Module 6.1 – Applicant tutorial E-Submission Food Chain platform SCRIPT

Applicant and food operator tutorial:
A hands-on guide for the preparation and submission of the dossier

00:13	We have divided the authorisation path for food chain-related dossiers into five structured phases. Any pre-submission activities take place directly with EFSA, and later, possibly years later, they integrate with the dossier directly once input begins. This practical guide is from the Applicant's perspective, where we explain how to prepare requests to safeguard confidential data, and how to submit. Let's assume you're ready to proceed. So how can you access the ESFC platform?
00:43	You connect using your EU authentication login… ideally using an email which the applicant company already has pre-registered with EFSA's User Management System. Agree to cookies, read the disclaimer, then log in. You'll see a list of your dossiers either under evaluation or in preparation, with their status flagged. But here we'll a 'Create new dossier' from scratch.
01:11	Select the Food Domain – in this case Food Contact Material – the intended sub-domain and application type. For this domain, you must specify your first-target member state to submit your application to, and choose a Member State Competent Authority.
01:28	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. Each step is reflected in EFSA guidance.

01:40	A dossier can be developed over multiple sittings without time-constraint. The top notification bar lets you grant access to other users via the drop-down, and the notification icon signals any dossier activity.
01:56	This left pane shows the dossier status and is split into three sections following legislative requirements. Down below, the Competent Authority may be changed any time prior to submission, and after that point directly with e-submission support team.
02:11	The question button here pre-loads a support email, but EFSA provides wide-ranging online support. For this demo, some fields offer no confidentiality treatment. A red file icon will indicate content that will be not be disseminated, while a 'white' icon indicates content that will be disseminated – as determined by legislation.
02:32	Now input the dossier on behalf of the food business operator applicant in the active content area. Input the Applicant name. If you were registered by that Applicant with EFSA, you will see a drop-down from which to select them. This connection will pre-fill some administrative fields for you, but you can also proceed manually.
02:51	Identify the 'Person responsible', who will become the one point of contact for the assessors. All fields can still be overwritten. Supply the information-set for the Subject of the Request.
03:07	Now list any authorisation information that applies to EU member states or countries outside the EU. Upload any Data Sharing agreements that cover the entire dossier. Click 'Add document' for multiple agreements. Now upload a Cover Letter.

03:28	Click to the Public Summary. Upload a dossier summary that does not contain personal or confidential data – and here assume a non-professional audience. Now move to the Technical Dossier.
03:41	If the Applicant sought advice from EFSA for the preparation of this dossier content, they would have received a Pre-Application ID which you can input here. This enables EFSA to pre-populate certain fields. Click 'Add' if there are multiple identification numbers connected to this dossier.
03:59	Here you should identify any studies which were pre-notified with EFSA, but you omit from this dossier. Provide a justification for each omission. Click 'Add' to input additional Study IDs, bearing in mind the principle that all studies are required, positive or negative, to inform the overall assessment of risk.
04:17	Proceed through each field in the Technical Dossier. You will find help available, in context, with every section.
04:25	For this example, let's consider your Physical Properties document to be non-confidential. Upload, and as part of its metadata, define the document type.
04:50	Chemical Properties though, holds confidential content. First upload the fully confidential and unredacted document version and click the three dots to 'Request confidentiality treatment'. The status badge switches to 'Confidential'. Again, define the document type, but be sure to read the Intellectual Property Rights help note.

04:56	Now upload your non-confidential document version with all personal data and confidential elements digitally redacted and blacked out – understanding that this will be disseminated after validation of the dossier on EFSA's public portal.
05:09	With a single confidentiality request in mind, explain your reasons.
	First establish its legal grounding for the assessor. Click 'Add confidential request' and select one ground from the list displayed.
	Provide a thorough justification, and the *verbatim* text excerpt.
	Now specify the exact position or section in the document.
05:33	For each request, you can give more clarity and context behind the disclosure risks by selecting one or more substantive screening criteria from the conditions check list.
	If you would like to make additional requests for the same information element, or make multiple requests in the same document, click 'Add confidential request' and follow the same procedure.
05:52	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.
	The three-dots allow you to return your document to non-confidential, or lets you update your document. Both actions will delete any confidentiality data you may have applied to it.
06:11	Now let's upload a confidential study, having already prepared a non-confidential version of it. Remember it's this non-confidential document version that will be publicly disseminated.
	Define it as a 'Study report', and the system will request its Study ID. That identification number was attributed to the study by EFSA in the pre-submission phase.
	Now let's request the confidentiality treatment.

06:50	If you support your dossier with a study which has not been pre-notified in EFSA's study database, you will not have a study identification number. You will need to justify why it was not pre-notified, and then proceed with the study inputs.
07:08	In some sections, certain mandatory fields may not be relevant in your case. So click 'Not applicable', but provide a public explanation why.
07:17	Finally, complete the 'List of annexes' section, and include any checklist which may be provided in EFSA guidance, which will help enable the dossier to meet the completeness and suitability requirements. Click 'Submit' and provide a final note. You can still return to edit the dossier.
07:30	The 'Complete action' button locks its content, and the dossier enters the next phase as will be indicated in your timeline overview, and now you have to wait for acknowledgement.
07:42	The next tutorial will show you the phases through which your dossier will pass, and how you interact with the authorities until the conclusion of the submission.