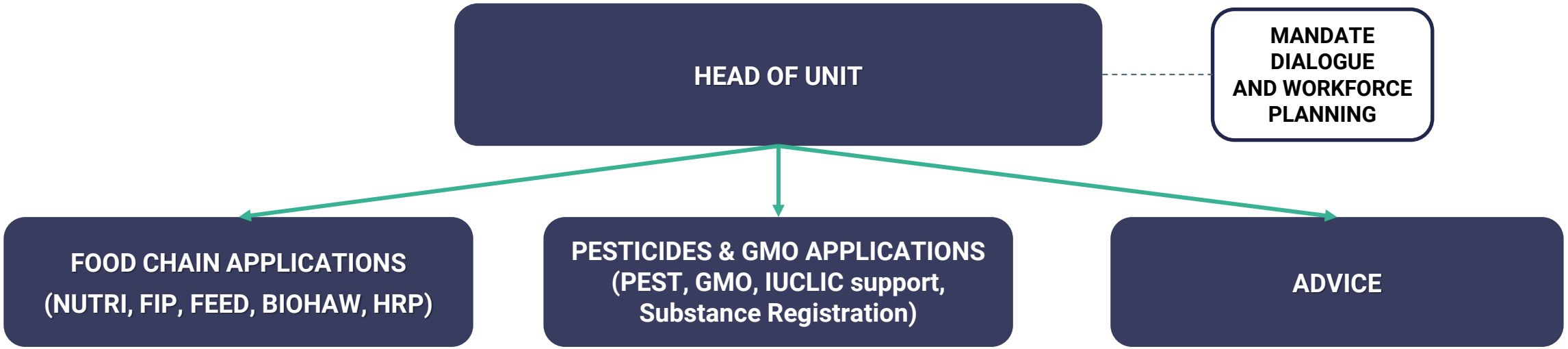
UPDATE FROM FDP UNIT ON POST-TR GMO DOSSIERS

efsa
EUROPEAN FOOD SAFETY AUTHORITY

FDP UNIT

FDP: Front-Desk & Workforce Planning



POST-TR GMO DOSSIERS

- 27 March 2021: implementation of the Transparency Regulation (Reg. (EU) 2019/1381)
- 18 post-TR GMO dossiers have been received so far, starting in May 2022:

GM PLANTS:

- 8 new single events
- 3 new stacked events
- 3 renewals

GM MICROORGANISMS:

- 4 new applications in parallel with FEED

ESFC TABLE OF CONTENT FOR GMO DOSSIERS

- 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
- The only ToC currently available for GMO dossiers is specific for **GM plants**

- EFSA and DG SANTE are finalising a Request for Change which will result in a **simplified ToC for e-submission of GMO dossiers, valid for all organisms**
- The estimated timeline to have the new ToC implemented is end of October 2023
- Note: The new ToC will only be deployed for NEW dossiers, not for ongoing nor for draft dossiers.
- Updated EFSA Administrative guidance and ESFC user manual will be published

ESFC TABLE OF CONTENT: NEW APPLICATION

Administrative Data	
Applicant's contact details	
Contact person/Person responsible for the dossier	
Applicant's EU representative contact details	
Subject of the request	
Scope of the application	**GMOs for food use**
	Food containing or consisting of GMOs
	Food produced from or containing ingredients produced from GMOs
	GMOs for feed use
	Feed containing or consisting of GMOs
	Feed produced from GMOs
	Genetically modified plants for food or feed uses
	Products other than food and feed containing or consisting of genetically modified plants with the exception of cultivation
	Seeds and plant propagating material for cultivation in the Union
Risk Assessment of presence at low level of genetically modified plant material in imported food and feed	
Existing authorisations in non-EU countries	Country
	Status
Data sharing agreement in place	
Cover Letter	

Summary	
Public Summary	

ESFC TABLE OF CONTENT: NEW APPLICATION

Technical Dossier	
Pre-Application Information	
Have you received a pre-application identification from EFSA?	Pre-Application Identification
If necessary, please provide the study identifications of studies that have been notified in the database of study notifications (established by EFSA) that have not been included in this application and/or have been withdrawn from the database. In addition, please provide justifications explaining the reasons why these studies were not included or withdrawn, respectively.	EFSA study identification
	Justification
Part I - General Information	
Unique Identifier	
General Information	
Part II - Scientific Information	
Hazard identification and characterisation	Information relating to the recipient or (where appropriate) parental organisms
	Molecular Characterisation
	Comparative analysis
	Toxicology assessment
	Allergenicity assessment
	Nutritional assessment
Exposure assessment - Anticipated intake/extent of use	
Risk characterisation	
Post-market monitoring on the genetically modified food or feed	
Environmental Risk Assessment	
Environmental Monitoring Plan	
Additional information related to the safety of the genetically modified food or feed	
Part III - Cartagena Protocol	
Part IV - Labelling	
Part V - Methods of detection, sampling and reference materials	
Part VI - Additional information to be provided for GMOs and/or food/feed containing or consisting of GMOs	
List of annexes, references and checklist	

ESFC TABLE OF CONTENT: RENEWAL

Administrative Data	
Applicant's contact details	
Contact person/Person responsible for the dossier	
Applicant's EU representative contact details	
Subject of the request	
Existing authorisations in the EU	Country
	Status
Existing authorisations in non-EU countries	Country
	Status
Data sharing agreement in place	
Cover Letter	

Summary	
Public Summary	

ESFC TABLE OF CONTENT: RENEWAL

Technical Dossier	
Pre-Application Information	
Have you received a pre-application identification from EFSA?	Pre-Application Identification
If necessary, please provide the study identifications of studies that have been notified in the database of study notifications (established by EFSA) that have not been included in this application and/or have been withdrawn from the database. In addition, please provide justifications explaining the reasons why these studies were not included or withdrawn, respectively.	EFSA study identification Justification
General Information	
Unique Identifier of the authorised GMO	
General Information	
Information to support the Risk Assessment	
The authorisation for the placing of the GM food and/or feed onto the market in the EU	
Post-market monitoring and post-market environmental monitoring reports	
New information- Systematic search and evaluation of literature	
New information- Updated bioinformatics	
New information- Additional documents or studies performed by or on behalf of the applicant	
New Information- Overall assessment	
Monitoring plan and proposal for improving the conditions of the original authorisation	
Cartagena Protocol	
Labelling	
Methods of detection, sampling and reference materials	
Post-market environmental monitoring plan	
List of annexes, references and checklist	

ESFC TABLE OF CONTENT: RFI INFO

- Each section of the dossier is unlocked for modifications by the applicant only in case Request of Information (RFI) is done by EFSA in that section
- Note that, with the simplified ToC, broader sections will be unlocked by the RFIs
- Please, always indicate the changes made in the dossier, also if not requested by EFSA (spontaneous changes)

- In case of need for changes in sections that are NOT unlocked by an RFI:
  - If the application is with the applicant: re-submit your dossier at your earliest convenience, indicating the requests that have been addressed so far and the requests for opening additional section(s). We will then open the sections indicated.
  - If the application is with EFSA: send an email to FDP (FDP@efsa.europa.eu) clearly indicating the sections that need to be unlocked. As soon as we have completed the check, we will issue a new RFI and open all the needed sections.

SUBMISSION OF BIOINFORMATIC STUDIES

- For practical reasons related to their assessment, we kindly ask the applicant so submit all bioinformatic studies in the section "**Molecular characterization**":
  - Flanking sequences (disruption of known coding sequences or regulatory elements)
  - Open reading frames in flanks: similarity to toxins and allergens
  - Open reading frames in the insert: similarity to toxins and allergens
  - Newly expressed proteins: sequence similarities with allergens, toxins, or other biologically active proteins
  - Newly expressed proteins: coeliac disease potential
  - Homologous recombination / Horizontal Gene Transfer (HGT)

NOTIFICATION OF STUDIES

- Obligation to notify studies prior to their starting date (art 32b of the General Food Law Regulation, as amended by the Transparency Regulation)
- Update of the Q&As on EFSA's Practical Arrangements (28 August 2023) exempting certain analytical measurements from notification of study obligations (see question 4)
- For questions on the Q&A update, please contact EFSA via the Ask a question tool

LOA

- GM plants containing stacked events: Letter(s) granting consent of access to applications for concerned single events from the applicant owning the respective information.
  - We kindly invite the applicants to include in the LoAs for specific studies (e.g. 90 day) all the details that could help EFSA to easily retrieve the information, like Study nr + author + date

- GM plants containing single events: As clarified by the European Commission*, single events should be subject to separate and stand-alone applications.
  - We encourage the applicants to avoid the use of LoAs in single event applications, and to provide all study reports in the dossier, even if previously provided to EFSA, in order to facilitate CC and RA phases.

*EC letter to EuropaBio [Ref. Ares (2013)3227877-11/10/2013]

FINAL TIPS: HARMONISATION OF APPLICATION SUBJECTS

In FDP we are working on the harmonisation of applications subjects, per area, and will be shown in OpenEFSA as follows:

GM PLANTS

- Application for **authorisation** of genetically modified *GM event + organism* in accordance with Regulation (EC) No. 1829/2003
- Application for **authorisation** of genetically modified *GM stacked events + organism and (part of) its subcombinations* in accordance with Regulation (EC) No. 1829/2003
- Application for **renewal** of genetically modified *GM event + organism* in accordance with Regulation (EC) No. 1829/2003
- Application for **renewal** of genetically modified *GM stacked events + organism and (part of) its subcombinations* in accordance with Regulation (EC) No. 1829/2003

GM MICROORGANISMS (Category 3)

- Application for **authorisation** of *product* from genetically modified *microorganism (genus + species + strain)* in accordance with Regulation (EC) No. 1829/2003
- Application for **renewal** of *product* from genetically modified *microorganism (genus + species + strain)* in accordance with Regulation (EC) No. 1829/2003

CLE OBSERVATIONS

- **In case of a clarification question, relevant sections of the application are sometimes locked and cannot be used for answering the question**
  - Proposal: All relevant sections should be unlocked in case of EFSA questions

- **In view of the agreed format of uploading sections in Part II, when sending questions, the relevant higher level of a specific section should be unlocked as well as sections where Annexes, References, Appendices are supposed to be uploaded.**

- ***If the application structure in E-SFC will not be changed in the short term, is there pragmatic way to fill in the sections that are not used (currently, for all of those sections, applicants need to tick "not applicable" and then provide a justification)?***

CLE OBSERVATIONS

- Some study types in the dropdown list are duplicated
- Please consider the given day (and not specific time) when establishing deadline for the response
- *How is EFSA using the completeness check list (Appendix A) and other Appendices? Are they still useful and needed ?*

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