative and sustainably produced foods.

The industry contributes over **€ 40 billion** to annual turnover of EU food and drinks industry

The industry invests **3-8%** of turnover in R&D (depending on sector)

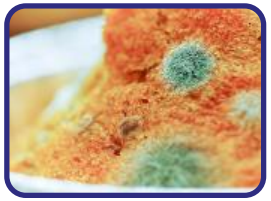
## Specialty food ingredients are used for a reason

### Provide a technical & market response to public health needs

- **Healthy ageing** (vitamins and minerals, maintenance of normal blood cholesterol concentrations...)
- **Compensating for changing diets** (fibre rich ingredients)
- **Replacing less healthy alternatives** (e.g. sugar substitutes, fat replacers...)
- **Combating allergies** (novel approaches involving prebiotics and probiotics and alternative protein sources )

### Contribute to the sustainability of food systems

- Improve **resource efficiency** by using all valuable components of raw materials & **reducing downstream losses**
- Help make **processing of foods more efficient** → limiting the quantity of raw materials required for production → energy saving & reduction of GHG
- **Reduced environmental impact**



### Contribute to the safety & convenience of foods

- **Stop foods from deteriorating too rapidly**, e.g. by preventing undesirable micro-organisms from growing
- **Maintain a food's nutritional profile**, e.g. by preventing vitamins, essential amino-acids & unsaturated fats from degrading (e.g. antioxidants)
- **Mitigate the formation of undesirable components** such as acrylamide generated in a wide range of cooking processes

## Specialty Food Ingredients, essential to today's varied Food & Drink offer

**Shopping Basket**
***(with and without specialty food ingredients)***


**Shopping Basket**
***(without specialty food ingredients)***

EU specialty food ingredients

## Membership

**41**
members, representing more than…

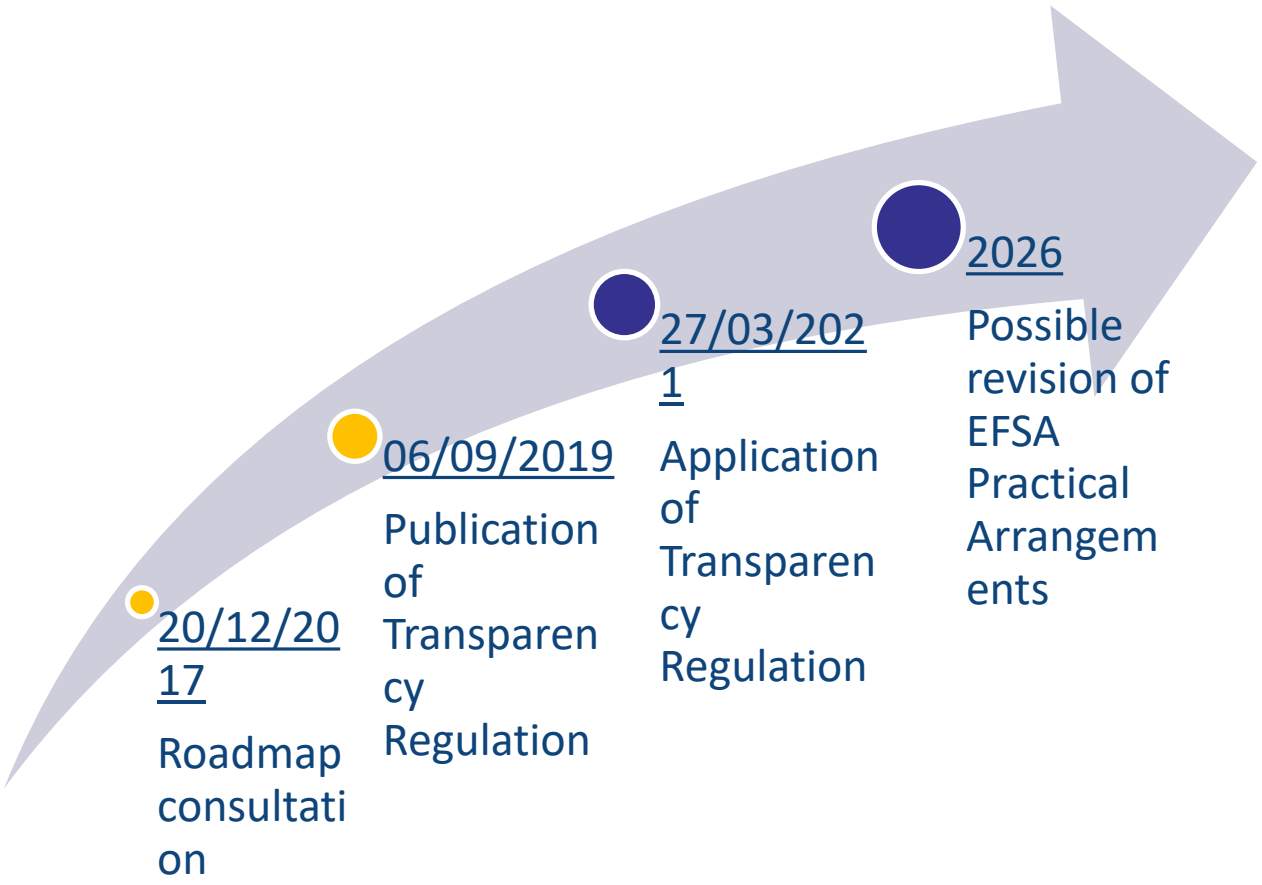
**… 200**
international and national specialty food ingredients companies

About
**22%**
SMEs*


*< 250 employees and TO < € 50 m.
These are guesstimates 2013, based on internal data gathering amongst our diverse membership (CEFIC is a member of EU Specialty Food Ingredients but is excluded from calculations due to unclear representation of industrial chemicals vs specialty food ingredients).

## Content

- Introduction to EU Specialty Food Ingredients
- **From the adoption of the Commission proposal...**
- ... To the application of the Transparency Regulation
- What's next?


20/12/2017
Roadmap consultation
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2026
Possible revision of EFSA Practical Arrangements

## Commission proposal – industry concerns (1)
## Connecting the dots

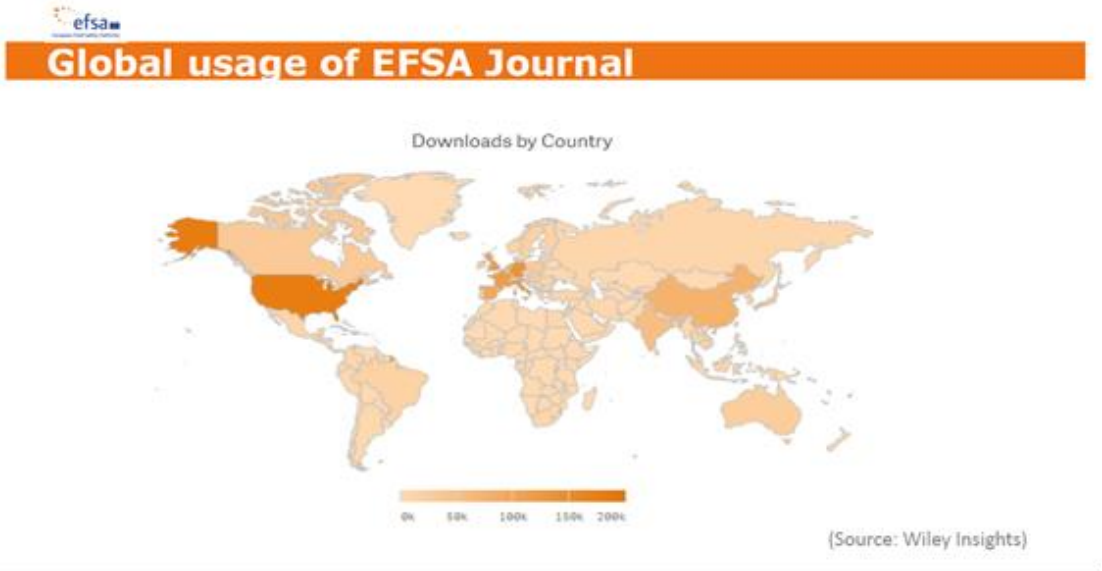
**Proactive automatic disclosure on EFSA website of non-CBI at the time the application is submitted to EFSA flags a company business strategy to competitors around the world: it is all about connecting the dots!**

- In contrast to other products (e.g. medicines, plant protection products, GMOs, etc.), novel foods and food improvement agents are generally NOT protected by patents. Their authorisations are generic, therefore useable by competitors.

- The pro-active automatic disclosure of non-protected and generic EU innovation on EFSA's website gives competitors a free hand to develop the innovative ingredient on an accelerated pace.

Despite the proposed measures have no equivalent in the EU legislation, no impact assessment has been carried out.

## Commission proposal – industry concerns (2)
## EFSA information is used outside the EU




Source: EFSA Management Board Dec. 2018

## Commission proposal – industry concerns (3)
## Case study (over-simplified)

After five years of R&D, a European SME has isolated a natural bacteria strain able to ferment a by-product issued from the manufacturing of soya flour, with the aim to produce with an exceptional yield a novel food ingredient that increases the bioavailability of dietary iron.

The SME prepares an application to EFSA for both the authorisation of the substance as a novel food ingredient and the authorisation of the health claim: 'increases the bioavailability of dietary iron". For this purpose they follow the EFSA guidance documents.

EFSA considers the application admissible and **publishes the non-confidential version of the application (incl. studies).**

The SME's business plan is based on the **progressive launch of the ingredient on the EU market**: a bank loan is subscribed to be able to offer a reasonable price during the scale-up phase of the production and reach out to the first clients, until the progressive increase in production volumes enables the economies of scale necessary for a fully competitive market price.

A global company located in a Eastern third country, with a strong expertise in fermentation and microorganism screening, has put in place a daily monitoring of EFSA's website in order to stay tuned with early developments in their business sector: **the non-confidential version of the European SME's dossier is immediately spotted and deemed very interesting for their own company given their easy access to soya sourcing at competitive prices, and their large-scale fermentation facilities.**

The disclosed information allows the scientific team of this global company **to grasp with an expert eye the technicalities of the dossier**: a R&D project is immediately set in place to try and replicate the production of the novel ingredient. The business goal of the company is to prepare for the production at large scale and export to the EU at a very competitive price the very same ingredient as soon as the European SME has obtained a positive assessment by EFSA of its ingredient and related health claim, and the subsequent positive decision by the European Commission to permit it on the EU market, around two years later.

## Commission proposal – industry concerns (4)
## Complaint to the European Ombudsman

**European Ombudsman**

Decision
20/03/2019

The Commission presented the legislative proposal to the EU legislature in April 2018. Parliament and Council reached political agreement in trilogue negotiations on 12 February 2019.

The absence of an impact assessment was raised by the rapporteur of the European Parliament's Committee on Environment, Public Health and Food Safety when considering the Commission's legislative proposal. The explanatory memorandum to the Committee's report, adopted on 29 November 2018, concludes that *"the proposed transparency rules could seriously damage the innovative strength and competitiveness of the European food industry"*. Therefore, it is *"hard to understand why the Commission chose not to carry out an impact assessment"*.

I take the view that it was for the co-legislators in this case, if they considered it necessary, to invite the Commission to reconsider its position as to the need for an impact assessment or to carry out their own impact assessment[1]. As Ombudsman, I am not in a position to reassess this choice of the co-legislators.

## Content

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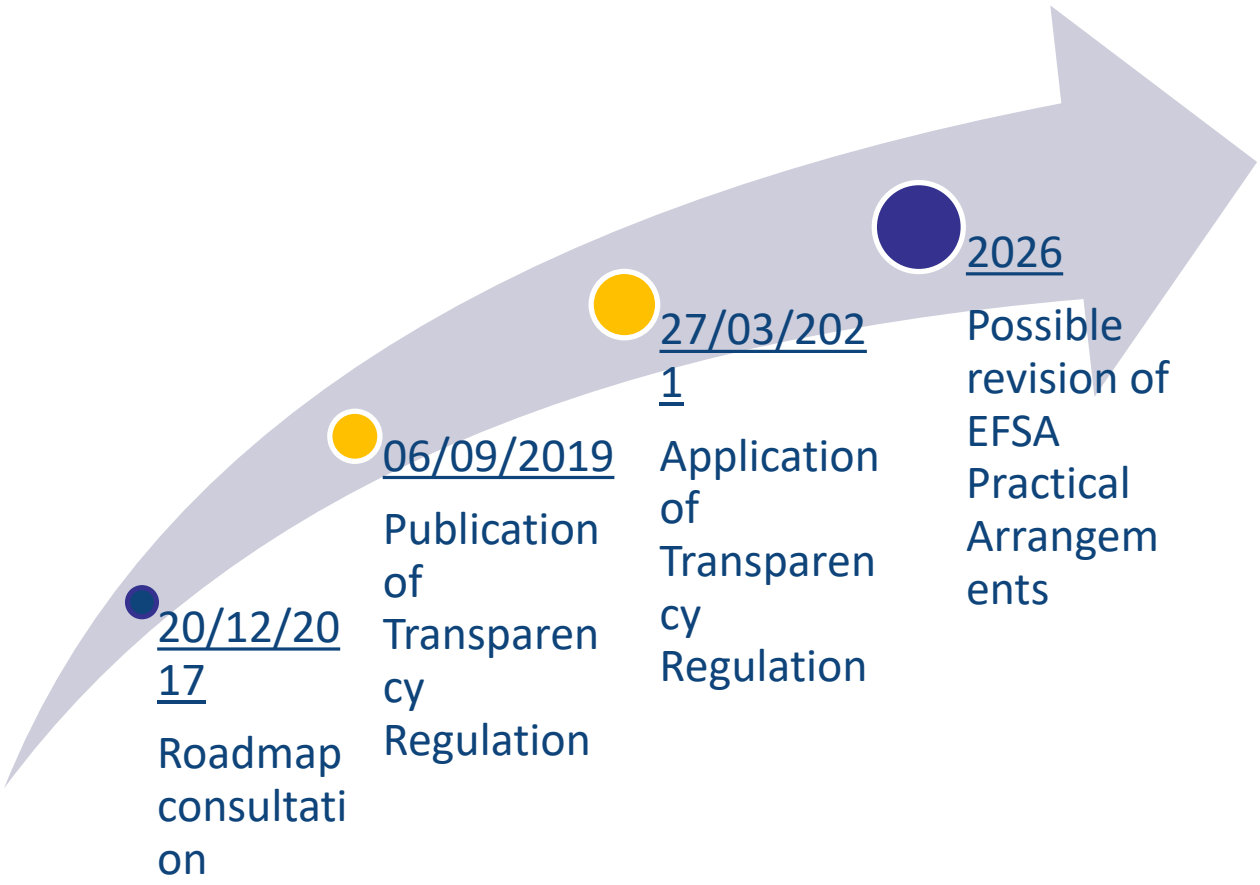
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## Transparency Regulation
## A few improvements (1)

- Pre-submission advice: not immediately published, and only as a succinct overview
- Scope of eligible confidential information extended for:

### Novel Food Ingredients

- where applicable, 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 that novel food, except for information which is relevant to the assessment of safety;
- where applicable, detailed analytical information on the variability and stability of individual production batches, except for information which is relevant to the assessment of safety.

### Food Improvement Agents

- where applicable, 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 and products in which the applicant intends to use the substance subject to the authorisation, except for information which is relevant to the assessment of safety;
- where applicable, detailed analytical information on the variability and stability of individual production batches of the substance subject to the authorisation, except for information which is relevant to the assessment of safety.

## Transparency Regulation
## A few improvements (2)

- Notification of studies:
  - Internal labs are not requested to co-notify
  - The application is processed after 30 days even if the lab does not co-notify ( & vice-versa where the co-notification is expected from the business operator )
  - No procedural consequences if studies requested for the re-evaluation of FA are not notified

- Public consultation: publication of comments/additional studies submitted by third-parties

- Withdrawal of applications: possibility to protect the confidential information

## Transparency Regulation But…

- Notification of studies:
  - Complex process
  - Administrative burden
  - Need for specialised staff or consultants to manage
  - Broad definition of studies
- Submission of application in Standard Data Formats – not yet in place (“semi-structured dossiers”)
- Cumulative criteria for justification of a confidentiality request: if included in the PAs to “assist applicants” and are “rebuttable presumptions”, why shall non-compliance be justified?
- Potential delay in the risk assessment process due to public consultation (e.g., claims)
- Re-use of disclosed data:
  - No system in place to track who is re-using the disclosed data
- etc.

## Content

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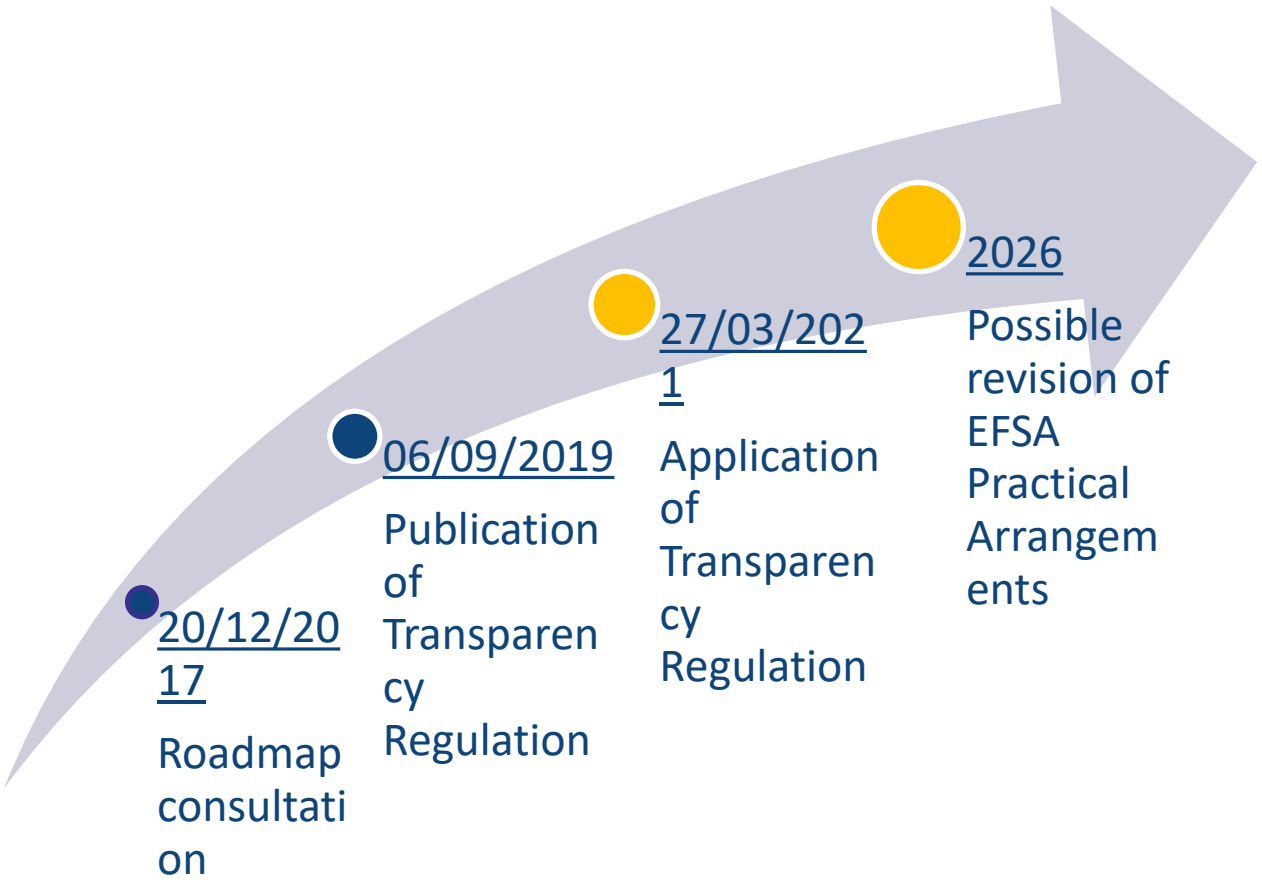
- ...To the application of the Transparency Regulation
- **What's next?**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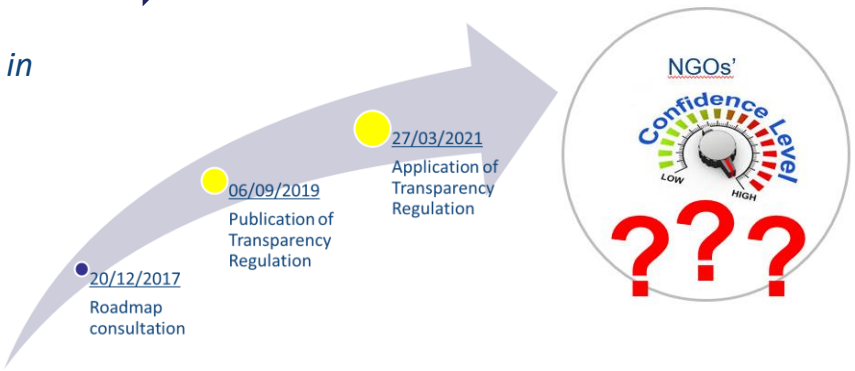
**EU Specialty Food Ingredients** welcomes the intention of the European Commission and of the co-legislators to address the societal demand that the risk assessment process in the area of food is more transparent to the extent that:

- It protects the competitiveness of the European specialty food ingredients sector, which is based on high innovation investments and know-how

→ Internal membership survey to assess the impact & provide feedback to EFSA/DG SANTE

- It *"contributes to the Authority acquiring greater legitimacy in the eyes of the consumers and general public in pursuing its mission, increases their confidence in its work and ensures that the Authority is more accountable to the Union"*

→ Will the performance be measured?




# THANK YOU

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Specialty food ingredients, sustainable solutions for the food system – Infographic

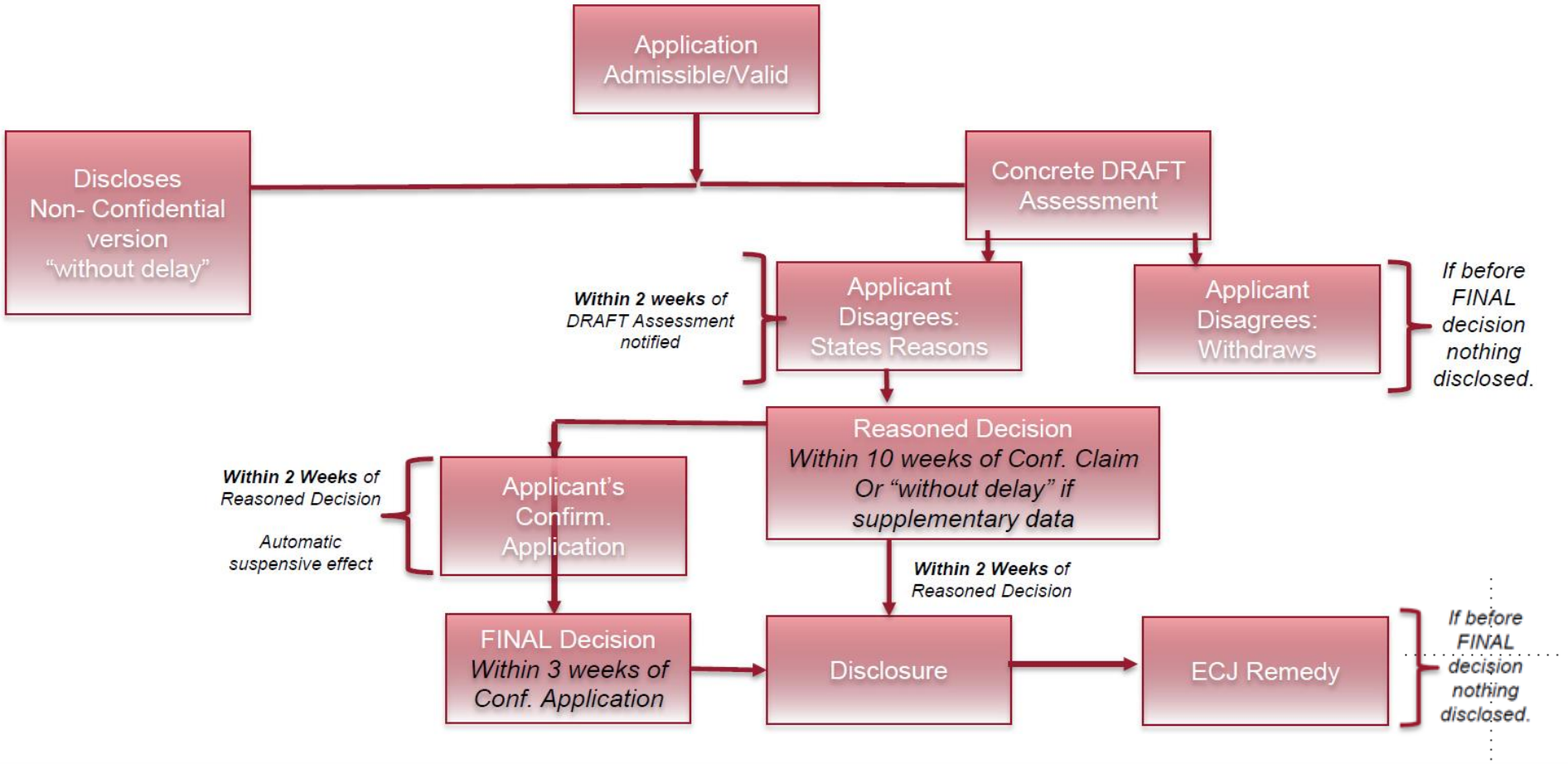
How specialty food ingredients help meet specific dietary needs – Infographic

Specialty food ingredients, the indispensable link in the sustainable food chain - Video

# Legal Remedies - Topics

- Timing of Disclosure & Procedures
- General Court Remedy
- Interim Relief
- Damages

# Timing of disclosure (faster than anywhere else)



# Annulment Action

**Article 263 TFEU**

Any natural or legal person may…institute proceedings against an act addressed to that person or which is of direct and individual concern to them, and against a *regulatory act* which is of direct concern to them and *does not entail implementing measures*.

- regulatory act is = 'all acts of general application apart from legislative acts'
- whether act is legislative or regulatory is 'based on…*procedure* which led to its adoption'

- Brought within 2 months + 10 days for distance.

# Interim measures

**Article 278 TFEU**

**No automatic interim relief before CJEU** (because presumption of lawfulness).

**Interim measures hurdle is very high** and historic success rate low (though a few notable successes on PPPs). Three cumulative tests:

- ***prima facie* case**: basically sound or doomed to fail?
- **urgency**: serious and irreparable damage (not purely financial)
- **balance of interests**: must outweigh the *status quo*

**Analysis is very fact pattern specific and the judge exercises a wide discretion.**

Confidential economic information redacted from Orders.

# Damages

**Article 340 TFEU**

**Damages**

- damage suffered by claimant
- illegality
- direct causal link between the damage suffered by the claimant and the illegality

# Questions & Answers

## Q&A