

# Introduction to the ESFC

0:12

On the 27th of March 2021, the E US new Transparency Regulation entered into force the E submission food chain platform.

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The ESFC is now the main tool with which the applicant can create and manage their dossiers.

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The Commission and EFSA systems interact for all the domains impacted by the transparency regulation.

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Their collaboration has built a more coherent ecosystem which incorporates transparency requirements within the existing independent science evaluation process.

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The confidentiality assessment process and public dissemination are the foundations for this evolution in food and feed safety regulation using the ESFC platform.

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All the main stakeholders are around the table and also from the 27th of March the public dissemination of non confidential information has begun for valid dossiers on Efsa's public portal.

1:05

EFSA supports applicants with pre submission advice, possibly years before their submission.

1:11

On request it will directly provide scientific and practical advice so applicants can prepare the most thorough dossier through the pre Notification of studies.

1:19

EFSA will enable applicants to register their planned commissioned and carried out studies as required by the Transparency Regulation.

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EFSA will generate reference numbers during the pre submission phase that will later be requested on the ESFC platform.

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This platform becomes the only focus once the dossier content is ready for input which can be completed over multiple visits and only an EU authentication login is required for access.

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The applicant selects from the food domain the authorisation type and application type for dossier submitted to a Member State.

1:52

Select a recipient, organization or competent authority.

1:56

This combination generates a unique link to the template for the dossier, table of contents and to the business process that this dossier will follow when submitted.

2:05

Each step is reflected in EFSA guidance.

2:08

The templates have been designed through collaboration between the business units of both Digisante and EFSA to ensure that all information required by legislation is included in the dossier.

2:19

On the ESFC platform, you can manage multiple dossiers in the same place.

2:24

So now you're ready to prepare your dossier.

2:26

Split into these three sections, complete the administrative data information as required, provide a public summary and proceed to the technical dossier.

2:39

Bear in mind that the summary will be disseminated.

2:43

Provide the study ID for any studies that were notified to EFSA during PRE submission but will not be provided in this dossier, as well as a justification for their omission in any section.

2:53

When you provide a study report that was not pre notified, you will also be required to provide a justification.

3:00

If you wish to request confidentiality on data elements within your document, the transparency legislation requires you to provide a non confidential document version with sensitive parts marked and blanked out.

3:12

First, upload the unredacted confidential document, but be sure to read the Intellectual Property Rights help note and click the dots to request confidential treatment.

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Define the document type, then select one legal ground for each request.

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Provide a detailed justification for why that ground applies.

3:36

Then include the exact content, wording, and position for absolute clarity.

3:41

Finally, if necessary, choose one or multiple conditions that provide context to the request.

3:46

There can be multiple requests for each information element or multiple elements in each document.

3:51

Requests will be assessed by a member of the legal team of the appropriate actor in the process for that domain.

3:57

Now upload the redacted non confidential version, understanding that this version will be disseminated when complete.

4:04

Select Submit.

4:06

A confirmation dialogue shows the next step of the business process that the dossier will reach.

4:11

After acknowledgement of receipt and possible questions, the dossier is forwarded to EFSA.

4:15

The dossier is now identified by a question number.

4:19

EFSA may request information from the applicant to ensure the dossier is suitable or valid to begin the risk assessment.

4:26

At that moment, only the non confidential information will be disseminated on the open EFSA portal.

4:34

During risk assessment, further requests for information may be sent to the applicant, including a response deadline.

4:41

The applicant can, if necessary, request an extension to that deadline.

4:45

They will be informed about any clock stop that will extend the risk assessment process.

4:50

Only the section for which the authority is requesting further information will be unlocked.

4:55

For update.

4:56

Requests for information and all other notifications arrive by e-mail and appear on the dashboard.

5:03

View the question, respond, then resubmit the updates with a comment.

5:07

You will always be able to access the previous information by clicking Check updates.

5:12

Your timeline will be updated alongside other interactions and process steps for the dossier.

5:18

In parallel, EFSA carries out the Confidentiality Assessments for most domains and this process may trigger clarifications to ensure that the supply justifications are sound and like all interactions, such clarifications are sent by e-mail and dashboard warnings which appear in the Confidentiality Assessment section.

5:37

You will be informed about the authorities decisions through the ESFC platform.

5:42

Applicants and stakeholders will be pre notified within days prior to the publication of Efsa's adopted scientific output under embargo.

5:51

The Risk Management phase now begins and applicants will be notified of the outcome.