Advisory Group Food chain Food Chain and Animal and Plant Health
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EFSA Practical Arrangements on pre-submission phase and public consultations

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Structure - one consolidated set of rules

- **Chapter I – General aspects**
  - Definitions (study, laboratory, regulated product etc.)
  - Registration/Pre-application ID
  - Requirements in relation to submission of applications

32a

- **Chapter II – General pre-submission advice (GPSA)**
  - Scope
  - Modalities for requests and provision of the advice
  - Specific provisions for pesticides (new substances and renewals) and MRLs

32c(1)

- **Chapter III – Intended renewal applications**
  - Notification of new intended studies
  - Public consultation on intended studies
  - Renewal pre-submission advice (RPSA)

32b

- **Chapter IV – Notification of studies**
  - Modalities for the submission of study notifications
  - Information to be provided by applicants when submitting the applications
  - Verification of compliance with study notification obligations and procedural consequences

32c(2)

- **Chapter V - Public consultation on submitted applications**
  - Scope
  - Procedure
  - Use and disclosure of the results

PAs: 'application' - '(potential) applicant' = application/notification - '(potential) applicant/notifier'

Chapter I - General aspects

Traceability

Registration

- potential applicants or laboratories or testing facilities + third parties to first register in the EFSA system supporting pre-submission activities

Pre-application ID

- assigned by EFSA to potential applicants (individually or jointly) prior to initiating pre-submission activities in connection with a given regulated product / given regulated product area
- to be later indicated by applicants when submitting the application

Definition

- 'Study' (~ GLP Directive) means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data with respect to the properties and/or the safety of that test item, which is relevant for submission to appropriate regulatory authorities
  - **IN** – Studies carried out in field conditions, observational studies, efficacy studies, laboratory analyses
  - **OUT** – literature reviews
- 'Multisite study'
- 'Starting/planned completion date of a study'
- 'Laboratory and testing facility'

Scope

- Union law → EFSA to provide a scientific output
- Application based sectors
- Advice requested to EFSA
- **IN** - Advice on rules applicable to, and the content required for, an application
- **OUT** - advice on the design of the studies (unless study design addressed in guidance documents), questions related to hypotheses to be tested, risk management and any other aspects going beyond the information available in the rules and guidance documents or guidelines
- Available in relation to intended applications for first **approvals / authorisations** and for **renewals**
- **Non-committal nature** for both the potential applicant and EFSA/MS

Chapter II – General pre-submission advice

Modalities

- Segregation of duties
- Up to two (non-overlapping) requests submitted through the applicable IT tool at least six months before planned submission date
- Administrative check → accepted/rejected within 15 wd
- Provision of the advice
  - reply in writing as default option within 15 wd from the acceptance
  - meetings only if necessary, organised within 20 wd from the acceptance
  - summary to be shared with the potential applicant and published only once the application is considered valid/admissible

Specific for PPPs/MRLs

- Potential applicant to indicate the relevant national competent authorities (RNCA) → requests transmitted to them
- EFSA in close cooperation with RNCA
- 20 wd for written advice
- Possible diverging views between EFSA and RNCA → advice and summary
- Advice and summary → all national competent authorities
- Submission of the application → RNCA to assess admissibility → information to EFSA → public disclosure of summary of GPSA

Chapter III – Intended renewal applications

Notification of intended studies

- If on 27 March 2021 potential applicant intends to carry out new studies
- Single submission
- Information to be notified
- At least five months before the date of commissioning/start of the intended studies
- Dedicated section of EFSA database

Public consultation

- Administrative check (10 wd) on received information
- Stakeholders and the public
- 3 calendar weeks
- Comments published upon the closure
- Review the comments relevant for the risk assessment

Renewal pre-submission advice

- **Modalities** ~ to GPSA but systematic
  - Written advice as default or meeting if necessary
  - Within 30 wd
  - **Summary**
    - includes results of PC (how EFSA has taken comments into account)
    - shared with the potential applicant for information and disclosed once application is declared valid/admissible

Notification obligations

Specific provisions for PPPs renewals ~ GPSA

Submission of study notifications

- **Who**
  - Potential applicant + laboratory / testing facility → simplification → co-notification
  - Specific scenario of multisite study
- **What**
  - Studies commissioned / carried out as of 27 March 2021, including those requested by EFSA or the MS after the submission of the application during either the assessment of validity/admissibility of the application or the risk assessment
  - Information to be notified → to allow identification of notified studies to be linked with the submitted studies in corresponding applications and enable verification of compliance
- **When**
  - Before the starting date of the study
  - If delay → valid justification or study to be considered as "non-notified"
  - Withdrawals possible → valid justification or to be considered as "non-included" study

Info to be provided when submitting applications

- **Pre-application ID**
- **Study identifications generated by the database**
- **Justifications** to explain
  - Non-notification in the database of studies included in the application (32b(4))
  - Non-inclusion in the application of studies previously notified (32b(5))
  - Delayed notification and withdrawals

Verification of compliance

- Article 32b(4) and (5) TR → belong to **assessment of validity/admissibility**

- PAs → cases in which **EFSA responsible to decide on the validity, exclusively or jointly with COM**

- **Compliance** with NoS obligations if
  - match between information notified in the database and the content of the application, or
  - justifications provided to explain deviations are considered valid

  - Notified study information + valid justifications to be disclosed without delay after the application is declared valid/admissible and the confidentiality decision-making implemented

Procedural consequences for non-compliance

- Application declared **non valid**
- Applicant invited to **re-submit** a new application + identification previous application
- Assessment starts **six months after** new application submission, provided that
  - notification of the studies included in the application but not previously notified in the DB, or
  - submission of the study previously notified in the DB and initially not included in the application
  - in case of unjustified withdrawal, submission of the data delivered by the relevant laboratory or testing facility even without having the study completed

- Procedural consequences when EFSA detects, during its risk assessment, that studies previously notified are **not included** in the submitted application **in full** (Article 32b(6) TR)

Chapter V – Public consultation on submitted applications

- If confidentiality claims, the PC takes place on the basis of the version of the application made public by EFSA **following the confidentiality decision-making** (if judicial action → non-confidential version as submitted by the applicant)

- Procedure similar to the one designed for the PC at pre-submission phase

- **Comments** received published upon closure of the PC

- **Results** (how EFSA has taken the received comments into account during the RA) published after the adoption of the relevant scientific output on the submitted application

Annex I – Intended studies for renewal

- **Study Title*** shall report the title of the study. In case the original title is not in English, an English translation shall also be provided.
- **Potential applicant(s)*** is a repeatable field containing the information to identify the organisations that intend to submit an application for the renewal of the authorisation or approval.
- **Former application id*** shall contain the identifier of the application to be renewed.
- **Study scope*** section shall comprise of the following information elements:
  - **Study intended area*** shall report the regulated product area of the future application or notification for renewal that the study is meant to support.
  - **Study type*** shall report the type of the study.
  - **Study objective*** shall report the narrative where the objective shall be described.
  - **Test item*** shall report the identification of the study test item related to the regulated product that is subject of the application under renewal. Depending on the type of the test item, information on its components shall also be provided.
- **Study design***
  - **Study guideline*** shall report the guideline or guidance document followed by the study, if any; or, if the intended study does not follow any study guideline, the **Study design description*** shall contain the description of the design of study including the hypothesis.
  - **Study detailed protocol (optional)** shall contain more detailed information and further elaborating methodology, statistical considerations, and organization of a study. The protocol usually also gives the background and rationale for the study.

Annex II - Notification of studies

- **Study Title*** shall report the title of the study. In case the original title is not in English, an English translation shall also be provided.
- **Study Starting Date*** shall reports the starting date of the study as defined in Section 3, letter f).
- **Study Planned Completion Date*** shall report the study planned completion date as defined in Section 3, letter g).
- **Potential applicant(s)*** is a repeatable field containing the information to identify the organisation(s) that commissioned or carried out the study.
- **Laboratories*** is a repeatable field containing the information to identify the laboratory or testing facility carrying out the study commissioned by the business operator(s).
- **Study scope*** section comprises of the following mandatory information elements:
  - **Study intended area*** shall report the regulated product area of the future application that the study is meant to support. More than one area can be indicated.
  - **Study type*** shall report the type of the study.
  - **Study international standard certification*** shall report the standard certification of the study.
  - **Study objective*** shall report the narrative where the objective is to be described.
  - **Test item*** shall report the identification of the study test item related to the regulated product that is subject of the future application. Depending on the type of the test item, information on its components shall also be provided.
  - **Study internal reference id assigned by the business operator/laboratory or testing facility (optional)** shall report the identifier of the study as assigned by the business operator/laboratory or testing facility.