



# CONFIDENTIALITY ASSESSMENT PROCESS



**AD HOC MEETING WITH GMO  
INDUSTRY REPRESENTATIVES  
19 MARCH 2025**

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## SPEEDING UP THE CONFIDENTIALITY AND RISK ASSESSMENT: PROCESSING TIMES



- Provide functioning e-mail address and ensure **business continuity** (e.g. referring to functional mailbox, ensure messages forwarded to colleagues in absence) – let us know if you change contact person



- **Faster reply** to EFSA`s requests for clarifications = **faster confidentiality assessment, launch of Publication Consultation and adoption of Scientific Opinion**



- If you **agree** with EFSA`s draft decision + **reply** to EFSA before the legal deadline expressing explicitly your agreement
- if you agree with EFSA's final decision + **confirm that you will not submit a confirmatory application** = **faster confidentiality assessment, launch of Publication Consultation and adoption of Scientific Opinion**



## LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUESTS - I

### Confidentiality Excerpt and Section:



**Provide a direct quote if very short, otherwise precisely identify** the location(s) of the information item(s) claimed confidential in the confidentiality request by referring to the **name of the document, page and number of the paragraph**



## LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUESTS - II



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



**Avoid repeating the same information** under ‘Excerpt and ‘Section’ – extra work and no added benefit



## LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUESTS – III

### ✓ Example 1

- **Excerpt:** 'Joe Black, ADM Research Analytical Manager'
- **Section:** Pages 1, 3 and 5

### ✓ Example 2

- **Excerpt:** 'names, email addresses and signatures'
- **Section:** 'Section 2.1, page 3, paragraph 2 to page 4 paragraph 5'

### ✓ Example 3

- **Excerpt:** 'names, email addresses and signatures'
- **Section:** Pages 1 to 20

### ✓ Example 4 – information contained in zip folders

- **Excerpt** 'Market shares'
- **Section:** PMEM zip folder, 2025 Annual monitoring report



## LESSONS LEARNT- SUBMISSION OF CONFIDENTIALITY REQUESTS – IV

### What's in it for me?



**Save time** when filling in the confidentiality excerpt and section and tailor it to the specific circumstances

Clearer indications = **faster confidentiality processing times** → **acceleration of risk assessment**



# CONFIDENTIALITY REQUEST SEQUENCE INFORMATION I

Article 30(2)(a) of Regulation (EC) No 1829/2003:

DNA sequence information, except for sequences used for the purpose of detection, identification and quantification of the transformation event.



## CONFIDENTIALITY REQUEST SEQUENCE INFORMATION II

### SINGLE EVENT GMO plant

- **Single DNA event**
- Provide **full sequence of the inserted DNA fragment(s)** (Genbank file(s): gb or gbk)
- The information relating to the **sequences used for the purpose of detection, identification and quantification of the transformation event must always be disclosed**



## CONFIDENTIALITY REQUEST SEQUENCE INFORMATION II

### STACK/STACKED GMO plant

- Contains **multiple DNA fragments** each **derived from a SINGLE GM event**
- Provide **full sequence of each event** integrated in the STACK GM plant
- Provide Genbank files of each single event in the context of the STACK GM plant
- The information relating to the **sequences used for the purpose of detection, identification and quantification of the transformation for each SINGLE event** must always be disclosed



## CONFIDENTIALITY REQUEST SEQUENCE INFORMATION IV

- The DNA sequence information from the detection method requested by the EURL (primer 1 binding site, probe binding site, primer binding site 2) cannot be accepted as confidential since it is used for the purpose of detection, identification and quantification of the transformation event
- **Submit the information in the document 'CRL format' under Part V**  
Methods of detection, sampling and reference materials



# CONFIDENTIALITY REQUEST SEQUENCE INFORMATION V

## What's in it for me?

If applicants report the sequences used for the purpose of detection, identification and quantification of the transformation event under Part V

- **Detailed DNA sequence** set out in the sub-folder 0.4 – Final Event Sequence **in** the **7-zip sequence pack** can be fully claimed confidential
- Impact on Confidentiality Assessment: **Confidentiality request on sequence pack can be approved**; increased likelihood of all confidentiality requests being approved and moving directly to notification of final Confidentiality Decision
- Impact on speed of Risk Assessment



## CONFIDENTIALITY REQUESTS ON VALID DOSSIER AND ADR

### When are Confidentiality Requests (CRs) processed by EFSA?

- All **CRs** submitted in the context of the **valid dossier** are processed by EFSA **prior to the Public Consultation**
- All **CRs** submitted in reply to **ADR** are grouped together and put **on hold until the Scientific Output has been adopted**

→ non-confidential version of additional information submitted by applicant will be published and implemented in the Scientific Output pending EFSA's Confidentiality Assessment



# FILENAMES

## Which filenames should I use?

Marked, redacted, sanitised, public, public access, conf, non-conf, CI, nCI... →  
Inconsistent naming

- ✓ **Confidential** version
- ✓ **Non-confidential** version



**THANK YOU FOR  
YOUR ATTENTION**



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