




# PRACTICAL IMPLEMENTATION ON THE NEW ACT ON SAFENERS AND SYNERGIST

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# ARTICLE 7 OF COMMISSION REGULATION (EU) 2024/1487



A vertical sequence of five white circles connected by a thin brown line. The circles are positioned to the left of five horizontal bars of different colors (dark blue, teal, green, light green, and orange). The bars contain text related to Article 7 of Commission Regulation (EU) 2024/1487. The first circle is partially obscured by a large orange 'D' shape on the left edge of the slide.

Applicants for the approval of a safener or a synergist are required to notify studies in line with Article 32b(2) of the General Food Law (GFL).

Notified studies should include information and details on the utilisation of alternative testing methods and the rationale for their use.

Applicants for the approval (or the renewal of the approval) of a safener or a synergist may request general pre-submission advice (GPSA) in line with Article 32a(1) of the GFL. The reply to the GPSA request is given by EFSA and the MS.

Applicants for the renewal of the approval of a safener or a synergist shall notify intended studies in line with Article 32c(1) of the GFL. The renewal pre-submission advice (RPSA) is provided by EFSA jointly with MS.

Pre-submission activities for safeners or synergists applications will be made possible on Connect.EFSA by releasing new functionalities.



# **NOTIFICATION OF STUDIES (NOS)**

# NOTIFICATION OF STUDIES

EFSA will make available on Connect.EFSA two **new Food Domains**, e.g. *Pesticide peer review - safeners or synergists (new approval)* and *Pesticide peer review - safeners or synergists (renewal of the approval)*.

From a pre-application ID, potential applicants will be able to **create** new NOS or **add** existing ones.

The study design section will be used to describe and detail the utilisation of alternative testing methods.

The screenshot shows the 'Pre-Application ID' interface for 'Application for a safener/synergist'. At the top right, there are three buttons: 'Edit', 'New Study', and 'Add Studies', with a dropdown arrow next to 'Add Studies'. Below these buttons, the ID 'EFSA-ID-2022-001294' is displayed. The interface has two tabs: 'Details' (selected) and 'History'. A legend indicates that '\*' denotes required information. The 'Details' section shows the 'Request Name' as 'Application for a safener/synergist' and the 'ID' as 'EFSA-ID-2022-001294'. There is a small edit icon next to the request name.

The screenshot shows the 'Study Design' section, which is highlighted with a red border. It contains two main input areas: 'Study Guideline' and 'Study Design Description'. Below these, there are two more input areas: 'Study Detailed Protocol' and another empty field. Each input area has a small information icon (i) next to it.



# **PRE-SUBMISSION ADVICE**

**#Connect.EFSA**

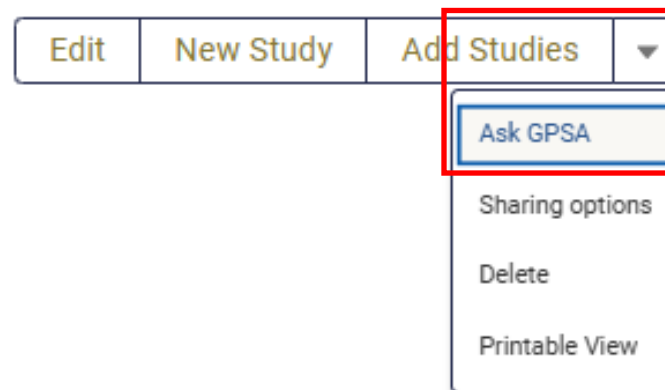


# GPSA

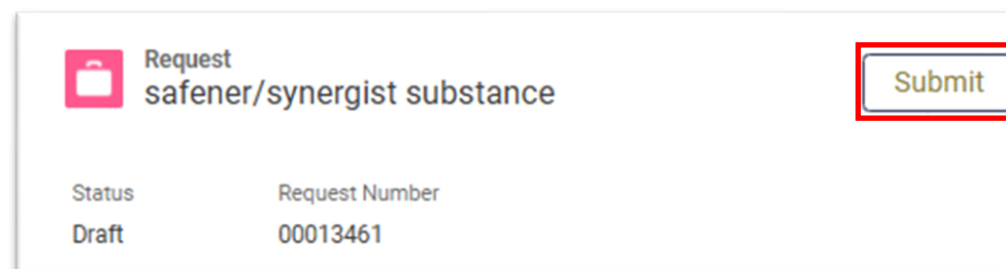
From a pre-application ID, potential applicants will be able to **ask a new GPSA** to EFSA.

The GPSA request shall be then submitted indicating the MS to be involved in the reply.

MS contact people assigned to GPSA will be informed about the new GPSA submission and will be involved by EFSA in the reply.



A screenshot of a web interface showing a horizontal menu with four items: 'Edit', 'New Study', 'Add Studies', and a dropdown arrow. The 'Add Studies' item is highlighted with a red box, and its dropdown menu is open, showing four options: 'Ask GPSA' (highlighted with a blue box), 'Sharing options', 'Delete', and 'Printable View'.



A screenshot of a web interface showing a 'Request' form. The form has a pink icon of a briefcase and the text 'Request safener/synergist substance'. A red box highlights the 'Submit' button. Below the form, there is a table with two columns: 'Status' and 'Request Number'. The 'Status' is 'Draft' and the 'Request Number' is '00013461'.

Status	Request Number
Draft	00013461

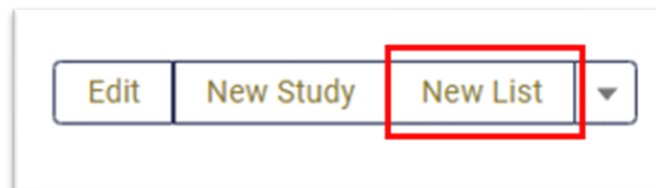


# RPSA

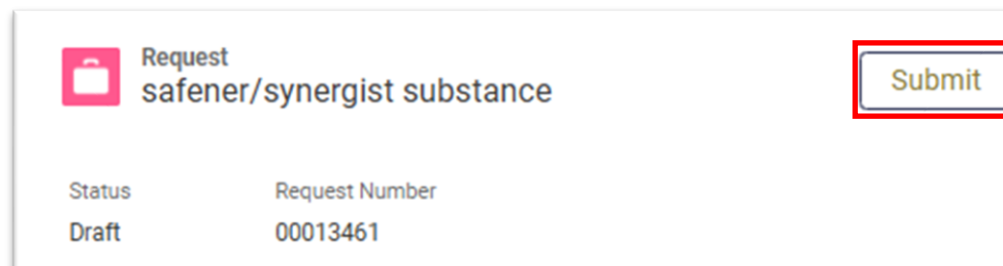
From a pre-application ID supporting the renewal of an approval, potential applicants will be able create a **new list of intended studies**, in line with Article 32c(1) of the GFL.


The List shall be then submitted indicating the RMS and Co-RMS to be involved in the RPSA.

MS contact people assigned to RPSA will be informed about the new List submission and will be involved by EFSA in the RPSA.



Edit New Study New List ▼



 Request  
safener/synergist substance

Submit

Status	Request Number
Draft	00013461

# GENERAL PRE-SUBMISSION ADVICE

 Report: Contacts & Accounts <b>Contacts with qualification</b> Report with contact qualification detail for pre-submission activities							
Total Competent Organisations	Total EU Member States	Total National Authority in EU MS	Total GPSA for peer review	Total RPSA for peer review	Total GPSA for MRL	Total GMO (Higher plants)	Total GMO (Other than higher pla...
38	38	38	27	31	36	0	0

- EFSA manages a list of contact people in the MS Competent Authorities that collaborate in drafting GPSA and RPSA replies.
- Currently contact people are indicated by each MS and assigned to one or more of the following groups:
  - GPSA for peer review
  - RPSA for peer review
  - GPSA for MRL
- New groups dedicated to safeners and synergists may be created to better manage the MS contribution.





# IUCLID

#Connect.EFSA



# IUCLID FOR SAFENERS AND SYNERGISTS

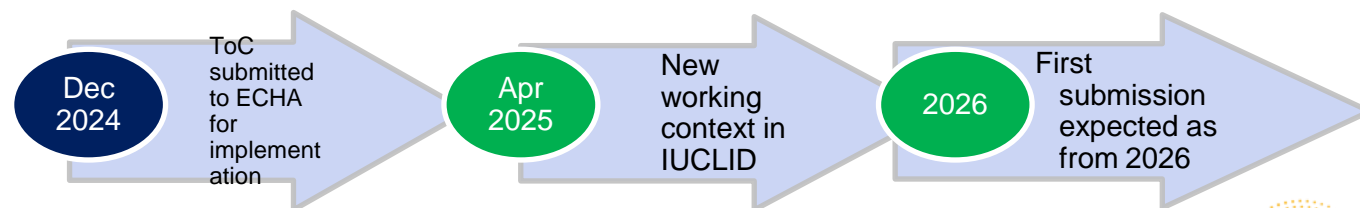
- [COMMISSION REGULATION \(EU\) 2024/1487](#) of 29 May 2024 defines the data requirements for the approval of safeners and synergists in the EU and establishes IUCLID as the standard data format for the submission
- Data requirements similar to those required for the approval of active substances. In addition, **supplementary data** in relation to the demonstration of **efficacy** of the safeners and synergists are required.
- Meeting held with EC on 07/10 to clarify a few technical aspects regarding implementation of the new Table of Content in IUCLID



# IUCLID FOR SAFENERS AND SYNERGISTS

The screenshot displays the IUCLID interface for 'EU PPP Safeners and synergists'. The 'Working context' dropdown is highlighted with a green box. The left sidebar shows a list of sections, with '6 Efficacy data' highlighted and circled in green. The main content area shows fields for 'Mixture/Product name\*' (TESTLE), 'Public name', 'Legal entity owner' (EFSA Agency | Helsinki | Finland), and 'Third party'. The 'Other identifiers' section is also visible.

- A new working context in IUCLID is being prepared and will be deployed in IUCLID in April 2025
- To meet the data requirements of COMMISSION REGULATION (EU) 2024/1487 the IUCLID OHT on Efficacy is being improved to host data on efficacy trials



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