



# **Digital enhancements overview**

To implement the provisions of the Transparency Regulation, EFSA has introduced new digital tools and a dedicated web portal. Since March 2021, when the regulation entered into application, EFSA has been working to enhance these tools. These improvements will continue over the coming months, taking into consideration user feedback.

This document contains information about the main upcoming digital enhancements, the timing of the releases and the specific changes that will be implemented. The overview will be regularly updated and is subject to change.

Applicants can find more information about digital tools and portals pertaining to the submission of applications, as well as training sessions, animated tutorials and other supporting material on the <u>Applications toolkit</u> page.

# **Upcoming IT enhancements on April 12 2023 \*:**

# e-submission of applications through ESFC

- Relevance for:
  - Applicants and/or their Consultants

- ESFC applicants will now be notified directly in the ESFC platform when a review of an initially accepted confidentiality request, in line with Article 39c of Regulation (EC) No 178/2002 (hereinafter "Article 39c"), is initiated.
- ESFC applicants will also be notified of the relevant Article 39c draft decision directly in the ESFC platform, on which they may submit comments.
- ESFC applicants will receive the Article 39c decision directly in the ESFC platform, against which they may submit a confirmatory application, challenging EFSA's Article 39c decision to reject a confidentiality request, and receive a decision thereon.
- ESFC applicants will now be able to provide study information such as the EFSA Study Identification ID, study details and related justifications for the following 3 additional document types:certificate of analysis, raw data and other supporting documents.
- ESFC applicants will now be able to use a new workflow to manage all the activities that
  follow the submission of complementary information following an EFSA inconclusive
  scientific opinion related to feed additives, in compliance with the regulation in place. The
  submission of feed additives applications will now be carried out through the ESFC platform
  only.



#### Notification of Studies through Connect.EFSA

- Relevance for:
  - External users registering on behalf of their organisation or users registered by EFSA

#### New functionalities:

- The co-notification process has been simplified by removing the "co-notify with remarks" option. External users will still be able to add comments/remarks when going through the conotification process.
- Users will have the possibility to select a co-notifier already at the creation of the study record or while this is in a draft status. When submitting the study notification, they will be able to confirm or change this information.
- During the co-notification process, laboratories based outside the EU will receive an email alert if they have been included in a study notification: they will not be required to register and conotify the study, but will still be allowed to do so, should they wish to.
- During the co-notification process, if the co-notifier realises they have been wrongly assigned to a study notification, they can promptly inform the notifier about the mistake by entering the "Select Operations"-menu of the relevant study record and checking the "Wrong Co-notifier"-box. The notifier will then be able to amend and correct the mistake within a timely manner.
- Enhancements to the recently introduced reporting functionality will be made available. This will include a new default pre-application ID group on study reports and a new report listing all studies will be introduced.

# Public Access to Documents (PAD) through Connect.EFSA

- Relevance for:
  - o External users registering on behalf of their organisation or users registered by EFSA
  - All users of Connect.EFSA

- The Ask a Question form has been redesigned with a new and simpler interface that will help registered and unregistered users in the selection of their area of interest to easily choose to which service they want to direct a question and to select the Public Access to Documents (PAD)-option knowing that this entails a processing of the request under the provisions of Regulation (EC) No 1049/2001.
- External registered or unregistered users accessing Connect.EFSA will be able to submit applications for access to documents by uploading files in support of their request together with filling in the mandatory fields in the Ask a Question form.



# Competent Organisations list in Connect.EFSA

- Relevance for:
  - All users of Connect.EFSA

#### New functionalities:

Visitors of the EFSA website viewing the list of Competent organisations (i.e., the organisations designated under Art. 36 of Regulation (EC) 178/2002) will have more possibilities to search for organisations through increased filtering options. They will be able to filter by country, combinations of scientific competences, combinations of remits and search by organisation name or abbreviated name. They will also be able to export the search results.

# **OpenEFSA**

- Relevance for:
  - o All users of OpenEFSA

- OpenEFSA will include a new section on experts, showing the list and composition of EFSA's Scientific Panels and Working Groups, scientific experts and their roles.
- Improvements to the questions search features will be implemented, providing better search accuracy, and the matching content will be highlighted. Questions previously consulted will also be displayed in a different colour, to help users identify them more easily.
- A more accurate and detailed representation of the steps in the pesticides applications process on the question's timeline will be available. Moreover, specific mandates will be shown in the timeline instead of the overarching one, where applicable.
- The risk assessment deadline for MRL applications will be displayed only while the risk assessment process is still ongoing. It wil not be displayed during a 'stop-the-clock'-procedure pending additional data requests.
- Design updates will be implemented to match EFSA's new corporate identity, as well as usability improvements for mobile users.
- Previously unavailable links to scientic opinions for past pesticides questions will now be available.



# **Previous IT enhancements on February 01 2023:**

# Intended studies handling and pre-submission advice through Connect.EFSA

- Relevance for:
  - o Business Operators and/or their Consultants

#### New functionalities:

- Business Operators and/or their Consultants will have the possibility to involve a Member State in a request for general and renewal pre-submission advice also for GMO Directive 2001/18/EC-Part C notifications; the general or renewal pre-submission advice will be provided by EFSA in collaboration with the Member State.
- Business Operators and/or their Consultants will have the possibility to access reports in Connect.EFSA: they will be able to see an aggregated view of their records (such as studies, pre-application IDs, etc.), and they will have the possibility to filter these records. Furthermore, it will be possible to export these reports in Excel or CSV formats.

# e-submission of applications through ESFC

- Relevance for:
  - o Applicants and/or their Consultants

#### New functionalities:

• A new template is now available in ESFC for Extraction solvents-applications (application type=extraction solvents).

#### Public consultations feedback in Connect.EFSA

- Relevance for:
  - Business Operators and/or their Consultants

#### New functionalities:

 Public users of Connect.EFSA without a registered account providing comments to public consultations will have the possibility to register their affiliation category in the relevant field of the feedback form, making information about their affiliation visible in the comments published on OpenEFSA.



## **OpenEFSA**

- Relevance for:
  - All users of OpenEFSA

#### New functionalities:

- Questions that are considered as non-valid following the completeness check will remain visible in OpenEFSA with their status displayed.
- Substances related to a question will be visible in OpenEFSA only upon verification of the information included in the application.

# Previous IT enhancements on October 12 2022:

#### e-submission of applications through ESFC

- Relevance for:
  - o Applicants and/or their Consultants

#### New functionalities:

- ESFC applicants can now submit an application for a "Traditional Food from Third Countries", in the context of Article 16 of Reg (EU) 2015/2283, following the non-authorisation by the Commission of a "Traditional Food from Third Countries" notification, by using the new feature for starting an application through the notification dossier.
- ESFC applicants are now able to read longer texts in the Legal assessment, Consultation Request and Clarification Request fields are now increased up to 20,000 characters.
- ESCF applicants are now able to indicate whether the new dossier corresponds to the resubmission of a dossier previously declared non-valid due to non-compliance with Article 32b, Regulation (EC) No 178/2002, on the Notification of studies obligations. Applicants can link the new dossier with the previous non-valid dossier, providing the corresponding identifiers of the non-valid dossier.

# Studies notification and intended studies handling through Connect.EFSA

- Relevance for:
  - o Business Operators and/or their Consultants

#### New functionalities:

• The Study title field length has been extended from 80 characters to 300 characters to provide users with the possibility to insert longer study titles.



- It is now possible for both parties involved in the study notification, the Notifier and Co-Notifier, to authorise the same third-party entity working on their behalf to notify and co-notify a study.
- Study Type and Study Guideline picklists have been improved to allow users to search more
  easily among values and select the most relevant, when, for instance, creating or editing a
  draft study notification record.

## Ask a Question through Connect.EFSA

- · Relevance for:
  - o All users of Ask a Question

#### New functionalities:

• Users can now attach files to their submitted request. All information regarding the same request will be stored in the files-section.

#### **OpenEFSA**

- Relevance for:
  - o All users of OpenEFSA

#### New functionalities:

• A new dedicated message field is now available on the question's page, to inform users about possible deviations to the process as regards the progress of mandates and dossiers.

# **Previous IT enhancements on July 27 2022:**

## Account Registration and Management through Connect. EFSA

- Relevance for:
  - o External users registering on behalf of their organisation or users registered by EFSA

#### New functionalities:

• External users registering on behalf of their organisation will now be provided with additional assistance while specifying their own organisations in the registration form in Connect.EFSA. The system will suggest a pre-verified list of results, adapting dynamically according to the text inserted, and will allow the user to select one of the accounts in the list and auto-complete the fields "Organisation Name", "Organisation English Name", and other fields that refer to the account (i.e. "Country", "Small/Medium Enterprise"), without allowing the user to change this information. The user will be able to insert a name different from the organisations' names that the system proposes. In this case, he/she will have to fill in all fields.



## Pre-Application ID and intended study handling through Connect.EFSA

- Relevance for:
  - o Business Operators and/or their Consultants

#### New functionalities:

- A single access point for potential applicants working on their Pre-Application IDs has been created, overcoming the separation between Pre-Application IDs for new applications and for renewal applications. When potential applicants create a new Pre-Application ID and select a food domain or an application type related to a renewal, they will be able to submit a List of Intended Studies supporting such a renewal.
- The List of Intended Studies has been moved to a dedicated page with a new layout and can
  be considered separate from the Pre-Application IDs supporting a renewal application. From
  this dedicated page, potential applicants can create intended studies by entering the necessary
  information, as foreseen by the EFSA Practical Arrangements. Information on the status of the
  List and the related renewal pre-submission advice has also been moved to the List of Intended
  Studies
- Business operators can now add a study to Pre-Application IDs using the relevant *add studies* button if such a study has already been notified/co-notified and it is not withdrawn.
- More flexibility in managing studies supporting a future application for renewal has been introduced. Potential applicants will be able to submit a List of Intended Studies to obtain a renewal pre-submission advice and create and notify other studies supporting such renewal from the same Pre-Application IDs. In addition, it will be possible to notify an intended study if the status of the List of Intended Studies is in "draft", "clarification needed" or "closed" status.
- The field length for "Study Internal Reference ID" has been increased to 250 characters.

## e-submission of applications through ESFC

- Relevance for:
  - Applicants and/or their Consultants

- Applicants now have the possibility to indicate whether the study has been notified with delay
  and together with inserting a justification for the delayed notification (i.e. after the starting
  date), as required by the Practical Arrangements. This change is also reflected in OpenEFSA
  where the justification will be displayed along with the corresponding metadata of the
  document.
- Applicants will now receive more information on the confidentiality decision taken, and in particular: the name of the Authorising Officer who has signed the Decision, the date on which the Decision has been signed and the content of the decision letter (including recitals, Legal Remedies, etc.).
- The existing mechanism for calculating the validation deadline in EFSA's Risk Assessment tool has been adjusted considering the EFSA working calendar and the different stages/actions of the application lifecycle. Specifically, the applicant will be able to see in ESFC the new



deadline to respond to the Request For Information or RFI (RFI deadline), and the provisional Suitability/Validation deadline, which will be recalculated upon receipt of the RFI response and/or requests for deadline extensions.

Regarding the redaction of personal data, if after 2 RFIs by EFSA the Applicant has not provided
the requested changes in their ESFC dossier, EFSA will carry out the redaction. After the
redaction of a document, the Applicant will receive the sanitised document. The Applicant can
visualise the sanitised document under the tab "Confidentiality Assessment" on the left side of
the page under the column "Sanitised" by clicking on the link.

#### **OpenEFSA**

- Relevance for:
  - All users of OpenEFSA

#### New functionalities:

- Improved search and filtering features, including:
  - o enhanced search auto-suggestions;
  - o improved global search result page;
  - o extended filters on Questions list, including new filters by authorisation type or status;
  - o enhanced search for public consultations.
- Rationalised evidence section for non-pesticides applications: submitted studies and related info are now visible only in the dossier viewer.

# Previous IT enhancements on May 04 2022:

# Notification of Studies Database through Connect. EFSA

- Relevance for:
  - o Business Operators and/or their Consultants

New functionalities applicable to the Notification of Study process will allow:

- The Business Operator or their Consultant creating a 'New Study' linked to a Pre-Application
  ID or Pre-Application ID for renewal to change the owner of the notification by selecting a
  Business Operator different from the one set at the level of the Pre-Application ID or PreApplication ID for renewal.
- An additional control was implemented in the co-notification process. For example, a given
  organisation cannot, at the same time, take on the role of business operator notifying the study
  and that of the representative of the external laboratory that is supposed to co-notify the same
  study.
- More space will be made available in the relevant form for the justification for delayed/withdrawn notifications. It will also be possible to edit this information after notification. In addition, it will be possible to insert a justification for a delay in the notification of a study carried out by an internal testing facility of a business operator.



## e-submission of applications through ESFC

- Relevance for:
  - Applicants and/or their Consultants

#### New functionalities:

- The request for information generated by EFSA during the suitability check related to Novel foods, Food additives, Food enzymes and Food Flavourings will be sent to the European Commission, which in turn, will share it with the Applicant as necessary (instead of EFSA sending it directly to the Applicant as before), as defined in the relevant sectoral regulations.
- After the validation of the application, the Applicant or their Consultant will be allowed to add and delete documents and confidentiality treatment requests only for replying to additional data requests from EFSA and only for the sections 'unlocked' for this purpose, even if the confidentiality assessment process is still on-going.
- The Applicant will be able to submit and receive alerts from EFSA for notifications under Directive 2001/18/EC on the deliberate release of GMOs into the environment.

### **OpenEFSA**

- · Relevance for:
  - o All users of OpenEFSA

#### New functionalities:

• Improvements regarding the "last updated date"-field pertaining to Questions, to reflect all relevant content updates of Questions.

# **Previous IT enhancements on April 05 2022:**

#### Public consultations on OpenEFSA

- · Relevance for:
  - All users of OpenEFSA

#### New functionality:

- Ability to download the full list of comments received during a public consultation in a single PDF file.
- Users will now be able to download the list of Questions that appear in a search result in a CSV file format.

# **Previous IT enhancements on February 02 2022:**

Notification of Studies Database through Connect. EFSA



- Relevance for:
  - o Business Operators and/or their Consultants
  - Laboratories

New functionalities applicable to Pre-Application ID and Pre-Application ID for Renewal will allow the users to:

- Delete "Pre-Submission Advice" if not yet submitted to EFSA
- Delete "Notification of Study"/"Intended Study" if not yet notified/submitted to EFSA, and not associated to another pre-application ID
- Delete a "Component" created by the user using the option "Create New Component". The "Component" is not part of the EFSA Param Catalogue, and it is not used in other notifications.
- Delete/Remove Relationship "Shared with/On behalf of" from the "Shared with" box
- Remove an existing "Notification of Study"/"Intended Study" added to a pre-application id
- Remove a "Component" added from the EFSA Param Catalogue to the pre-application ID
- Delete "Pre-Application ID for New Application/Renewal" if no notification of study or no presubmission advice request has been already created

New functionalities applicable to a Notification of Study/List of Intended Studies for Renewal linked to a Pre-Application ID/Pre-Application ID for Renewal will allow users to:

- Delete a "Component" created by the user while creating a notification, using the option "Create New Component". The "Component" is not part of the EFSA *Param Catalogue*, and it is not used in other notifications.
- Delete/Remove Relationship "Shared with/On behalf of" from the "Shared with" box
- Remove a "Component" added from the EFSA Param Catalogue to the Notification of Study

#### Organisations and contacts registration through Connect. EFSA

- Relevance for:
  - o Any external party registered on Connect.EFSA.

New functionalities applicable to competent organisations and contacts registration:

- New field that will further characterise the contacts linked to a competent organisation will be added. This additional attribute will facilitate the identification of the contacts meant to contribute to the General Pre-submission Advice and/or Renewal Pre-submission Advice. The new attribute will be managed by the EFSA staff and will be visible to external stakeholders.
- Splitting the United Kingdom into Great Britain and Northern Ireland in the Country list: The United Kingdom will be replaced by United Kingdom (Great Britain) and United Kingdom



(Northern Ireland) in Country drop-down list. The new values will be available in the Account registration form, Notification of Studies Database Pre-Submission Advice, Public Consultation and AskAQuestion.

# Expected next release date: End of Q2 2023

\* N.B. Please note that the release date may be subject to change. External parties are invited to regularly check this overview for updates.

# **Ask a Question Service**

You have a question about EFSA's work? Contact our Ask a Question service!