



## Confidentiality & IPR E-Submission Food Chain platform SCRIPT

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	<p><i>Here we provide more clarity on the confidentiality process during the lifecycle of the application within the ESFC platform.</i></p>
<b>Step 1</b>	<p>How the Applicant enters confidentiality requests for documents uploaded into E-Submission Food Chain platform.</p>
00:00	<p>To support a dossier through the risk assessment, the Applicant will need to provide complete and unedited information.</p> <p>Some documents will need no request for confidentiality at all - so these will not enter the confidentiality process.</p> <p>The Applicant may consider other documents to contain confidential elements which will require confidentiality treatment.</p>
00:34	<p>All documents flagged as 'non-confidential' will be automatically disseminated on the OpenEFSA portal once the dossier is considered 'valid'.</p> <p>That point of validation also starts EFSA's confidentiality assessment process for all the other documents for which the Applicant has requested confidentiality treatment.</p>
00:56	<p>Let's assume you are the Applicant and you want to add a confidential document.</p> <p>Despite the fact that the badge shows by default 'non-confidential', first upload the confidential and unredacted document version.</p>



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	<p>Browse to, and upload, your document then define the document type. Then click the three dots to 'Request confidentiality treatment'.</p>
01:18	<p>At that moment the status switches to 'Confidential'.</p> <p>Information claimed to be confidential will not be disseminated unless EFSA takes a decision rejecting one or more confidentiality requests.</p>
01:32	<p>Now explain your reasons for requesting confidentiality for each redacted information element.</p> <p>Click 'Add confidential ground' to select one legal ground from the pulldown list. Remember there is help available in every section.</p> <p>Provide a verifiable justification, the <i>verbatim</i> text excerpt of that information, and provide its document position in the 'Related section' field.</p>
01:57	<p>Finally, you can select one or several applicable conditions that explain the disclosure risks for each selected confidentiality request. And there may be multiple requests in the same document.</p> <p>Now upload the non-confidential version of your confidential document, with any confidential elements digitally redacted and blacked out. This will be disseminated after dossier validation.</p> <p>If you would like to add a new document, click 'Add document' and follow the same procedure if you consider parts of it to be confidential.</p>
02:29	<p>Once the dossier is ready, you can submit it.</p>



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	<p>The dossier will be first received by the Commission or Member State Competent Authority, depending on the food sector, and it will be forwarded to EFSA for risk assessment.</p>
<b>Step 2</b>	<b>How EFSA receives confidentiality requests and when the confidentiality assessment process starts.</b>
02:53	<p>As applicant, you will be informed by email notification and on the dossier overview when the dossier is valid.</p> <p>At that moment EFSA can start the confidentiality request review.</p>
<b>Step 3</b>	<b>How the EFSA legal assessor and Applicant interact together during the confidentiality process.</b>
03:15	<p>If EFSA requires further information in order to make a decision, they will send a clarification to the Applicant via the ESFC platform.</p> <p>Such clarifications on confidentiality requests are notified to the Applicant by email and the bell icon.</p> <p>At that moment only, a 'Confidentiality assessment' tab appears, which simplifies for the Applicant the follow-up of the confidentiality process on the ESFC.</p>
03:45	<p>The Applicant reads the clarification and responds with free-text. No files can be uploaded. Click 'Reply' and it is sent to EFSA. The 'Pending' badge switches to 'Replied'.</p> <p>EFSA considers whether the reply is suitable, and makes a draft decision for that single confidentiality request.</p> <p>If the Applicant doesn't reply to the request for clarification, EFSA will send the draft decision without having their input.</p>



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04:16	<p>This draft decision arrives in the dashboard, with the badges 'Agree' or 'Not agree'.</p> <p>From the reception of the draft decision, the Applicant has a further two weeks to state a view on each 'Not agreed' decision, beyond which the opportunity to comment is lost and the process continues.</p>
04:31	<p>During the same period, the Applicant may withdraw the entire dossier - this will effectively prevent the disclosure of elements claimed confidential, but will also terminate the evaluation procedure of the dossier.</p> <p>If the dossier has not been withdrawn, EFSA finalises and signs a decision for each confidentiality request, taking into account the Applicant's stated view, if any.</p> <p>If the Applicant does not agree to EFSA's Final Decision, they have two weeks in which to submit a confirmatory application.</p> <p>A button will appear for the Applicant to trigger the process, which is handled within the ESFC system.</p>
<b>Step 4</b>	<b>How EFSA informs the Applicant of the sanitised version of the confidential document.</b>
05:20	<p>The Applicant will be notified by email and the bell icon. The document 'sanitised' by EFSA will be accessible in the dossier in the relevant section and in the confidentiality assessment dashboard.</p> <p>If at least one confidentiality request is <b>not</b> agreed by EFSA, then the version of the document as provided by the applicant is 'sanitised' by EFSA.</p> <p>That means the corresponding information from the confidential version of the document, for that specific confidentiality request, will be revealed.</p>



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05:52	<p>The document 'sanitised' by EFSA will appear on the OpenEFSA portal and will replace the non-confidential document version as provided by the Applicant.</p> <p>If, however, all the confidentiality requests within one document are agreed, then the non-confidential version of the confidential document as submitted by the Applicant will remain published on the OpenEFSA portal.</p>
06:18	<p>Confidentiality requests may be submitted by the applicant with regard to additional information provided by the Applicant during the authorisation process. In this event, the confidentiality requests will follow the same confidentiality process followed for those submitted on the initial dossier, if any.</p> <p>EFSA's Practical Arrangements provides more detail.</p>
	<p><b>How to handle Publicly available documents (such as publications or studies) with Intellectual Properties Rights owned or not owned.</b></p>
06:42	<p>Publicly available documents with IPR owned or not, are not subject to confidentiality decision-making, as previously outlined, but rather to a veracity check of the information provided, and of the presence of the full and valid reference for the risk assessment.</p> <p>While the Applicant cannot claim confidentiality on publicly available documents, IPR impacts all disclosures.</p>
07:15	<p>The Applicant will be required to state the IPR status of each document uploaded.</p> <p>The radial button by default is set to 'Not publicly available'.</p>



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	<p>If the document the Applicant wants to upload is public, but they don't own or cannot obtain the IPR for reproduction on EFSA's website, the Applicant will have to select the 'IPR not owned' option.</p> <p>The Applicant will be required to upload the full version, that will not be disseminated, and to submit the relevant bibliographic references to these documents indicating where they are available to the public, for dissemination on the OpenEFSA portal.</p>
07:54	<p>If the document the applicant wants to upload is public, but they hold the IPR for reproduction on EFSA's website, the applicant will have to select the 'IPR owned' option.</p> <p>The applicant should provide the full version that will be disseminated on the OpenEFSA portal - keeping in mind that publicly available documents, cannot be claimed as confidential.</p>