UPDATE FROM FDP UNIT ON POST-TR GMO DOSSIERS

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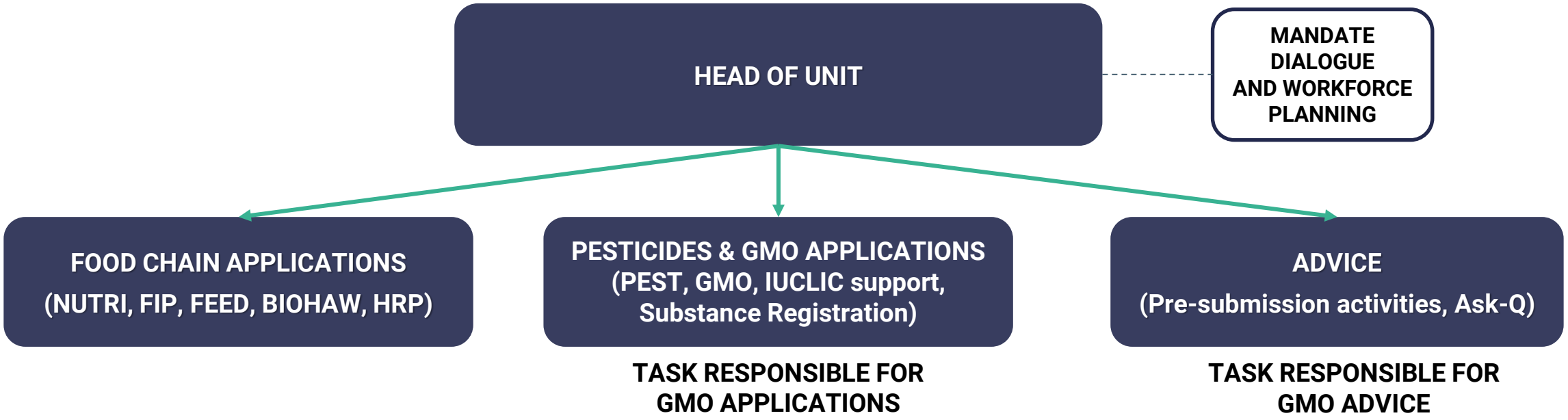

POST-TR GMO DOSSIERS OVERVIEW

- 41 post-TR GMO dossiers have been received so far, since May 2022:

GM PLANTS:

- **10 new single events**
- **7 new stacked events**
- **20 renewals**: 3 in 2022 and 17 in 2024

GM MICROORGANISMS:

- **4 new applications** in parallel with FEED

NOTIFICATION OF STUDIES (NOS)

NoS obligations

- Studies must be notified prior to their starting date (art 32b of General Food Law)
- What falls within a definition of "study": Question 4, part B of Q&A to Practical Arrangements (update 28/08/2023)

Studies to be notified

- Stability, efficacy and safety studies
- Studies to demonstrate absence from the product of viable cells and recombinant DNA of a production microorganism

Studies exempted from NoS obligations

- Analysis to assess the **identity/composition of a product**, including the determination of its impurities and whole genome sequencing
- Analysis to determine **physico-chemical properties**
- **Method validation** studies

NOTIFICATION OF STUDIES (NOS)

Examples of **safety studies** to be notified in a GM plant application

- **Toxicity studies:** e.g., 90-day oral study, 28-day oral study, acute oral toxicity
- **Human or animal testing** for assessing the allergenic potential of Newly Expressed Proteins (NEPs)
- **Evaluating agronomic and phenotypic endpoints:** includes, among others, information on biotic and abiotic stressors, and addresses aspects relevant for the environmental fate and behaviour of the GM plant (thus going beyond the sole characterisation of the GM plant)

Examples of **studies exempted from NoS** in a GMO application

- **Molecular characterisation, protein characterisation, compositional analysis**: corresponds to analytical measurements to assess the identity/composition of the GM plant and to determine its physico-chemical properties

PRE-SUBMISSION ACTIVITIES & ASK A QUESTION

Notification of studies (NoS)

- For questions on type of studies to be notified (question 4 to the Q&As on EFSA's Practical Arrangements), please contact EFSA via the Ask a question tool

General Pre-submission Advice (GPSA)

- For questions regarding the applicable rules and the content of guidance documents in preparation of your application (instructions for requesting a GPSA in section 3.11 of the User guide on pre-application ID)

Ask a Question

- For questions regarding the status of applications, procedural steps, administrative/scientific requirements and/or IT tools (webform)

SUBMISSION TIPS – RFI RESPONSES

RECOMMENDATIONS TO REPLY TO EFSA'S REQUEST FOR INFORMATION (RFI):

- When asked for missing information, please, integrate the missing information into the corresponding documents **of the dossier** or in the metadata of each document, as applicable. Do not only provide the information in the response to the RFI.

- Using the free-text box available in each section of the ESFC platform, indicate the changes made with a brief description of the new information provided.

SUBMISSION TIPS - REFERENCES

Articles/publications available in the public domain on which the applicant does not have intellectual property rights (IPRs)

- Flag as 'Yes (publicly available), IPR not owned' and include the bibliographic citation in the free-text box 'IPR reference'.

In case of a high number of references (and IPR not owned)

- The use of zipped folders is accepted
- Flag the full folder as 'Yes (publicly available), IPR not owned' and provide the list of bibliographic references in a separate pdf.

Subfolder "0.6_References" in the sequencing package (and IPR not owned)

- We advise the applicant to include the pdf reference files only in the confidential version of the folder and put a list of bibliographic references in the public version.

The list of bibliographic reference is published in Open EFSA upon validation, but not the corresponding IPR-protected pdf files.

MORE SUBMISSION TIPS

LATEST GMO GUIDANCE DOCUMENTS PUBLISHED:

2024 Technical Note on the **quality of DNA sequencing** for the molecular characterisation of genetically modified plants (replacing the 2018 version)

2023 **Animal dietary exposure** in the risk assessment of feed derived from genetically modified plants

Please, make sure to follow their requirements. Otherwise, it will be asked in the RFI.

OTHER RECURRENT RFIs:

- Confidentiality: please, pay attention to:
  - the correspondence between confidential and public files and earmarked vs. sanitized information.
  - the presence of exposed personal data.
- Bioinformatic analyses: in case of old database release dates without proper justification, explanations are asked in the RFI.

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