



**FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
11-12 JUNE 2024**

FEEDBACK FROM DE

Notification of studies:

1. It is unclear to DE and to many applicants, which date is binding as the "study start" of a study for notifying in 'EFSA's database of study of notification'? The information in Article 2, letter (e) of the EFSA Practical Arrangements on pre-submission phase and public consultations and in "Questions and Answers on EFSA Practical Arrangements" is not sufficient. Is the date of signature of the study plan by the study director, the date of the audit of the study plan or the experimental start date?

In the context of the admissibility check, the relevant regulatory body must ensure the compliance of the application with the obligations of study notification, including the obligation that the studies were notified before the starting date.

Different dates included in a study report may be considered for the starting date. The examples in the following slides show for three different studies the date included in the dossier as the starting date and screenshots of the various dates available in the study reports, which might be considered.



FEEDBACK FROM DE

Notification of studies:

- Article 2, letter (e) of the EFSA Practical Arrangements on pre-submission phase and public consultations:

“Starting date of a study” means the experimental starting date, that is to say, the date on which the first study-specific data are expected to be collected; in the specific case where the experimental starting date is difficult to estimate, the starting date of a study is determined as follows:

- (i) for studies conducted according to an established protocol, the starting date of a study means the date of signature of this protocol;
- (ii) for studies not conducted according to an established protocol, the starting date of a study means the date of definition of the study plan.



FEEDBACK FROM DE

- Notification of studies (1st Example):
 - Study starting date indicated in IUCLID Dossier for the study: 16.03.2021 (in study report: date of the study initiation)
 - Dates available in the study report, which might be considered for the starting date :

Type of Audit / Inspection	Date of Audit	Date of report to Principal Investigator	Date of report to Study Director	Date of report to Management		
Study plan	28 Jan 2021	-	01 Feb 2021	01 Feb 2021		
Study plan amendment 1	01 Apr 2021	-	01 Apr 2021	01 Apr 2021		
Experimental Phase		Honey sugar check	08 Jun 2021	-	08 Jun 2021	08 Jun 2021
Study plan PI Part			18 Mar 2021	18 Mar 2021	18 Mar 2021	18 Mar 2021
Study plan amendment 1 PI Part			13 Apr 2021	13 Apr 2021	13 Apr 2021	13 Apr 2021
Experimental Phase		Sampling test item solution, Application	14 Apr 2021	14 Apr 2021	14 Apr 2021	14 Apr 2021

Activity	Date
Study initiation	16 Mar 2021
Experimental start (field phase)	12 Apr 2021
Experimental end (analytical phase)	05 Jul 2021



FEEDBACK FROM DE

- Notification of studies (2nd Example):
 - Study starting date indicated in IUCLID Dossier for the study: 21.03.2021 (date not found in the study report)
 - Dates available in the study report which might be considered for the starting date :

	Date of Audit	Date of Report to Study Director	Date of Report to Management
Study Plan	18 Mar 2021	18 Mar 2021	18 Mar 2021
Experimental Phase*	01 Apr 2021	01 Apr 2021	01 Apr 2021
Raw Data	27 – 30 Aug 2021	30 Aug 2021	30 Aug 2021
Final Report	22 – 27 Sep 2021	27 Sep 2021	27 Sep 2021

Document	Date of Document
Study Plan	24 Mar 2021

Item	Activity	Date
Study initiation	Signature of study plan by Study Director	24 Mar 2021
Experimental start	Preparation of stock solution	01 Apr 2021
Experimental end	Last printout of raw data	30 Aug 2021
Final report	Signature of final report by Study Director	11 Oct 2021



FEEDBACK FROM DE

- Notification of studies (3rd Example):
 - Study starting date indicated in IUCLID Dossier for the study: 06.05.2020 (in study report: date of the study plan)
 - Dates available in the s

	Date of audit	Date of report to Study Director	Date of report to Management
Study plan -	29 Apr 2020	29 Apr 2020	29 Apr 2020
Study plan amendment 1 -	12 Jul 2021	12 Jul 2021	12 Jul 2021
Experimental Phase¹ Fortification of Storage Stability Samples	20 Jul 2020	20 Jul 2020	20 Jul 2020

Item	Activity	Date
Study initiation	Signature of study plan by Study Director	Fehler! Verweisquelle konnte nicht gefunden werden.
Experimental start	Preparation of stock solution	11 May 2020
Experimental end	Last printout of raw data	15 Jun 2021
Final report	Signature of final report by Study Director	22 Jul 2021

Document	Date of Document
Study Plan	06 May 2020
Study Plan Amendment No.1	12 Jul 2021



FEEDBACK FROM DE

Notification of studies:

2. Is it necessary for the applicant to change the “study end date” from the expected completion date of the study report to the actual completion date of the study report (e.g. signature date of the final study report) in the notification of the study in the database?



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