Process and responsibilities for study notification of pesticide dossiers

Intake phase

Applicant

- Obligation of **study notification** pursuant to Article 32b(2) and (3) of the GFL Regulation
- Obligation to create and indicate in IUCLID all the **Pre-Application IDs** which are associated to the study notifications relevant for the application
- Obligation to **submit** or **justify** all the relevant notified studies in the application

RMS/EMS

- Responsibility to carry out the **assessment** of the compliance with the obligations of study notifications laid down in Article 32b(2) and (3).
- Responsibility of applying the procedural consequences in the event that the application is not considered valid e.g. six month suspension of the assessment after the re-submission of the application, in case of unjustified/not properly justified non-complicance with study notifications obligations

EFSA

- Responsibility to provide the RMS/EMS with all the relevant elements required for the assessment of the compliance with the obligations of study notifications, strictly on a need-to-know basis.

Declaration of Admissibility

Risk assessment phase

Applicant

- Obligation of **study notification** pursuant to article 32b(2) and (3) of the GFL Regulation

RMS/EMS

- Can request the applicant to provide additional studies

EFSA

- EFSA's scientific units can request the applicant to provide justifications regarding any missing data in relation to notified studies.
- Responsibility to assess the justifications and to suspend the risk assessment process by six months, in case of non-valid justifications or non-submission of the missing data.

In case of basic substance applications, the EC is responsible for assessing the compliance with the obligations of study notifications

Applicants

When preparing your application, make sure to **notify** your studies in EFSA's Notification of Studies database before their starting date and to **submit** in the application all relevant notified studies and information on study notifications (NoS), including, where applicable, any NoS **justification**!!

A NoS justification must be provided for:

- Studies notified but not submitted in the application
- Studies notified with delay, i.e., after the study starting date
- Studies notified and later withdrawn
- Studies commissioned or carried out after 27 March 2021, not notified but submitted in the application

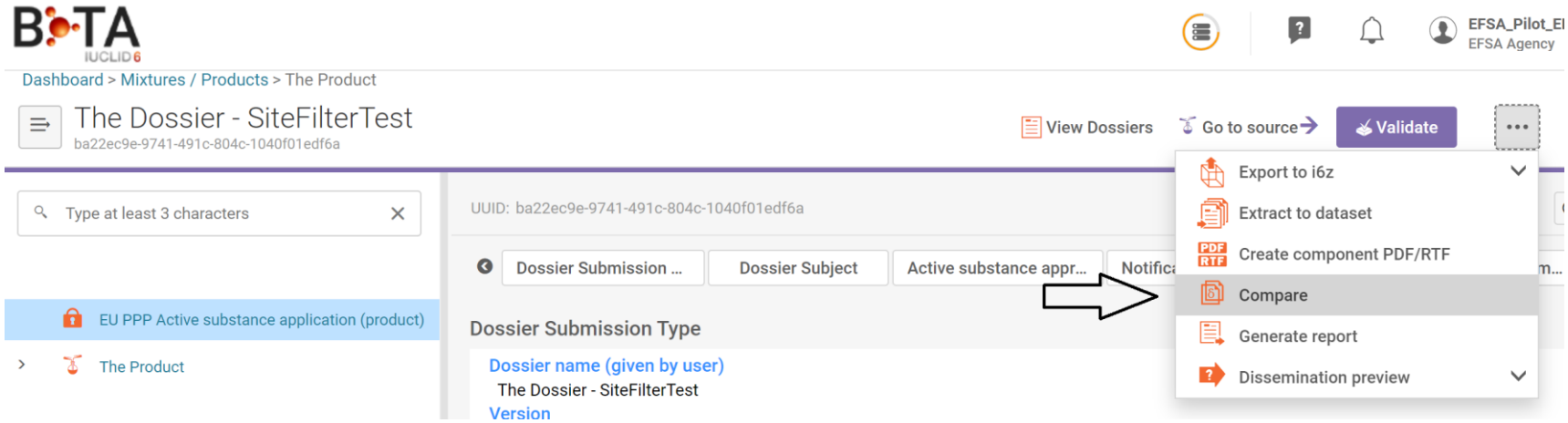
Notification obligations are applicable to studies commissioned or carried out after 27 March 2021.

For studies commissioned or carried out before 27 March 2021, the applicant can indicate this as a justification for not having notified the study in the 'Remarks' field of the literature reference entity

RMS/EMS

EFSA is providing the RMS/EMS with a new NoS extraction following every resubmission of a dossier.

To avoid duplication of work during the assessment of the NoS, please use the 'Compare tool' in IUCLID to verify what information has changed compared to the previous dossier version.



Please always consult the document 'Comment.txt' in the relevant DMS folder as it may contain some tips to be considered by the RMS/EMS when assessing the compliance with the obligations of study notifications

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In case of basic substance applications, the EC is responsible for assessing the compliance with the obligations of study notifications

References

- Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain
- EFSA's Practical arrangements on pre-submission phase and public consultations
- Questions and Answers on EFSA Practical Arrangements
- User Guide – Notification of Studies

If you have any questions, please do not hesitate to contact us via the Ask a Question tool.