

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







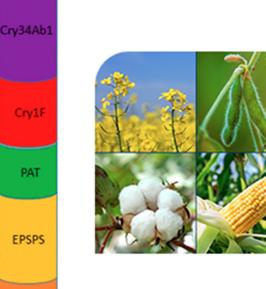




CONFIDENTIALITY REQUEST SEQUENCE INFORMATION II

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



Cry35Ab1

AAD-1



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, Cl, nCl... \rightarrow Inconsistent naming

- ✓ Confidential version
- √ Non-confidential version





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