



## Module 6.3 – Applicant tutorial E-Submission Food Chain platform SCRIPT



### Applicant and food business operator tutorial: Applicant interactions during risk assessment – focusing on the confidentiality process

00:14	<p>The valid dossier enters Risk Assessment.</p> <p>The process end-date displays, by which time EFSA should adopt an opinion. For Food Contact Materials it would be seven months.</p>
00:24	<p>At this moment, any non-confidential content elements are posted on the OpenEFSA dissemination portal. Validity also prompts the start of EFSA's legal assessment of each confidentiality request, which may trigger clarifications.</p> <p>This process is unconnected to the authorisation assessment. It runs in parallel and does not show on the authorisation timeline.</p>
00:47	<p>Clarifications for confidentiality requests are notified by email and the bell icon. Using this new 'Confidentiality assessment' tab, view one or multiple clarifications.</p> <p>This dashboard shows the path, with a final decision either upholding or rejecting each request.</p>
01:08	<p>Any 'pending' clarifications can be addressed by clicking 'Reply'. Document uploads are not possible, only free-text.</p> <p>Once the answers are in place, click 'Reply to clarification'. The badge switches to a 'Replied', and the Authority is instantly informed.</p>
01:24	<p>You are not obliged to reply, but if you choose to, you need to respond as soon as possible because EFSA will take a draft decision within two weeks.</p>



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01:30	<p>Each draft decision on the confidentiality request arrives in the dashboard. From that date the Applicant has a further two weeks to state its view, beyond which, the opportunity to comment is lost and the process continues – because each request must be concluded in a fixed timeframe.</p>
01:48	<p>EFSA delivers a final reasoned decision on each request, taking into account the Applicant's stated view, if any.</p> <p>If the Applicant does not agree to EFSA's final decision, it may submit a confirmatory application asking EFSA to reconsider its decision.</p>
02:02	<p>Now EFSA amends, or 'sanitises', the Applicant-provided non-confidential document to reflect its assessment decisions on the requests for confidentiality.</p> <p>That means the corresponding information from the confidential version of the document, for that specific rejected confidentiality request, will be revealed.</p>
02:22	<p>The new version appears on the dashboard. This replaces the original non-confidential document already published on the dissemination portal.</p>
02:32	<p>Meanwhile, requests for additional information on dossier content can be made at any time, with a deadline assigned to each.</p> <p>View the request, go to the unlocked section, and supply the data there as before and leave a comment. The question flag turns green.</p> <p>As in earlier phases, you should complete all requests for additional information before resubmitting your updates.</p>



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03:04	<p>If you need to request a deadline extension, click the button that appears on the timeline and set your preferred date for EFSA to consider, with an explanation. You will be notified of its decision.</p>
03:18	<p>In this case, the Chemical Properties section requires more detail – information which you consider to be confidential.</p> <p>You should prepare a non-confidential version, and request confidentiality treatment to parts of your supplementary document using the standard procedure.</p> <p>Provide a message and click ‘Add response’. Then resubmit your update.</p>
04:00	<p>EFSA may also activate its stop-clock procedure if, for example, there are substantial data anomalies, requiring considerable time for the Applicant to address.</p> <p>This holding period will not count towards EFSA’s time-commitment to conclude each dossier submission, so it could extend the process.</p>