AD HOC MEETING WITH
INDUSTRY REPRESENTATIVES
5-6TH OCTOBER 2023

# E2E RISK ASSESSMENT PROCESS & CONFIDENTIALITY ASSESSMENT

EUROPEAN FOOD SAFETY AUTHORITY

# PRE-TR APPLICATIONS: STATE-OF-PLAY [UPDATE 05-10-2023]

Number of pre-TR dossiers @EFSA: **15**

**1** stopped at CC phase [Additional Information to be delivered to EFSA]

**3** stopped by “single first principle”

**3** stopped >6 months [Additional Information to be delivered to EFSA]

**8** ongoing Risk Assessment

- **6** StC [Additional Information to be delivered to EFSA]
- **1** StC [Additional Information to be delivered to EFSA] + StC EURL
- **1** StC EURL

# POST-TR APPLICATIONS: VALID DOSSIERS [UPDATE 05-10-2023]

| DOSSIER ID | VALIDATION DATE | MEMBER STATE | CROP | EVENT |
|---|---|---|---|---|
| GMFF-2022-5890 | 29/08/2022 | NL | maize | SINGLE |
| GMFF-2021-2473 | 21/12/2022 | NL | maize | SINGLE |
| GMFF-2021-1530 | 09/01/2023 | NL | maize | SINGLE |
| GMFF-2022-6595 | 01/12/2022 | NL | soybean | SINGLE |
| GMFF-2021-0071 | 04/05/2023 | NL | maize | SINGLE |
| GMFF-2022-11270 | 16/05/2023 | NL | oilseed rape | STACK |
| GMFF-2022-11530 | - | BE | soybean | SINGLE |
| GMFF-2022-10651 | 02/05/2023 | NL | maize | SINGLE |
| GMFF-2022-6232 | 20/06/2023 | NL | maize | STACK |
| GMFF-2023-14732 | - | NL | sugarbeet | SINGLE |
| GMFF-2023-17394 | - | NL | soybean | STACK |

# POST-TR APPLICATIONS: RA STATE-OF-PLAY [UPDATE 05-10-2023]

| | |
|---|---|
| GMFF-2022-5890 | RA ONGOING<br>RUNNING |
| GMFF-2021-2473 | RA ONGOING<br>STOPPED |
| GMFF-2021-1530 | RA ONGOING<br>STOPPED |
| GMFF-2022-6595 | RA ONGOING<br>STOPPED |
| GMFF-2021-0071 | RA ONGOING<br>STOPPED EURL |
| GMFF-2022-11270 | RA ONGOING<br>STOPPED |
| GMFF-2022-11530 | CC PHASE |
| GMFF-2022-10651 | RA ONGOING<br>RUNNING |
| GMFF-2022-6232 | STOPPED<br>SINGLE FIRST PRINCIPLE |
| GMFF-2023-14732 | CC PHASE |
| GMFF-2023-17394 | CC PHASE |

# RENEWAL 2024 WORKPLAN

Number of Renewal dossiers expected in 2024: **18**

the 18 RX dossiers are expected to be submitted: **February-April 2024**

- **Single Events 15**
- **Stack Events 3**
- **Crops: maize [5]; soybean [5]; cotton [7], oilseed rape [1]**

# CLE ADMINISTRATIVE OPEN POINTS: ADDITIONAL DATA REQUEST

- To refer to study reports, please consider using study report numbers instead of study author names when sending questions. This would reduce time for preparation of submission packages by reducing unnecessary confidentiality claim requests.

# CLE ADMINISTRATIVE OPEN POINTS: ADDITIONAL DATA REQUEST

- **The system allows only for one set of questions to be handled at the same time**
  - Proposal: It should be possible for EFSA to send any new questions as soon as available (as done in the past e.g. the clock remains stopped)

**YES,** it is feasible for EFSA to deliver “parallel” ADRs to the applicant

**Outline Procedure**

- “parallel” **ADR-N** is anticipated by E-mail [attached Cover Letter + Annex] and uploaded in ESFC upon delivery of Additional Information [**ADR-N-1**]
- the corresponding Additional Information will need to be submitted via ESFC

Contact: ral@efsa.europa.eu

# CLE ADMINISTRATIVE OPEN POINTS: ADDITIONAL DATA REQUEST

- *How to deal with sets of questions that have different deadlines (within the same request)?*
- *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)?*

**YES,** it is feasible for the applicant to deliver "partial" Additional Information via ESFC

**Outline Procedure**:

**APPLICANT**
- uploads the reply in the relevant section
- indicate "in the section/s that is/are not ready that the information is "under preparation" and any other relevant input (e.g. expected date of submission of the missing information/data)

**EFSA**
- download the partial Additional Information > Risk Assessment by GMO Experts
- issue a "follow-up ADR" on the pending sections

The clock remains stopped until all requested AI are submitted

Contact: ral@efsa.europa.eu

# CLE ADMINISTRATIVE OPEN POINTS: SPONTANEOUS INFORMATION

48 Spont AI were received in the period 2019 [January 1st]-2023 [October 1st]; 52 applications were screened [41%]

Administrative guidance for the processing of applications for regulated products (update 2021)

**2.13** "The spontaneous submission of information by an applicant on its own initiative and without a formal request for information by EFSA is possible but limited to **newly produced data** and/or information which was **not available** to the applicant **at the time of the submission** of the application and/or information which was **not previously requested** by EFSA. Spontaneous information should be submitted **as early as possible during the Risk Assessment process**, and the applicant should **explain how it may influence the Risk Assessment**"

Administrative guidance for the preparation of applications on genetically modified plants (update 2022)

**2.11** "The spontaneous information should be provided through the ESFC **exclusively following preliminary contact with the relevant EFSA Unit** which will indicate the path to submit the spontaneous information"

**Outline ESFC Procedure**:

- contact ral@efsa.europa.eu with the request and justification to open the relevant ESFC section for the upload of the Spontaneous Information
- upload in the relevant section/s and submit
- No stop-the-clock mechanisms

# ADDITIONAL INFORMATION FOR RISK ASSESSMENT

Additional information is submitted upon EFSA's request, and spontaneously by the applicants, as soon as relevant information is available.

Goals: Efficient and shorter review process, facilitate RA workflow and resource planning

- Combination of requests from multiple RA areas; timeline for response
- Written notification to EFSA with a date for submission of additional/spontaneous information, in advance
- Written notification to EFSA on any updates (i.e. anticipated delivery) related to the proposed date of additional information submission, in advance when possible

# POST-TR APPLICATIONS: CONFIDENTIALITY ASSESSMENT STATE-OF-PLAY

As of March 27th 2021, EFSA is in charge of the Confidentiality Assessment of GMO dossiers and Additional Information provided by the applicant throughout the the Risk Assessment phase.

Number of post-TR dossiers VALID: **8 new applications + 3 renewals**

Average number of Confidentiality Requests [except personal data]: **52** [high SD]

**6** EFSA Confidentiality Decisions were issued:

- **4** Public Consultations were closed [1 new application + 3 renewals] NO public comments
- **2** Public Consultations are open [new applications]

**1** EFSA Confidentiality Draft was issued [new application]

**4** Confidentiality Assessments are ongoing [new applications]

# CONFIDENTIALITY ASSESSMENT – KEY MESSAGES

**Identify clearly the information claimed confidential by**

- referring to all elements claimed confidential and
- locating the information in the document(s) – document, page, paragraph
- avoiding general statements like “throughout the document” and “in all documents”

**Explain why the information should be kept confidential** and ensure that the justification supports the elements earmarked/masked as confidential

**Ensure** that the **earmarking** of the confidential version **corresponds with** the **masking** of the non-confidential version

# CONFIDENTIALITY ASSESSMENT – KEY MESSAGES

**Refer to the correct legal basis.** When the qualification is not self-evident, **you must justify why this element falls under that legal basis**

**Ensure that information claimed confidential** in one part **is not visible in another part** of the document

**Ensure** that the **condition boxes are ticked** and/or **additional justification is provided**

**Properly name documents** to avoid confidential information in the file name and distinguish between the confidential and non-confidential version

# CONFIDENTIALITY ASSESSMENT – KEY MESSAGES

Provide functioning e-mail address and ensure **business continuity** (e.g. referring to **functional mailbox**)

**Faster reply** to EFSA`s requests for clarifications **=** **faster processing** of your confidentiality requests

If you **agree with EFSA`s draft decision + reply immediately** to EFSA expressing explicitly your agreement **= faster issuance of the final decision**

# CLE ADMINISTRATIVE OPEN POINTS: CONFIDENTIALITY ASSESSMENT

- As regards the confidentiality assessment, the system does not allow to identify partial acceptance/rejection which creates confusion

- Timely confidentiality assessment as in some cases it has not been completed after more than 35 weeks from validity and it delays in the launch of the public consultation.

# EFSA REPLY: CONFIDENTIALITY ASSESSMENT

## Partial acceptance/rejection

- EFSA explored the possibility of better reflecting the status "partially rejected/approved".
- EFSA's confidentiality assessment tool was developed, and the applicant can now verify whether a confidentiality request has been partially rejected/approved rather than completely rejected by looking at the columns "EFSA decision" and "EFSA considerations" in the Annex of the draft/final decision which can be downloaded via ESFC and which states clearly for which elements confidentiality has been rejected.

## Timely confidentiality assessment

- Due to the large number of confidentiality requests received and in order to avoid the delay of the launch of the public consultation, EFSA currently assesses the confidentiality requests in line with a priority indication provided by the relevant Scientific Unit.

# LITERATURE SEARCH

- Launched a call for a new contract on ‘Methodological support for the performance of literature reviews within evidence-based scientific assessments’
- Assessment of compliance to the EFSA Explanatory Note on Literature Searching (EFSA, 2019)
- The Contractor will be requested to assess the Literature Search and Literature Updates packages submitted in Applications and Renewals dossiers
- 18 months from signature date

# LITERATURE SEARCH

In a previous GMO Applicants' meeting (19 May 2022):

Applicants highlighted the importance to preserve possibility of balanced and pragmatic approaches in line with the Explanatory Note

- Questions received that are NOT required by the Explanatory Note
- Not common practice for literature searches in general

- EFSA is taking into consideration the requests of the applicants and will continue to do so with the new contractor, in order to guarantee a leaner process.
- EFSA reserves the right to ask those questions, if needed

# LITERATURE SEARCH

From the **Explanatory Note on Literature Searching** (EFSA, 2019):

**Eligibility screening process**

- Rapid assessment (stage 1) for relevance based on information in the title and abstract of publications.
- Detailed assessment of full-text documents (stage 2).

**3.5.1.2. Results of the publication selection process**

- list of the bibliographic references for all excluded publications after detailed assessment of full-text documents for relevance, with justification for their exclusion.

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**EFSA to ask the applicants to provide a full list of all excluded publications from the first stage of eligibility screening process**

# Q&A