PRACTICAL IMPLEMENTATION ON THE NEW ACT ON SAFENERS AND SYNERGIST

Federico Morreale
Sara De Berardis
Alessandro Delfino

efsa
EUROPEAN FOOD SAFETY AUTHORITY

ARTICLE 7 OF COMMISSION REGULATION (EU) 2024/1487

- 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.

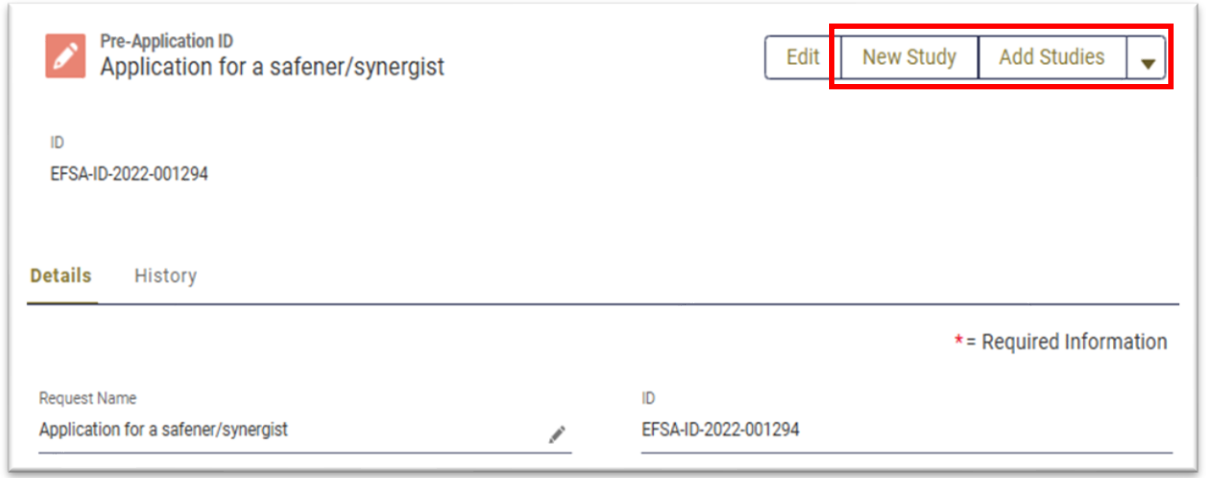
NOTIFICATION OF STUDIES (NOS)

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.



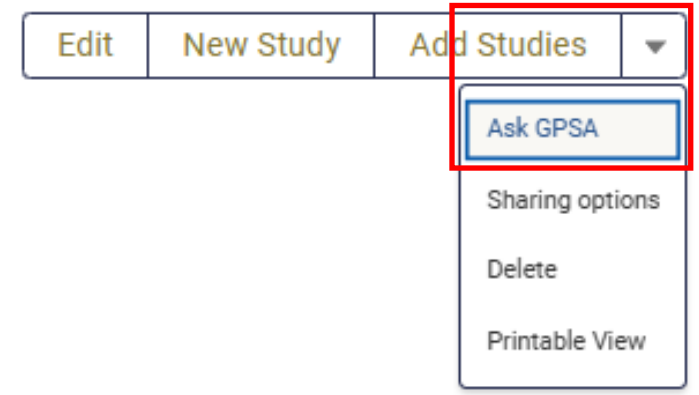
PRE-SUBMISSION ADVICE

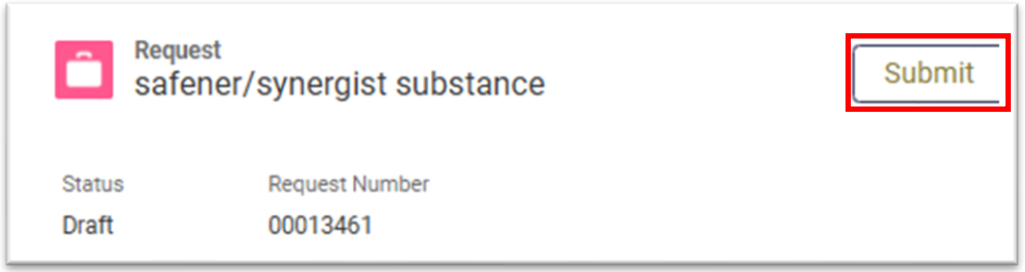
GPSA

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.



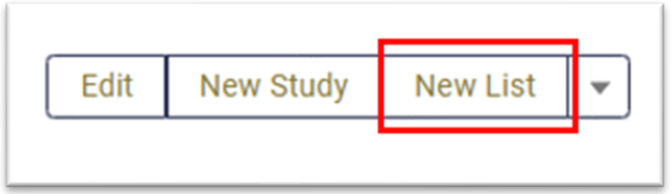


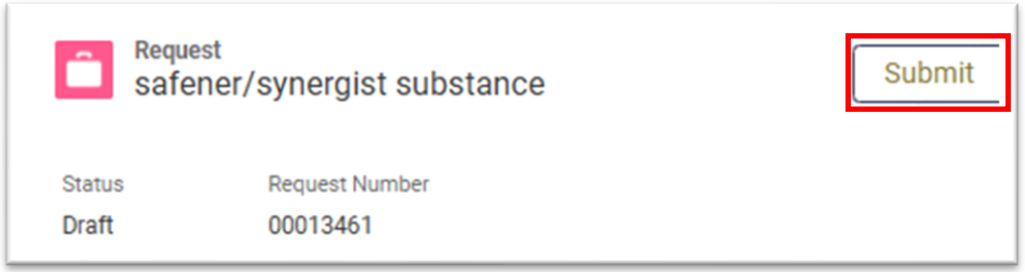
RPSA

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.





GENERAL PRE-SUBMISSION ADVICE

Report: Contacts & Accounts
Contacts with qualification
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

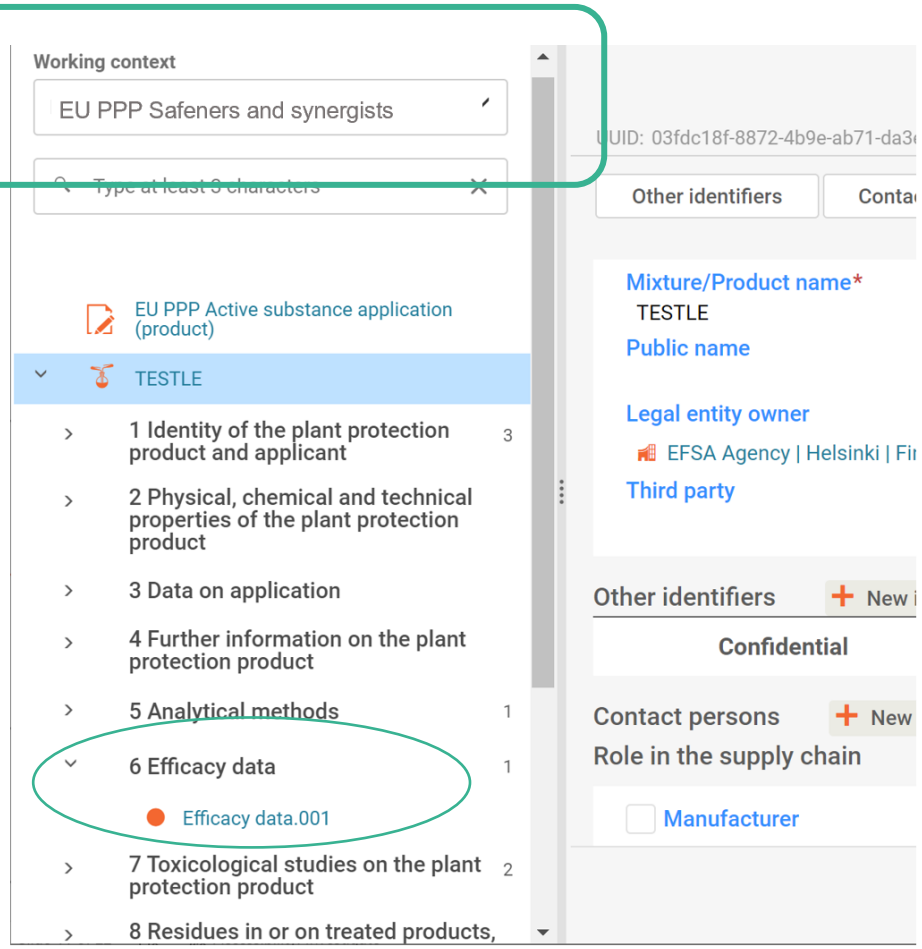
IUCLID FOR SAFENERS AND SYNERGISTS

- 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

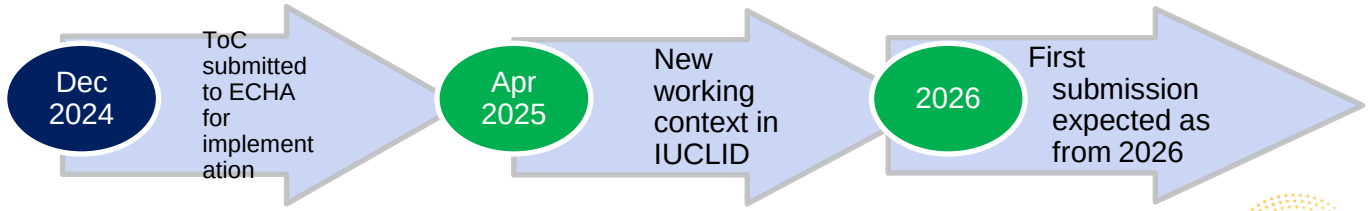
- Data requirements similar to those required for the approval of active substances. In addition, **supplementary data** in relation to the demonstration of **efficacy** of the safeners and synergists are required.

- 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



- 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



STAY CONNECTED

SUBSCRIBE TO
efsa.europa.eu/en/news/newsletters
efsa.europa.eu/en/rss
Careers.efsa.europa.eu – job alerts

LISTEN TO OUR PODCAST
Science on the Menu –Spotify, Apple Podcast and YouTube

FOLLOW US ON TWITTER
@efsa_eu @methods_efsa
@plants_efsa @animals_efsa

FOLLOW US ON LINKEDIN
Linkedin.com/company/efsa

FOLLOW US ON INSTAGRAM
@one_healthenv_eu

CONTACT US
efsa.europa.eu/en/contact/askefsa

efsa
EUROPEAN FOOD SAFETY AUTHORITY