

CropLife Europe - Administrative & procedural topics

Ad hoc meeting EFSA – GMO applicants
18 October 2021

Introduction



- This presentation is a continuation of an annual dialogue between EFSA and industry on administrative and procedural topics
- CropLife Europe would like to share experience and suggestions for procedural efficiency



Positive developments

- **Administrative guidance for the processing of applications for regulated products**
 - Clearly structured completeness check
 - After validation, for some applications risk assessment (RA) of different parts have been conducted in parallel
- **Streamlined process for renewal applications**
- **Use of transition periods**
- **Introduction of pre-submission advice**



Areas for improvement

Risk assessment timelines

- *“the Authority shall endeavour to respect a time limit of six months”*
- Average RA timeline in 2020-2021 is ~ 5 years for new products

Proportionate risk assessment including for breeding stacks

Number of “guidelines” and complexity

- ~ 35 guidelines applicable to GMOs since 2006

Interpretation of legislation and guidelines

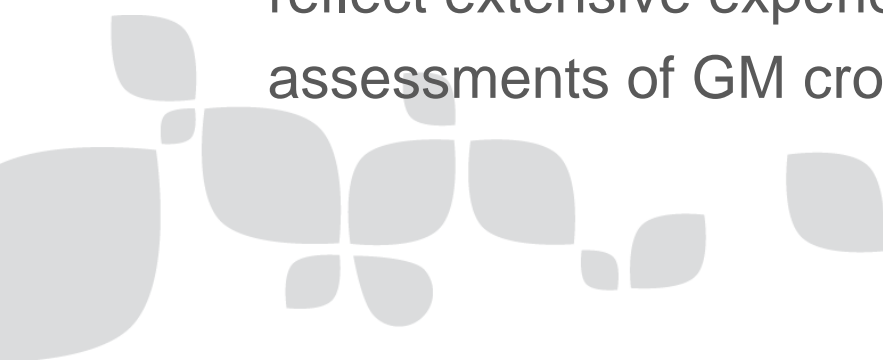


Suggestions for improvements



More transparency and proportionality of guidelines development

- with early involvement of applicants
- identification of the need and added value for RA
- ensuring proportionality principle as required by EU treaties
- realistic transition periods and clear description of elements included within the transition period
- reflect extensive experience of EFSA in the safety assessments of GM crops



Suggestions for improvements

- ▶ **Consistent interpretation** of legislation and guidelines
- ▶ **Improved dialogue** with applicants during risk assessment (e.g. applicants' hearings)
- ▶ **Consolidation of questions** during RA with key questions to be sent within 3 months of dossier validation, incl. their scientific rationale
 - In line with the Administrative guidance for the processing of applications for regulated products



Suggestions for improvements

- Questions from **JRC-EURL** should not prevent EFSA to risk assess the application and publish a scientific opinion
 - Consistent application of the stop-the-clock/restart mechanism also as regards JRC-EURL requests
- **Rationalisation of the risk assessment** incl. of breeding stacked events (proportional RA)



Suggestions for improvements


- ▶ **Science-based flexibility** in data requirements on a case-by-case basis e.g.
 - derogations incl. a clear mechanism to request/process them (Art. 5 of IR 503/2013)
 - limitation of the application's scope (Art. 27 of Regulation 1829/2003)
- ▶ **Transparency** on the planned meetings and agendas (GMO Panel WGs, Scientific Network for GMOs)



Transparency Regulation

Introduction of new IT tools

- Open EFSA portal
- EFSA Connect : Notification of Studies Database
- E-submission Food Chain platform

 ***Flexibility*** needed in use of new tools,
*and timely information in advance of
changes to the systems*



Open EFSA portal

- The new website is difficult to navigate and less transparent
- The meta data is not complete
- Delays in availability of information
- Issues with accessing information on individual dossiers
- Impossible to have overview of mandates

Suggestions

- *Display missing information*
- *More search options and filters to be added*
- *Export function of the search results*

Example



Other sites: EFSA OpenEFSA EFSA Journal Connect

efsa | open Home Questions Experts Calendar Search

DAS-81910-7

Filter

GMO x

GMO - EFSA-Q-2018-00457

Application for the placing on the market of genetically modified maize MON 89034 x 1507 x MIR162 x NK603 x DAS-40278-9 and sub-combinations independently of their origin,...

07/09/2021
Status: Ongoing Risk Assessment

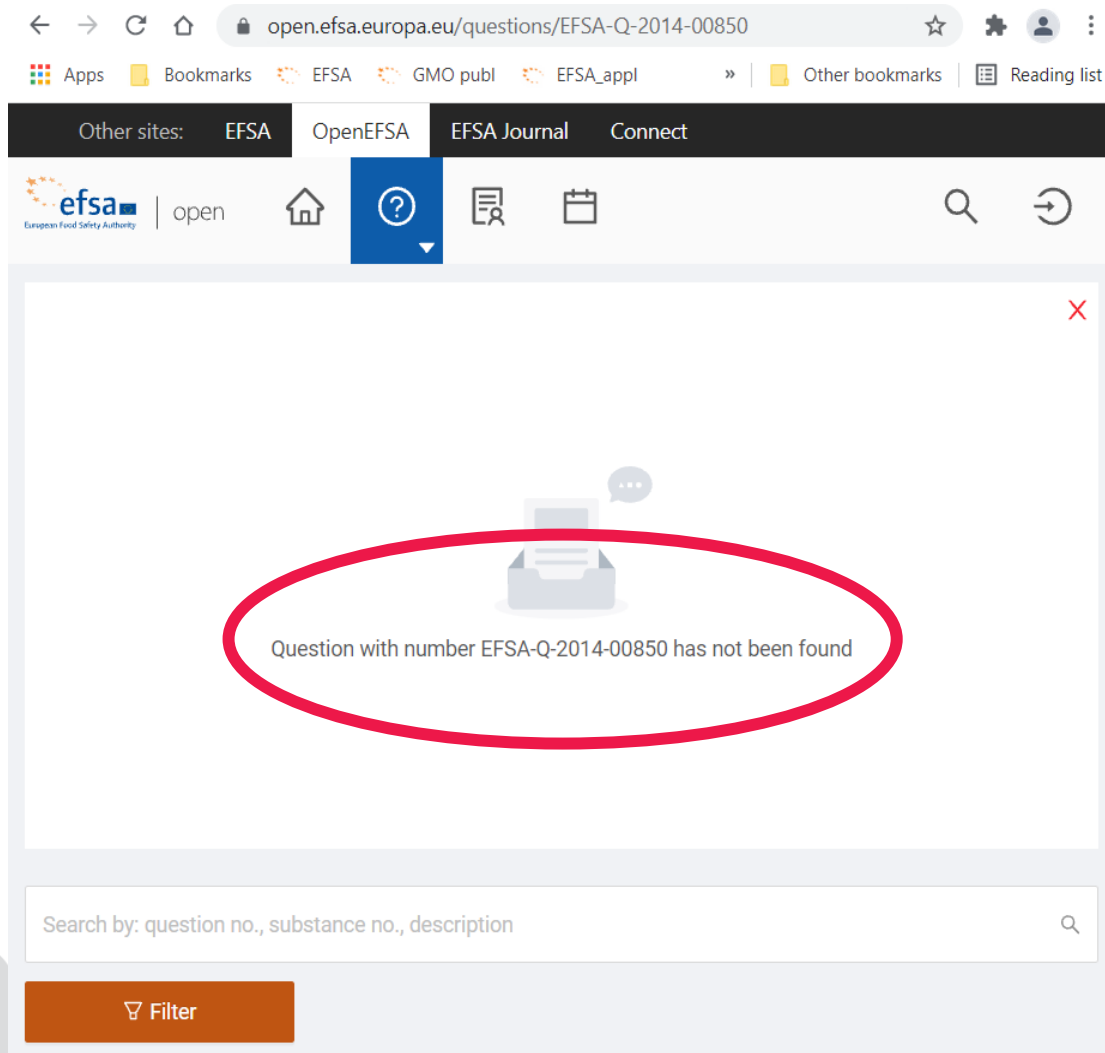
GMO - EFSA-Q-2020-00796

Assessment of new sequencing information on genetically modified cotton DAS-24236-5 x DAS-21Ø23-5

03/08/2021
Status: Ongoing Risk Assessment

Clockstop expected until 03/10/2021

Example



← → ↻ 🏠 🔒 open.efsa.europa.eu/questions/EFSA-Q-2014-00850 ☆ ⚙️ 👤 ⋮

📱 Apps 📁 Bookmarks 🌐 EFSA 🌐 GMO publ 🌐 EFSA_appl » 📁 Other bookmarks 📖 Reading list

Other sites: EFSA OpenEFSA EFSA Journal Connect

efsa European Food Safety Authority | open 🏠 ? 📄 📅 🔍 ↻

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Question with number EFSA-Q-2014-00850 has not been found

Search by: question no., substance no., description 🔍

Filter

EFSA Connect: Notification of Studies Database

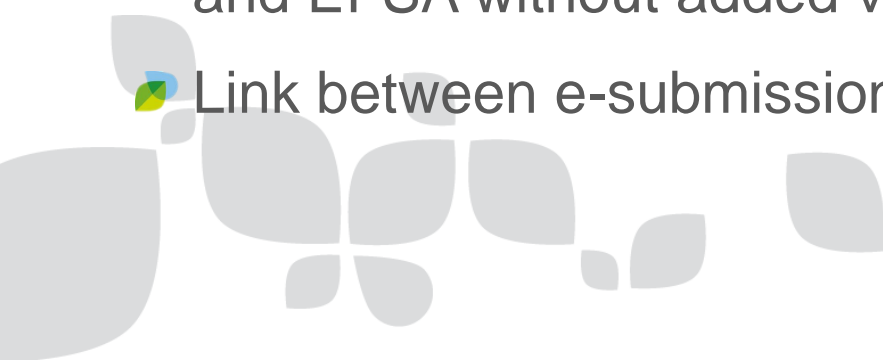
- Need to inform applicants in case of system updates
- CLE would appreciate feedback on how industry suggestions are being considered



E-submission Food Chain platform



- **Size** of a GM dossier can be up to 2 TB with more than 2500 files
- GM dossier divided in **more than 50 parts**
 - Information from one report or reference would be split across different parts
 - Increase the potential for errors
 - Challenging to have an overview of the application and even of one part (e.g. comparative assessment)
- **Increased complexity and workload** both for applicants and EFSA without added value
- Link between e-submission & EFSA Connect established?

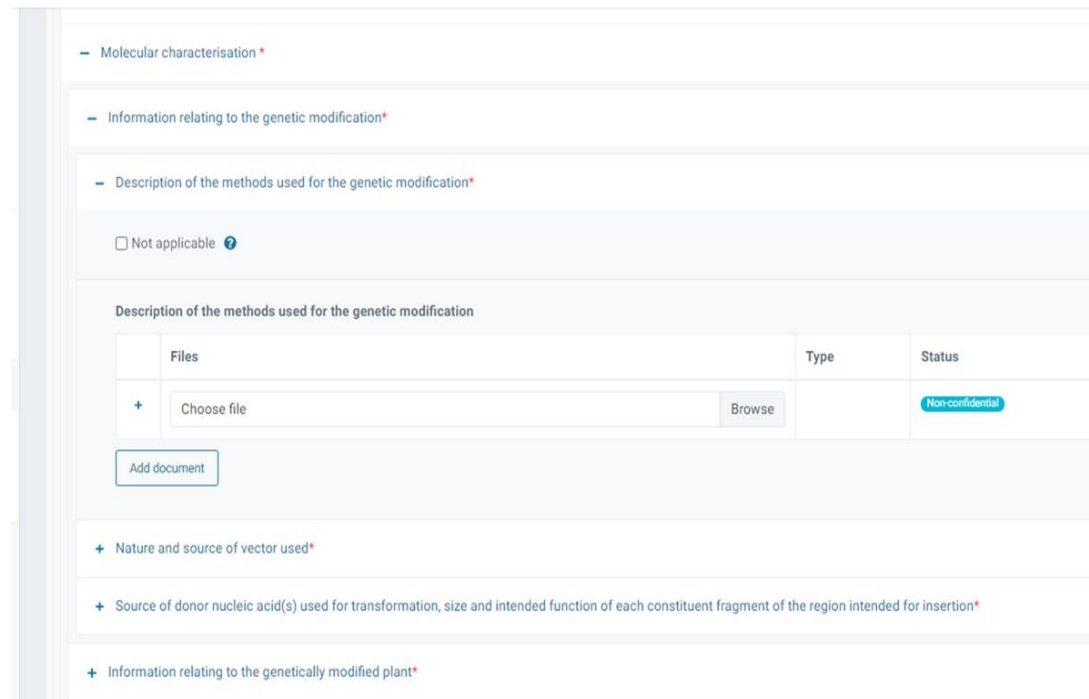


E-submission Food Chain platform




Suggestion:

- *Applicants would include all information under the first heading of each section and avoid further subdivision*



The screenshot displays a web form interface for the E-submission Food Chain platform. The form is organized into several sections, each with a heading and a plus sign to indicate it can be expanded. The sections are:

- Molecular characterisation *** (collapsed)
- Information relating to the genetic modification*** (collapsed)
- Description of the methods used for the genetic modification*** (expanded)
 - Not applicable 
 - Description of the methods used for the genetic modification**
 - A table with columns: Files, Type, and Status.
 - Under the Files column, there is a "+ Choose file" input field and a "Browse" button.
 - Under the Status column, there is a "Non-confidential" button.
 - Below the table is an "Add document" button.
- Nature and source of vector used*** (collapsed)
- Source of donor nucleic acid(s) used for transformation, size and intended function of each constituent fragment of the region intended for insertion*** (collapsed)
- Information relating to the genetically modified plant*** (collapsed)