3rd Sounding Board meeting
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EFSA's Practical Arrangements

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Trusted science for safe food

efsa
European Food Safety Authority

EFSA practical arrangements

1. Public Access to Documents (Reg. 178/2002, Art. 41)

2. Pre-submission phase and public consultations (Reg. 178/2002, Art. 32a, b, c)

3. Transparency and Confidentiality Assessment by EFSA (Reg. 178/2002, Art. 38 and 39d(5)

4. Consistency of MS confidentiality assessments (PPPs) (Reg. 1107/2009, Art. 7 and 16)

Informal consultation with SANTE

Informal Consultation with SANTE Expert Group GFL

Formal consultation with EC Expert Group GFL

Informal consultation with SANTE **Formal consultation with MS**

Advisory Group, Sounding Board

Adopted in March 2020

Adoption in 2020

Practical Arrangements on Transparency and Confidentiality (Articles 38 and 39-39e of the TR)

Proactive disclosure – main features

- Extensive proactive disclosure requirements
- Disclosure on EFSA's dissemination portal
- No IPR enforcement role
- Accessibility of documents, information and studies upon acceptance of "Terms of Reference"
- Limited liability

Confidentiality – main features

- Confidentiality exception to transparency
- Burden of proof on applicant
- Individual assessment of, and decision on, confidentiality requests
- Reasoned decision by EFSA
- Non-disclosure pending decision

Procedural requirements
Article 9 of the Practical Arrangements

- Applicants may submit confidentiality requests only via the IT tool(s)
- No fees
- Confidentiality requests
  - supported by verifiable justification
  - Identifying information whose confidentiality is claimed
- Applicants may not modify or complement confidentiality requests

Substantive screening criteria
Article 10 draft Practical Arrangements

- Closed positive List
- Potential harm to a significant degree
  - Information not publicly available
  - Interest acquired by legitimate mean
  - Negligible harm - rebuttable presumption
  - Novelty - rebuttable presumption
- Environmental information under Aarhus Regulation

Confidentiality Decision making process Article 11 of the Practical Arrangements

- Admissibility of confidentiality request
- Possibility to seek clarifications
- Mandatory consultation with applicant
  - Applicant comments by 2 weeks
- EFSA adopts decision by 8 weeks
  - Implementation by 2 weeks from notification
- Dissemination by EFSA not earlier than 2 weeks from notification

Confirmatory applications procedure
Article 12 of the Practical Arrangements

Confirmatory application

- By two calendar weeks from notification of decision
- No new confidentiality requests allowed
- Suspensive effect

Confirmatory decisions

- by 3 weeks from receipt of confirmatory application
- "segregation of duties"
- judicial review
- *Lex specialis* vis-à-vis "administrative review clauses"

Review of previously adopted decisions Article 14 of the Practical Arrangements

- Foreseeable effects on human health, animal health or the environment identified in EFSA's opinion
- Effects relate to items granted confidential status
- EFSA decision by 20 working days from adoption following same procedure in Article 11 of the PAs.
- EFSA decision on optional Confirmatory application by 10 working days from receipt following same procedure in Article 12 of the PAs.

Withdrawal of application dossiers
Article 15 of the Practical Arrangements

Prior to the adoption of the confidentiality decision

- Compliance with initial confidentiality requests
- deletion of published information or data for six months after receipt of withdrawal notification

After the adoption of the confidentiality decision

- Implementation of, and compliance with, the confidentiality decision if adopted
- Deletion of published data after six months from receipt of withdrawal notification

Annex & common provisions

- Annex & purpose
- Review of the Practical Arrangements

Practical Arrangements on Confidentiality (Articles 7 and 16 of Regulation (EC) No 1107/2009)

PAs on confidentiality decision making for plant protection products - scope

Article 7 New Active Substances	Article 16 Renewals
Specific PAs ensuring consistency of RMS / EFSA confidentiality decisions	Applicability of PAs of Article 39d(5)

Confidentiality decision making for New Active Substances

Rapporteur Member State consults EFSA by 4 weeks from receipt

EFSA's advice by 10 WDs from receipt

RMS draft decision to applicant by 1 week from EFSA's advice

RMS decision by 2 weeks from receipt of EFSA's advice

Implementation by 1 month from notification

Publication by EFSA

Confidentiality decision making for renewals

- EFSA shares draft decision with applicant
- Applicant comments by 2 weeks
- EFSA adopts decision by 10 weeks, including implementation
- (Confirmatory application by 2 weeks from notification)
- (Decision on confirmatory application by 3 weeks)
- Publication by EFSA

Confidentiality – Substantive screening criteria

Assessment of confidentiality requests
Shared Criteria

- Closed positive List
- Potential harm to a significant degree
  - Information not publicly available
  - Interest acquired by legitimate mean
  - No negligible harm – rebuttable presumption
  - Novelty – rebuttable presumption
- Environmental information under Aarhus Regulation

Practical Arrangements on pre-submission phase and public consultations (Articles 32a, 32b, 32c)

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

Traceability

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

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 per Pre-application ID
- IT tool
- At any time but at least six months before planned submission recommended
- Administrative check → accepted/rejected within 15 wd
- Default is reply in writing (within 15 wd from the acceptance), meetings only exceptional (within 20 wd from the acceptance)
- Summary of GPSA

Specific for PPPs/MRLs

- Potential applicant to indicate the relevant national competent authorities (RNCA) → requests transmitted to them
- EFSA in close cooperation with RNCA but within the scope of 32a
- 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 inform EFSA when declared admissible to proceed with 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
- Pre-application-ID
- Single submission
- Information to be notified
- At least five months before the date of commissioning/start of the intended studies (recommended)
- 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

Specific provisions for PPPs renewals ~ GPSA

Notification obligations

A. 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 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

B. 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

C. 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
  - EFSA Risk Assessment
  - Transmitted to MS when responsible for RA (Regulation (EC) No 1107/2009 on plant protection products and Regulation (EC) No 396/2005 on maximum residue levels of pesticides)

- **Results** (how the received comments are taken into account in the context of EFSA Risk Assessment) → published after the adoption of the relevant scientific output

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.

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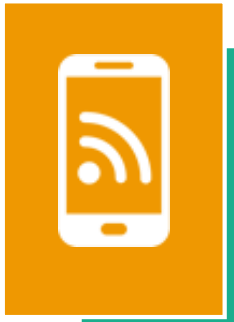

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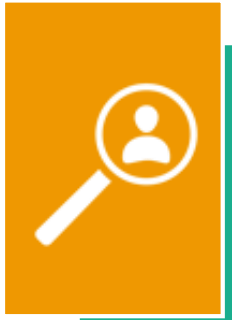

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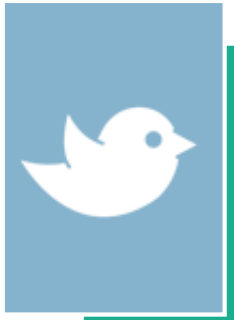

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