

A decorative graphic in the top-left corner consisting of several overlapping, rounded leaf shapes in various colors: red, yellow, orange, light green, dark green, and blue.

CropLife Europe's inputs to the 2nd Meeting of EFSA Tools Technical Group

Key messages

- **CLE sees the system developing positively with continuous improvements being made**
 - EFSA staff responsiveness is much appreciated.
- **We see opportunities for improvement in order to increase efficiency and accuracy of the system and data**
- **Opportunities for exchange and continuous dialogue are very much appreciated**

Open.EFSA

- No possibility to sort results
- Not feasible to conduct analysis of trends and derivation of statistics (e.g., not possible to track dates of submissions)
- Export function: the authorisation type, substance column, dossier received date are empty in the CSV file (for Pesticide Peer Review AIR)
- EFSA self-mandates are difficult to retrieve without knowing the exact topic to look for
- For some entries, difficulties in easily identifying them, as their display is not user-friendly, e.g., the question number appears in the “subject” field

New Reporting Functionality

- The functionality does not seem fully operational yet. Are improvements/fine tuning on-going?
- Italian language is used, e.g., filters and exporting options. The system language should be English
- When will customized reporting be available to end users?
- A report on all registered Contract Research Organizations (i.e. Labs) would be very useful. Suggest to create that report
- Report “My studies”:
 - ☐ Not all studies are visible, and in some cases NO studies are visible for selected applicants
 - ☐ Grouping by the unique EFSA StudyID does not create groups. If grouping is needed, it should be by the Pre-Application ID, or by relevant test item
 - ☐ The Pre-Application ID is missing. The report only contains the request name
- Possibility to extract a report including the justification of delay fields would be very helpful
- Status withdrawn not visible, studies indicated as draft, which is very relevant difference with respect to follow-up actions
- Is the reporting function accessible to Member States? What is the timing of the report generation ahead of the dossier submission?

 In the future, an import functionality allowing for validation would increase efficiency of the notification process.

Connect EFSA

■ 'Add Studies to Pre-Application ID'

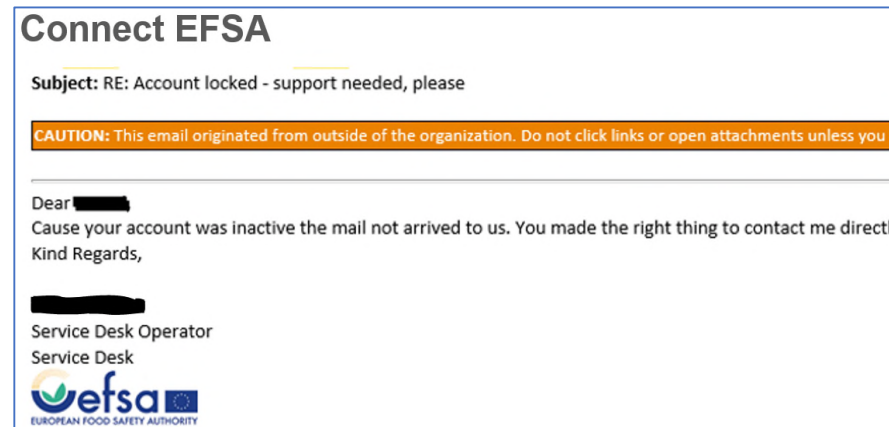
- Unresponsive wait times when performing any action within window
 - Searching for studies to add to pre-app ID

■ Study notification and matching requests

- Information provided at the time of Study notification will never match exactly the Study information present on the study report (i.e. Study report title, study dates). Applicants receive inconsistent requests to update all study notifications to exactly match the study reports. This seems unnecessary as it doesn't prevent the ability to match notified studies to their respective application in IUCLID/ESFC.

■ Account lock

- Tool locks access after one password attempt. Once access is locked, e-mails to the EFSA service desk to open a ticket aren't received because user has no 'active' account. Was only able to reinstate access by e-mailing a member of staff directly:



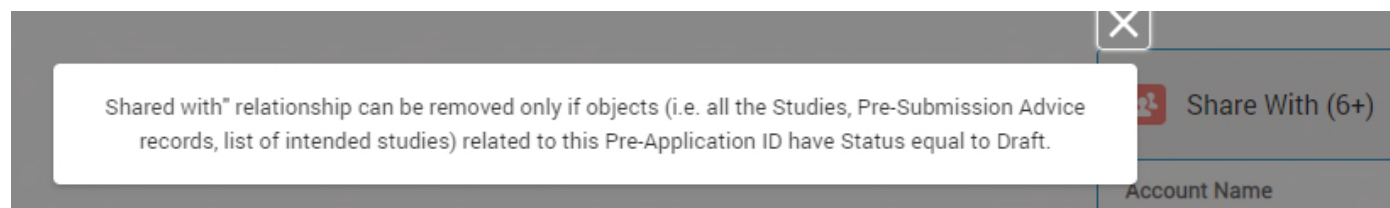
Connect EFSA

Editing Sharing settings

- It is currently only possible to remove 'shared with' relationships on 'draft' status notifications or pre-app IDs where ALL objects are in 'Draft' status. It must be possible to modify the 'shared with' relationship on notified studies and pre-app IDs, in case a Task force membership changes, or a study ownership is divested to another company, after a study is notified, or the pre-app ID has been submitted for the R-PSA process.

Case Study

- Renewal Pre-App ID for active substance created by leading applicant of Task Force
- Pre-app ID 'Shared with' 6 other task force members
- Submitted list of intended studies for R-PSA process
- 6 months later, two members of the Task Force decided to leave the Task Force. Contractually, the exiting members no longer have permission to access study information related to the Task Force
- **However, the leading applicant of the Task Force is unable to remove exiting Task Force member from pre-app ID and study notifications, due to system restrictions**



- Consequence of system restrictions: Confidential information in the EFSA database is now transparent to non-contractually obligated industry competitors

Challenges and opportunities for improvement

Data Owner (step 2):

- Can't see what company a contributor account is linked to.
- Can't see any other accounts linked to the same company entity
- Can't see any 'submissions' made by other contributors within the same company
- Contributor shouldn't be able to select ANY company/organization in the drop-down list – only the company entities related to your account should be visible
- Where are organization entities coming from? I.e. only 4 registered entities in ConnectEFSA, whereas there are at least 12 entities registered within Portalino for the same organisation
- GDPR conflicts – can see personal information related to ALL organisations

Contact (step 3):

- Limitation in the access to a given application (only 1 person allowed as contact) is too restrictive
- Can only select yourself as contact – would be helpful to select others
- E-mail is prepopulated with EFSA account e-mail address that we don't have access to receive e-mails
- Not possible to edit any contact fields – greyed out

Challenges and opportunities for improvement

Confidentiality Request (step 4):

- Good that we can upload zip files, rather than uploading files individually
- Document template provided by EFSA for requesting confidentiality for non-IUCLID related submissions, is not compatible with the format of information as presented in Portalino – no way to easily transcribe document template into Portalino.
- Not possible to upload the document which follows the EFSA guidance to request confidentiality, into Portalino – could be several hundred pages of confidentiality requests
- The field “excerpt of the text” does not seem relevant and necessary, since marked and redacted versions of the document are provided. Suggest to remove it.
- The fields “potential harm, worthiness of legal protection, environmental information and novelty” should not apply in case the selected ground is Art. 39 (e)(1) Personal data. Currently, those are mandatory field for any “ground” selected. Suggest to adapt accordingly – see screenshot on next slide
- LOV in Portalino for ‘Ground’ is a reference to articles, which normally goes into the ‘Justification’ column of the EFSA document template (i.e. ‘GDPR’ is a typical value to put in the ‘Ground’ field of the document template)
- The field “Ground”: the drop-down list is not complete, as it doesn’t include 1107 articles. Suggest to include a complete list
- Character limits within fields (i.e. 'Justification') is far too limiting to capture all confidentiality requests related to a particular article, within a file.
- Still not clear when we need to use Portalino for post-IUCLID and non-IUCLID PPP submissions vs. use the document template. Adding specific examples of when we would be expected to use Portalino would be helpful (i.e. sanitizing DARs/RARs). At the moment, applicants are being requested to use Portalino by EFSA (after already preparing a document with required information), with a very short timeframe provided.

Portalino

- 1. Subject
- 2. Data owner
- 3. Contact
- 4. Confidentiality requests

Confidential version *

+ Select

Public dissemination version *

+ Select

Confidentiality Request

Create each confidentiality request specifying the name of the file in which the request is present, the ground, the justification for each ground, the excerpt of the text, the related section and the confidentiality conditions. Your request will be sent to EFSA upon clicking the Submit button, after submitting no further changes will be allowed.

File name 1

Ground * ?

-- Select a ground --

Justification * ?

0 / 4000

Excerpt of the text *

0 / 4000

Related section *

0 / 255

Potential harm *

☐ Yes ☐ No

Worthiness of legal protection *

☐ Yes ☐ No

Environmental information * ?

☐ Yes ☐ No

Novelty *

☐ Yes ☐ No

+ Add another request