Digital enhancements overview

To coincide with the entry into application of the Transparency Regulation in March 2021, EFSA has rolled out a number of IT tools and a dedicated web portal to help stakeholders adapt to the new regulatory provisions.

EFSA has worked continually to improve the tools and gathered feedback from users through requests sent to EFSA's technical help desk and our Ask a Question service, meetings with external parties, and correspondence. This feedback has been invaluable in the planning of changes to the IT tools.

The IT enhancements will continue over the next months, with the addition of new functionalities. This overview provides information about the upcoming IT changes and is subject to regular updates and possible changes.

EFSA welcomes feedback through the Ask a Question service.

Latest IT enhancements on December 2023*:

Connect.EFSA

- Relevance for:

    o All individuals and organisations who want to register on Connect.EFSA to access a number of services accessible on the platform.
    o No action required for the users who are already registered on Connect.EFSA.

New functionalities:

- On Monday 4 December, a new improved registration process has been implemented on Connect.EFSA, addressing user feedback and enhancing the overall user experience. The registration process is now more efficient.

OpenEFSA

- Relevance for:

    o All users of OpenEFSA

New functionalities:

- From Friday 8 December, documents belonging to *Mandates* currently linked to the related *Questions* will be moved to a dedicated *"mandate documents"* list. This will simplify the navigation and provide a more direct access to mandate documents.
- EFSA will start to gradually release old information from the legacy Register of Questions, starting with a small batch in December. The complete release is scheduled for Q1 2024.

Previous IT enhancements on September 14 2023:

e-submission of applications through e-submission Food Chain platform (ESFC)

- Relevance for:

    o Applicants and/or their Consultants

New functionalities:

- A new workflow to manage all activities following the submission of a Traditional Food Notification will be available. The changes apply to New Traditional Food Notifications and to modifications of an already authorised Traditional Food.

- ESFC applicants will be given an appropriate amount of time to comment on the draft confidentiality decision, submit a confirmatory application, and reply to a request for clarification, taking into account the EFSA public holidays.

- In the context of Confidentiality Assessment, a unique ID number will be assigned to each confidentiality request and communicated through ESFC indicating to ESFC applicants the confidentiality request(s) that require their attention.

Portalino

- Relevance for:

    o Applicants and/or their Consultants

New functionalities:

- Portalino applicants will be able to withdraw a submission directly from Portalino if an EFSA output is no longer requested providing a reason for the withdrawal.

- Portalino applicants will be able to update (add/remove/change ownership) the submission owners and contact points throughout the process in case of business continuity needs.

- Portalino applicants will be able to make submissions which do not contain any confidentiality requests.

- In the context of Confidentiality Assessment, a unique ID number will be assigned to each confidentiality request and communicated through Portalino indicating to Portalino applicants the confidentiality request(s) that require their attention.

Pre-Application ID and Notification of Studies through Connect.EFSA

- Relevance for:

    o Business Operators and/or their Consultants

New functionalities:

- When adding a new component to a pre-application ID or to a study notification, business operators and/or their consultants will be prompted with a new and more visible button as well as an enhanced layout for adding new components - where the Pre-Application ID is an Identification number a potential applicant must request from EFSA that links to all activities of the potential applicant related to the pre-submission of a new application or of an application for renewal.

- A time-limited notification box on the Application page (for business operators and/or their consultants) or Studies page (for laboratories) will be introduced, allowing to notify users about newly introduced functionalities.

OpenEFSA

- Relevance for:

  o All users of OpenEFSA

New functionalities:

- The Additional Data Requests (ADR) Document submitted by the applicant will be made available in OpenEFSA only after the adoption of the opinion, to ensure consistency in the public version of the dossier available for consultation during risk assessment.

- The sections of Additional Data Requests (ADR) Documents linked to a 'stop-the-clock'-procedure - when EFSA requests supplementary information, the time limit laid down shall be suspended until that information is provided, pending additional data requests - will automatically become visible to the public. This new feature will render the public dissemination of ADR cover letters redundant, leading to their gradual discontinuation from publication.

- The accuracy of the search function has further been refined.

Previous IT enhancements on July 6 2023:

e-submission of applications through e-submission Food Chain platform (ESFC)

- Relevance for:

  o Applicants and/or their Consultants

New functionalities:

- ESFC applicants will be informed through the ESFC platform in case European Commission, Member States, or EFSA terminate an application, along with the reasons for termination.

- ESFC applicants will have the ability to read and reply to a request for additional information providing more details, thanks to the increased character limit in the text boxes and the

possibility to format the text.

- ESFC applicants will find in ESFC an updated food flavouring table of contents to build their application in line with the requirements of the new food flavouring guidance recently updated by the Food Additives and Flavourings (FAF) Panel.

- ESFC applicants will be informed through the platform in case an application is declared "Not Valid" and they will be able to view in ESFC the reasons for non-validity.

- ESFC applicants will have the possibility to view and consult the EFSA considerations as regards partially approved and rejected confidentiality requests. They will also have the possibility to raise a confirmatory application on the rejected parts of the confidentiality request. In additon, ESFC applicants will be notified if EFSA initiates a review of the approved parts of the confidentiality request, in line with Article 39c of Regulation (EC) No 178/2002.

- ESFC applicants and Portalino users, when submitting confidentialty requests, will have clearer options to indicate that the cumulative requirements listed in Article 10(b) of the EFSA practical arrangements on transparency and confidentiality are deemed as satisified.

Portalino

- Relevance for:

    o Applicants and/or their Consultants

New functionalities:

- Portalino applicants will be able to select the applicable domain from a drop-down list to facilitate the processing of the submission by EFSA.

- Portalino applicants will be automatically notified by email when the submission has been done, when a request for information is sent by EFSA, if a submission is rejected and when the confidentiality process has been updated.

Pre-Application ID through Connect.EFSA

- Relevance for:

    o Business Operators and/or their Consultants

New functionalities:

- Sharing functionalities has been improved. In addition to the possibility to share a pre-application ID record "on behalf of" an entity, business operators and/or their delegated consultants now have the option to share at the same time multiple studies which are linked to the pre-application ID with the relationship "on behalf of".

Public Consultations through Connect.EFSA

- Relevance for:

    o All users of Connect.EFSA

New functionalities:

- Accessing a consultation will be further simplified for users of Connect.EFSA where the document and/or the link made available for consultation will be displayed in a manner that allows users to easfily find the relevant document and/or link. Moreover, the information will be presented in a new layout, and all the files and links will be placed together on the page.

Targeted consultations

- Relevance for:

    o Member States and ad-hoc audience

New functionalities:

- Member States or external parties invited to comment in targeted consultations will have the possibility to attach files to their comments (one file per comment field).

Pre-Submission Advice through Connect.EFSA

- Relevance for:

    o Applicants and/or their Consultants

New functionalities:

- When submitting their requests for general pre-submission advice (GPSA) or renewal pre-submission advice (RPSA) in the area of plant protection products and maximum residue levels of pesticides or in the context of GMO Directive 2001/18/EC, potential applicants are no longer required to indicate the contact person within the relevant Member State Competent Organisation. The information required is limited to the country of the relevant Member State Competent Organisation.

Ask a Question and Public Access to Documents (PAD) through Connect.EFSA

- Relevance for:

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

New functionalities:

- The user experience for requesters using the Ask a Question service and public access to documents (PAD) applicants has been improved. When EFSA requests additional clarifications to their questions, users can now easily provide them by clicking the "reply" button available in the users' email tool (e.g. Outlook, Gmail, etc).

OpenEFSA

- Relevance for:

    o All users of OpenEFSA

New functionalities:

- OpenEFSA users will be able to download documents without login, while still requiring acceptance of the legal notice on intellectual property rights.

- Various usability improvements on the questions' search:
  o Improved accuracy of search results;
  o matching terms highlighted in search result;
  o possibility to sort results by *last updated date;*
  o visited pages are indicated in a different color;
  o possibility to open question in new page.

- Improved usability of supporting documents section, including the possibility to download all files at once. Overall usability improvements will be available for mobile users.

- New updates on the design will be implemented to further align OpenEFSA with EFSA's new corporate identity.

Newsletters, alerts, and other subscription products

- Relevance for:

  o EFSA Newsletter and alerts subscribers

New functionalities:

- The management of the EFSA Newsletter and alerts will be transferred to Salesforce: the platform provided by Salesforce will provide a one-stop shop for users to manage all their EFSA subscriptions and references.

Previous IT enhancements on May 12 2023:

OpenEFSA

- Relevance for:

  o All users of OpenEFSA

New functionalities:

- The OpenEFSA section on experts has been improved to show the list and composition of EFSA's Scientific Panels and Working Groups, scientific experts and their roles and Declaration of Interests (DoI).

Previous IT enhancements on April 12 2023:

e-submission of applications through e-submission Food Chain platform (ESFC)

- Relevance for:

    o Applicants and/or their Consultants

New functionalities:

- ESFC applicants will 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 final 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 cases where a study has not been notified or notified with delay, 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.

Notification of Studies through Connect.EFSA

- Relevance for:

    o External users registering on behalf of their organisation or users registered by EFSA

New functionalities:

- The co-notification process, which is the process where both the business operator of a study commissioned or carried out by them to support an application, and the laboratory or testing facility carrying out the study notify EFSA of certain information relating to the study, has been simplified by removing the "co-notify with remarks" option but still allowing the external users to add comments/remarks when going through the co-notification 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 co-notify 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:

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

New functionalities:

- 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 increasedfiltering options., They can 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:

  - All users of OpenEFSA

New functionalities:

- 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 made available.

- The risk assessment deadline for maximum residue level (MRL) applications will be displayed only while the risk assessment process is still . It wil not be displayed during a 'stop-the-clock'-procedure, when EFSA requests supplementary information, the time limit laid down shall be suspended until that information is provided, 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 including 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 and export reports in Connect.EFSA.

Public consultations feedback in Connect.EFSA

- Relevance for:

  o   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:

o All users of OpenEFSA

New functionalities:

- Questions that are considered as non-valid following the completeness check, that evaluates the data submitted within an application in light of the relevant sectoral legislation and EFSA's guidance documents, 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:

- Applicants submitting through the electronic submission system E-submission Food Chain Platform (ESFC) can now submit an application for a "Traditional Food from Third Countries" by using the new feature for starting an application.

- ESFC applicants are now able to read longer texts in the Legal assessment, Consultation Request and Clarification Request fields (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.

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.

- The drop-down menu relating to the Study Type and Study Guideline fields has 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.

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 dynamically suggest a pre-verified list of results and will allow the user to select one of the accounts returned in the list, or to insert a new Organisation name.

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 – where the Pre-Application ID is an Identification number a potential applicant must request from EFSA that links to all activities of the potential applicant related to the pre-submission of a new application or of an application for renewal.

- The List of Intended Studies – where the List of Intended Studies refers to the studies the applicant intends to perform for the purpose of the renewal of an authorisation or approval, including information on how the various studies are to be carried out to ensure compliance with regulatory Requirements - has been moved to a dedicated page with a new layout. From this dedicated page, potential applicants can create intended studies by entering the necessary information, as foreseen by the EFSA Practical Arrangements that lay down the arrangements for how the rules and measures specified in the Transparency Regulation operate in practice.

- 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 a 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 "draft", "clarification needed" or "closed".

e-submission of applications through ESFC

- Relevance for:

  - o Applicants and/or their Consultants

New functionalities:

- Applicants can provide justification for a study notified with delay in a dedicated field on OpenEFSA.

- Applicants will now receive more information on the confidentiality decision taken, 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 deadlines during the risk assessment process was adjusted taking into account the EFSA working calendar and the different stages/actions of the application lifecycle. The applicant will be able to see the new deadline in the E-submission Food Chain Platform (ESFC) electronic submission system.

- Personal data not sanitised/redacted by the Applicant following 2 EFSA requests, will be sanitised/redacted by EFSA, after which the Applicant will receive the sanitised document.

OpenEFSA

- Relevance for:

  - o 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.
- For non-pesticides applications: submitted studies and related info are now only visible in the so-called dossier viewer where all information that is part of an application is visible.

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 so-called 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 Pre-Application ID for renewal – where the Pre-Application ID is an Identification number a potential applicant must request from EFSA that links to all activities of the potential applicant related to the pre-submission of a new application or of an application for renewal.

- An additional control was implemented in the co-notification process, which is the process where both the business operator of a study commissioned or carried out by them to support an application, and the laboratory or testing facility carrying out the study notify EFSA of certain information relating to the study. 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 which the applicant or notifier will have to provide at the submission of the application, in cases of a delay or withdrawal of a study notification for the application to be considered valid or admissible. 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 the E-submission food chain platform (ESFC)

- Relevance for:

  - o Applicants and/or their Consultants

New functionalities:

- The request for information generated by EFSA during the suitability check, where a check is performed on whether the data submitted by the Applicant or their Consultant fulfils the data requirements to carry out the relevant risk assessment, 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, where the application is considered valid for risk assessment, 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:

  - o 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:

- New functionalities will be added to the Connect.EFSA platform which provides external parties with the possibility to engage with EFSA on a variety of topics (pre-submission activities, read frequently asked questions, take part in EFSA's public consultations, and submit requests for information or public access to documents) facilitating:

  o the use of the platform for business operators, their consultants, and laboratories in the Notification of Studies and Pre-submission advice processes. The new functionalities will apply to the so-called Pre-Application ID and Pre-Application ID for Renewal in the context of the Notification of Studies ;
  o the identification of the contacts of competent organisations that are meant to contribute to the General Pre-submission advice (PSA) - advice an applicant can request on the rules applicable to, and the content required for, the application prior to its submission - or renewal PSA in the case of an application renewal; furthermore, in the Country list of the contact registration used for the Notification of Studies Database, Pre-Submission Advice, Public Consultation and AskAQuestion, "UK", will be replaced by United Kingdom (Great Britain) and United Kingdom (Northern Ireland).

* N.B. Please note that the release date may be subject to change.

Ask a Question Service

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