

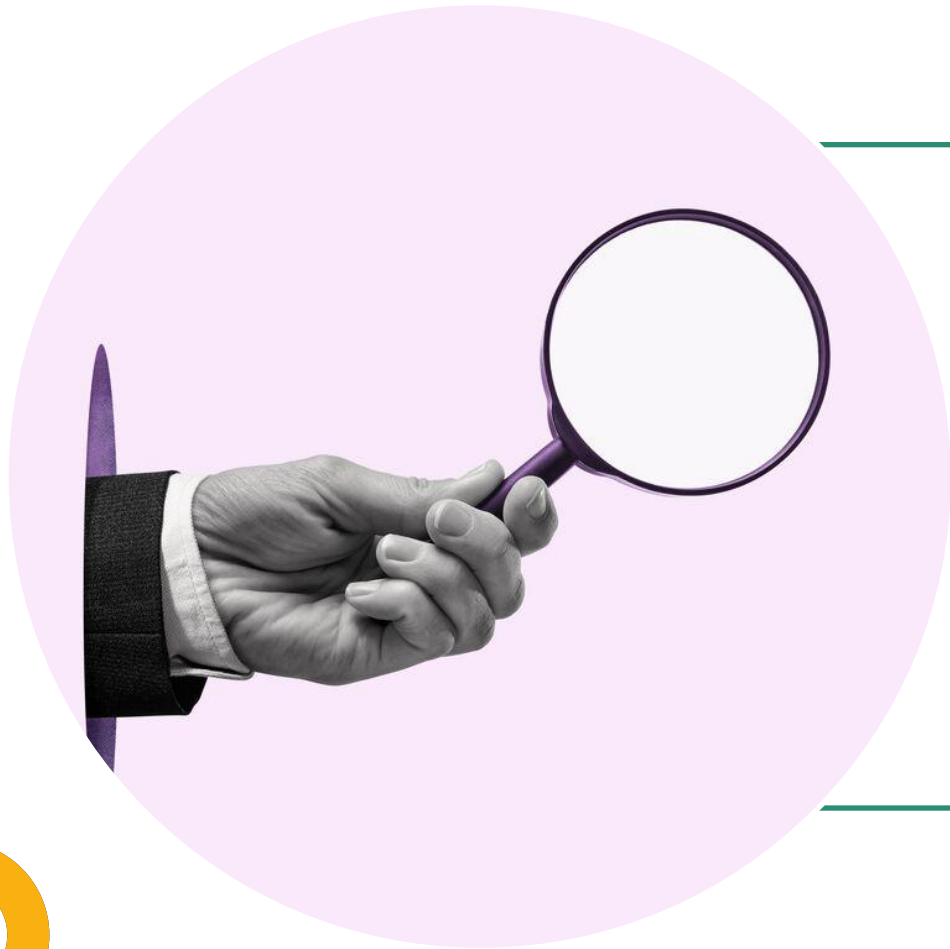


# **CONFIDENTIALITY ASSESSMENT OF FOOD ENZYME DOSSIERS**

Technical meeting on applications for food enzymes

Parma, 24 October 2024

# AGENDA



1

Overview confidentiality assessment & sanitisation

2

Lessons learnt

3

Questions & Answers



# Transparency Regulation

Regulation (EU) 2019/1381 on  
the transparency and  
sustainability of the EU risk  
assessment in the food chain  
("Transparency Regulation")

4 main pillars, focus of our  
discussion today: Transparency  
pillar

Amends the General Food Law ("GFL")  
and eight sectoral legislations, among  
which Regulation (EC) No 1831/2003

Applies to applications received by  
MS/EC on/after 27 March 2021



# TRANSPARENCY REGULATION PRINCIPLES



## Proactive Disclosure

**Art 38 GFL**

**Proactive disclosure e.g. for:**

Information data or studies submitted to support an application dossier

Information on which scientific outputs/opinions are based



## Confidentiality

**Articles 39-39e GFL**

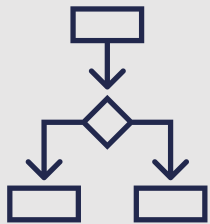
**Confidential status:**

Only for items included in the **closed positive list** of the Annex to the Practical Arrangements concerning transparency and confidentiality

Only if **substantive and procedural** requirements are met



# ARTICLE 39C – REVIEW DECISION MAKING



## Decision making process reflects first round

- First confidentiality assessment process
- Optional confirmatory application process



## EFSA reopens the confidentiality decision making process if:

- The decision relate to items granted confidential status
- The EFSA scientific output concerns foreseeable effects on human health, animal health or the environment,
- The decision relates to items in conclusions of an EFSA output



Change to **closed positive list** post-TR

Confidentiality may now **only be awarded if**

- the information falls under one of the legal grounds in the closed positive list:
  - **Article 39 and 39e of Regulation (EC) No 178/2002 (General Food Law)**
  - **Article 12 of Regulation (EU) No 1331/2008**
- the information claimed confidential is **not relevant to the assessment of safety** (where the exception is available)

### Article 39(2) of Regulation (EC) No 178/2002 - General Food Law

- 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;
- **quantitative composition** of the subject matter of the request, except for information which is relevant to the assessment of safety;





## Article 39(e) of Regulation (EC) No 178/2002

- 2. **names and addresses of natural persons** involved in testing on vertebrate animals or in obtaining toxicological information
- 3. **personal data** in accordance with the provisions of Article 3(1) of Regulation (EU) No 2018/1725

NB: name and address of the applicant , names of authors of published studies, and names of experts of EFSA WGs and panels shall always be made public (Article 39e(1) of Regulation 178/2002)







For the improvement agents' sector:

- **Article 12(3) of Regulation (EC) No 1331/2008**
  - (a) 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 or 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;
  - (b) 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.



# CONFIDENTIALITY CLAIMS SUBSTANTIVE REQUIREMENTS

- 
- **Identifying** clearly the information claimed confidential, by (i) referring to all elements claimed confidential (ii) locating them in the document (page/paragraph/line)
  - Indicating the **legal basis (grounds)**
  - **Explaining** why the item should be kept confidential

- 
- Information **not publicly available**
  - **Potential harm to a significant degree**
    - Information acquired legitimately
    - Negligible harm – rebuttable presumption
    - Novelty – rebuttable presumption



# Lessons learnt | Justifications supporting confidentiality requests



Make the explanation as closely related as possible to the information requested as confidential



In case the applicant is unable to confirm compliance with the substantive criteria by “ticking the boxes” in ESFC, they may

- Either provide an equivalent confirmation in the free text box or
- Provide the actual reasons why disclosure would damage the applicant



Examples of adequate justifications:

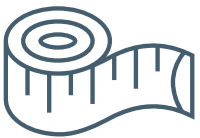
- Existence of a trade secret
- Explanation of absolute or relative importance of the information in question for the applicant



## Lessons learnt | Submission of confidentiality request(s) slide 1 of 3



**Justification** must support **elements earmarked or redacted** as confidential in documents submitted



**Tailored justification** to each element claimed confidential based on the ground invoked (no copy-paste or generic justification), **referring to items in closed positive list.**



## Lessons learnt | Submission of confidentiality request(s) slide 2 of 3

1

**One confidentiality request per document per legal ground**



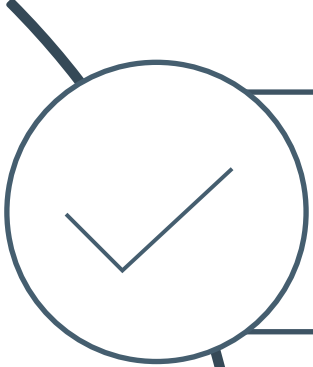
**Quote the excerpt if short, otherwise precisely identify** the location(s) of the information item(s) claimed confidential in the confidentiality request, at least by referring to the **name of the document, page** and **number of the paragraph**



**Avoid claims like “throughout the document”, “on all pages”** if this is not the case



## Lessons learnt | Submission of confidentiality request(s) slide 3 of 3



**Ensure** all applicable **conditions** are ticked or **justification is provided**



Refer to the correct legal basis. When the qualification is not self-evident, you must justify why this element falls under that legal basis



No unfounded confidentiality requests or requests on publicly available information



# Lessons learnt | Submission of documents slide 1 of 3



**Confidential** version and **public** version must always be submitted and **should match**



Properly **name documents to distinguish** between confidential and non-confidential version



**Avoid confidential information in the file name** of the non-confidential version





## Lessons learnt | Submission of documents slide 2 of 3



Where possible, **avoid using scanned documents**: they might hamper the search of the items you are willing to claim confidential



**Do not include watermark 'confidential'** on parts of documents that you do not claim confidential



Ensure that information claimed confidential in one part is **not visible in another part of the document**



## Lessons learnt | Submission of documents slide 3 of 3



Identify parts on which confidentiality is requested in a **clear and consistent** manner



Use a proper **redaction tool** which ensures:

- In confidential version: A proper **earmarking functionality**
- In public version: That information is **irreversibly redacted**



Whenever possible, perform **four-eyes checks** to ensure that you have correctly identified all the items for which you are requesting confidential status



## Focus point | Notification of Studies (NoS) database extract




Reply timely to consultations on Notification of Studies database extract

Clearly indicate

- The **study** to which the claim relates
- The **information claimed confidential**
- The **column** in which this information is located in the extract
- The **legal ground** under which confidentiality is claimed

Ensure the **conditions listed in Article 10** of EFSA's Practical Arrangements concerning Transparency and Confidentiality are **addressed**





Why not keeping all assessments and communications in the electronic system?

Draft and final confidentiality decision are communicated via the electronic system, unless exceptional circumstances do not allow this




How can we react in the system in case we disagree with assessments and conclusions on confidentiality?

- Submit comments on the draft decision in ESFC
- Submit confirmatory application on final decision in ESFC







Can names of contract research institutes (CRIs) be considered personal data?

“personal data” means any information relating to an **identified or identifiable natural person** [...]

Article 3(1) [Regulation \(EU\) 2018/1725](#)

- Names of **legal entities**  $\neq$  **personal data**, **unless** it links back to a natural person or enabling indirect identification of natural person
- A **justification** for categorising the legal entity’s name as personal data shall be provided to EFSA



# Q&A

