GMO Part C – MS-CA tutorial
E-Submission Food Chain platform
SCRIPT

Member State Competent Authority tutorial: Interactions with notifier and paths during authorisation

00:12	For this presentation, we have divided the authorisation process for GMO Part C notifications into five structured phases. The first phase will explain how the notifier will prepare and submit the notification to the Competent Authority of the Member State (MS-CA) where such a GMO is to be placed on the market for the first time.
00:31	The second phase will focus on the notification procedure. The third phase will provide details on the risk assessment, and especially how to send the Risk Assessment Report and start the Member States consultation.
00:45	The fourth phase will explain the two different paths that the dossier can follow, according to the result of the Member State's consultation. Firstly, if there is no objection from other Member States or the Commission or no objection maintained, and secondly, how the Commission will be able to engage EFSA on risk assessment if objections remain.
01:00	The last phase will show the final step of the authorisation process. This presentation is from the Competent Authority's perspective.
01:12	**Phase 1: How the notifier will prepare and submit the notification to the Competent Authority of the Member State.** In this phase, we will highlight how the notifier can request the confidentiality treatment of certain data in his dossier.
01:25	The notifier will connect using an EU authentication login. Ideally using an email, which the notifier has pre-registered with EFSA's User Management System. This will allow the e-submission platform to retrieve data from pre-submission activities that have taken place directly with EFSA.

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01:47	After logging in, the notifier will see his or her dashboard. If he or she has already created applications or notifications, the list of dossiers will appear here. For this presentation, we will show you how the notifier will create a completely new GMO notification.
02:04	Select the Food Domain, authorisation type and application type. Then select the target Member Sate and the Competent authority.
02:12	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 the GMO Directive.
02:25	The left dashboard shows the dossier status. The dossier is divided into three distinct sections following legislative requirements. Down below, the Competent Authority may be changed any time prior to submission, and after that point the notifier must contact the e-submission support team.
02:43	Now the logged-in user will input the dossier as the notifier or on behalf of the notifier, in the active content area. The notifier will have to identify the EU representative. The administrative section also includes any data-sharing agreements that cover the entire dossier, and a Cover Letter. The notifier will provide a public summary, and proceed to the Technical Dossier. The notifier has access to contextual help if needed.
03:28	If the notifier sought advice from EFSA for the preparation of this dossier content, he or she would have received a Pre-Application ID, which can be inputted here manually. If the user entering the dossier has been identified as the ‘contact person’ for this notifier, then the list can be automatically retrieved by the platform. Knowing the pre-Application ID enables the e-submission platform to pre-populate certain fields. The notifier might have multiple identification numbers connected to this dossier.

03:59	In this section, the notifier should identify any studies that were pre-notified with EFSA, but which are not provided in this dossier. For each omission, the notifier must provide a justification. The notifier will then proceed through each field in the Technical Dossier.
04:22	If confidential information will be included in the dossier, the notifier should first upload the fully confidential and unredacted file version, then specify the document type using the metadata list.
04:40	Click the three dots to 'Request Confidentiality treatment'. The status badge switches to 'Confidential'. Now upload the non-confidential file version with all personal data and confidential elements digitally redacted and blacked out. Now select one legal ground for each confidentiality request, and provide a detailed justification for why that ground applies in each case.
05:08	Then include the exact content wording and position for absolute clarity.
05:13	If the notifier wants to input a study report he will have to select 'Study report' in the document type, and the system will request its Study ID. That identification number was attributed to the study by EFSA in the pre-submission phase. If a study has not been pre-notified in EFSA's study database, the notifier will have to justify why it was not pre-notified, and then proceed with the study inputs.
05:44	When the dossier is complete, the notifier will click the 'Submit' button. An email is sent to notify the Competent Authority selected that a new dossier has been submitted. The contact points have been defined by the Member States for each food domain.
06:02	If the contact changes or it is not correct, you can contact the e-submission platform support to update and re-transfer the dossier to the correct account, if needed. The overview timeline shows the progress.

06:17	**Phase 2: Notification procedure.** How you will acknowledge the date of receipt of the notification. How you will forward the Summary of the dossier to the competent authorities of the other member states and the Commission. How you will be able to ask the notifier for additional information if necessary. Finally, how the valid and complete GMO notification will be shared with the competent authorities of the other member states and the Commission.
06:49	The user from the Competent Authority which received the dossier, will receive an email notification and can connect to the e-submission platform. There he or she will see the dossier submitted by the notifier.
07:08	The user has access to the entire content of the notification. All the information claimed as confidential can be easily identified in the dossier by the grey ‘Confidential’ status badge. By opening the sections, you can access all the detail of the confidentiality request.
07:36	The user clicks “Acknowledge”. He or she can enter a comment or attach a file (an acknowledgement letter for example) and send it to the notifier. The notifier receives an email including this information. At this stage the Competent Authority assigns a unique number to the dossier and communicates this number to the notifier.
07:51	Once the notification is acknowledged, you can forward the summary to the competent authorities of the other member states and the Commission. Click on “Send summary”. The summary as provided by the notifier is attached. You can still change it and provide another version if necessary. The Commission will publish the summary in the new GMO register, now developed by the Commission.
08:23	Once complete and valid, you can share the notification with the competent authorities of the other member states and the Commission. When the dossier is valid, the risk assessment and the confidentiality assessment process can start.

08:43	All the users involved in the dossier can see the progress through the overview timeline. For each confidentiality request, the e-submission platform will allow you to ask for clarifications from the notifier if necessary, send a draft decision, then a final decision and upload the 'sanitised' version.
09:10	**Phase 3: Risk assessment.** Once the risk assessment report is ready, you can send it through the e-submission platform. If the assessment report output indicates that the GMO in question should not be placed on the market, the MS-CA can click on the "Terminate" button to reject the notification, including the reason why.
09:30	To start the consultation, click on "Start the consultation". An email is sent to the competent authorities of the other member states and the Commission. During the consultation, the Competent Authority can still request additional information from the notifier.
09:44	Competent authorities of the other member states and the Commission can send comments or objections directly through the platform. At the end of the consultation, if there are no objections, you can proceed with the final authorisation step. If objections remain, then you can request the Commission to engage EFSA for a risk assessment.
10:06	**Phase 4: Member States Consultation review.** Once the consultation is finished, you can close it by clicking on "Consultation period finished". An email is sent to the competent authorities of the other member states and the Commission. The option to send comments or objections still remains open during the consultation output review.
10:28	If there is no objection, or no objection remains, the Competent Authority will complete the risk assessment by clicking on the "Objections resolved, risk assessment completed" button. A window opens and you can send a comment and attach the risk assessment report.

10:50	If objections remain, the Competent Authority can request the Commission to engage EFSA for the risk assessment. The Commission will receive an email notification and will be able to forward the dossier to EFSA.
11:00	The complete dossier will be automatically transferred by the e-submission platform to EFSA's system, including the non-confidential version of the files following the confidentiality assessment performed by the Competent Authority, and they will start the risk assessment. The dossier will be publicly disclosed on EFSA's public portal.
11:20	**Phase 5: Final step to the approval or rejection.** Once the written consent is ready to be sent, the Competent Authority can click on the "Authorise" button. A new window will be displayed. Write a comment, attach the written content, and send this to the notifier. The competent authorities of the other member states and the Commission will be informed by email.