16 November 2022

GMO Stakeholders Meeting

Update from FDP Unit on post-TR GMO dossiers

Trusted science for safe food

efsa
European Food Safety Authority

Post-TR GMO dossiers

- 27 March 2021: implementation of the Transparency Regulation (Reg. (EU) 2019/1381)
- Several post-TR applications (388) have been received by EFSA in all regulated products areas
- Only 4 post-TR GMO dossiers have been received so far, starting in May 2022
- Several comments have been received by GMO applicants on post-TR submission requirements and have been acknowledged by EFSA
- After 20 months of experience from TR implementation (6 months in GMO), we share some lessons learned.

ESFC Table of content for GMO

- Based on Implementing Regulation (EU) No 503/2013
- Part II – Scientific Information is currently structured on 6 levels
- In the practice it revealed to be very detailed for its purpose
- Proposals of workarounds to test a **simplified version** of the ToC

ESFC Table of content: simplified proposal

Part II - Scientific Information			Current workaround: Insert the data in the **first node** available:
	Hazard identification and characterisation	Information relating to the recipient or parental plants	
		Molecular Characterisation	Description of the methods used for the genetic modification
		Comparative analysis	Choice and description of the tested materials, including breeding tree…
		Toxicology	Testing of newly expressed proteins
		Allergenicity assessment	Assessment of allergenicity of the newly expressed protein
		Nutritional assessment	Nutritional assessment of the GM food
	Exposure assessment - Anticipated intake/extent of use		Human
	Risk characterisation		
	Post-market monitoring on the GM food or feed		
	Environmental Risk Assessment		General approach of the ERA
	Environmental Monitoring Plan		
	Additional information related to the safety of the GM food or feed		Review of Scientific Literature

Confidential raw data files

Raw data package:

- Sequencing
- Compositional analysis
- Agro-pheno analysis
- Tox 28-day study
- Tox 90-day study

Files typically included:

.fq
.fastqc
.fa
.aln
.ab1
.bam
.py
.qual

.sas
.sas7bdat
.xml

- Need a special software to be opened
- Not convertible into pdf
- Hundreds of files, in several subfolders
- Claimed as fully confidential by applicants

Confidential raw data files: current approach

CASE 1

- File entirely claimed confidential by applicant
- Files considered fully confidential in the preliminary evaluation

EFSA may accept the submission of a placeholder for the non-confidential version of the file

Files can be removed from the non-confidential version of the raw data package and can be replaced by a file that reports the LIST of all removed confidential files (one list per subfolder), mentioning that the files are considered confidential.

CASE 2

- File entirely claimed confidential by applicant
- Files NOT considered fully confidential in the preliminary evaluation

EFSA must perform a full confidential assessment

In the non-confidential version of the raw data package, applicants must provide, for each file, a corresponding document with the same name.

Please, note that this is **provisional** and **without prejudice to the outcome of the confidentiality assessment**.

Applications for GMO stacks

- GMO stacks dossiers contain data from the companies owning each single event's application
- Regardless of the type of application, applicants are responsible for compiling their applications with the administrative and scientific data required by the applicable framework
- **Pre-TR:** Companies supporting the application were providing password-protected information packages

Applications for GMO stacks

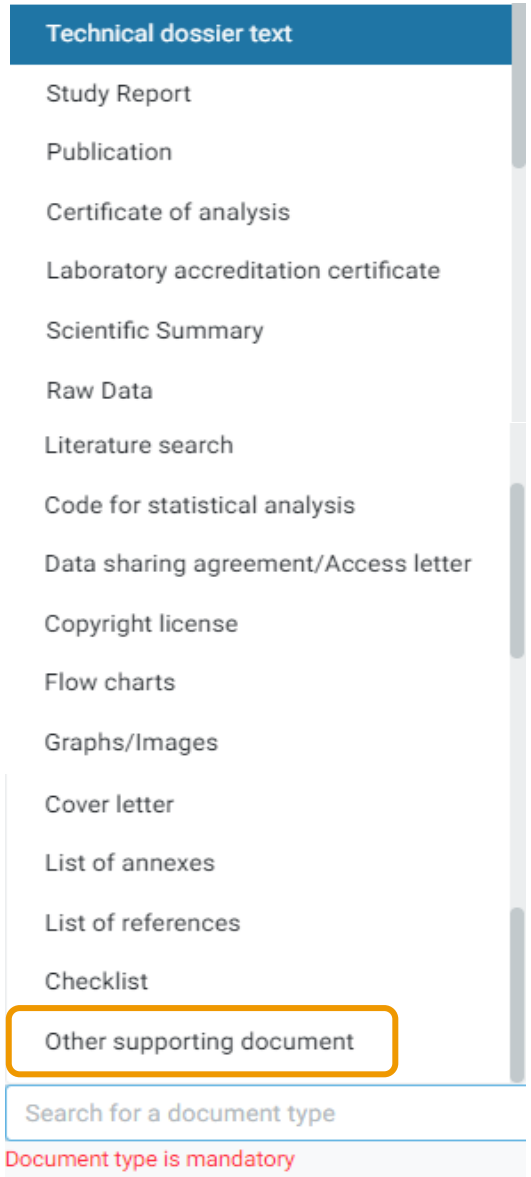
- **Post-TR:** The option of uploading password-protected files or zipped folders in ESFC is available, but only acceptable if applied to confidential files/folders, not to their public version
- The respective passwords should be sent to EFSA via email to both fdp@efsa.europa.eu and confidentialityrequestassessment@efsa.europa.eu by the data owner in order to facilitate both CC and confidentiality assessment processes.
- We would kindly recommend limiting the number of different passwords as much as possible, ideally receiving the same password for all the information derived from the same company.
- EFSA does not prevent the use of consultants in the preparation of applications submitted to the Authority

- Please, take into consideration the following aspects:
  - Any request for confidentiality must be inserted in ESFC by the applicant
  - RFIs, ADRs and requests for clarification during confidentiality assessment will be sent by EFSA to the applicant

NoS: justification for notification with delay

- Article 21(b) point IV of EFSA practical arrangements on pre-submission phase and public consultations (https://www.efsa.europa.eu/en/corporate-pubs/transparency-regulation-practical-arrangements): the delayed notification in the EFSA database should be justified by the applicant when submitting the application
- The justification for delayed notification has to be directly inserted in ESFC when providing the information on the EFSA study identification. Two new fields have been recently added in the metadata for this purpose. A contextual help note is also available for the applicants to consult further information
- Specific instructions:
  - Once the "Document type" of the uploaded file is indicated as "Study Report", the following question appears: "Have you received a EFSA study identification?"
  - By answering "Yes" to that question, you are requested to insert the EFSA study identification (e.g. EFSA-2021-12345678).
  - Once the EFSA study ID is correctly inserted, the following question appears: "Have you notified this study before the starting date?"
  - By answering "No" to that question you acknowledge the fact that the study was notified with delay, therefore, the following box appears: "Justification for not notifying the study or notifying it with delay" in which you can insert the justification text that you have indicated.

Document categories



- Currently, there is not a specific category available for Desk-oriented study reports (e.g. bioinformatic studies and exposure assessment).
- Please, use “Other supporting document”.

Final tips

- All Appendices of the dossier should be uploaded in the section "List of annexes, references and checklist":
  - Studies overview
  - Application overview
  - Bioinformatics overview
  - Protein summary
  - ERA info

- Avoid big watermark disclaimers in confidential study reports which might negatively impact the readability of the documents

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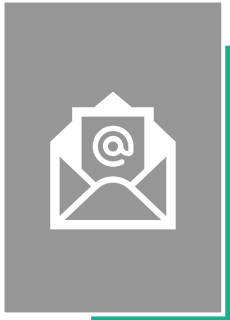

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