



Renewal obligations

The non-notifier's dilemmas

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Uncertainties and dilemmas

- What do I have to submit? What is “necessary”?
- Do I have an obligation to refer to existing data?
- Do I have a right to refer to existing data?
- When do I know what data is necessary?
- When do I know what data exists, who owns it, and when can I start negotiating to share that data?
- When can I decide to generate my own data, after taking all reasonable steps to share?



Necessary & Protected data

- Only necessary data must be submitted (Art. 43.2)
 - Changes in data requirements, criteria, guidance documents
 - “nice to know” or “need to know”
- Only necessary shall be protected (Art. 59)
- Applicants shall submit a list of studies for which data protection is claimed (Art.7.4 & 33.4)
- MS competent authorities shall keep those lists available, including the justification (*i.e.* why the studies were necessary, and why they should attract protection under Art. 59) (Art. 60)



Art. 60

- For each active substance (...) rapporteur Member States shall prepare a list of the test and study reports necessary for (...) renewal of the approval and make it available to the Member States and the Commission.
- For each PPP which they authorise, Member States shall keep and make available to any interested party upon request:
 - a list of the test and study reports concerning the active substance (...) and the plant protection product necessary for (...) renewal of the authorisation; and
 - a list of test and study reports for which the applicant claimed data protection under Article 59 and any reasons submitted in accordance with that Article.



List of Studies

List of Annex II studies which were considered

LIST OF INFORMATION, TESTS AND STUDIES WHICH ARE CONSIDERED AS RELIED UPON BY THE RMS FOR THE EVALUATION WITH A VIEW TO THE RENEWAL OF THE ACTIVE SUBSTANCE

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Article 60

List of test and study reports²

1. For each active substance, safener and synergist and adjuvant, rapporteur Member States shall prepare a list of the test and study reports necessary for first approval, amendment of approval conditions or renewal of the approval and make it available to the Member States and the Commission.

for the Annex I Renewal

Necessary vs. Relied upon

- First Annex I inclusion: Soil degradation:
 - Study A (1983, OECD 307, GLP): $DT_{50} = 58$ days
 - Study B (1995, OECD 307, GLP): $DT_{50} = 40$ days
 - DAR: selected endpoint: $DT_{50} = 58$ days
- Renewal, AIR 3: Soil degradation:
 - Study C (2000, OECD 307, GLP): $DT_{50} = 80$ days
 - new Guidance? No
 - new data requirement? No
 - new protocol? No
 - **Necessary Data? NO**
 - RAR: selected endpoint: $DT_{50} = 80$ days
 - Data relied upon with a view to the renewal? **Yes**
 - **Necessary? No.**
 - **Protected? No**

A study shall also be protected if it was necessary for the renewal or review of an authorisation. The period for data protection shall be 30 months. The first to fourth subparagraphs shall apply *mutatis mutandis*.

Justification necessary data

KCA 7.1.2.1.2 /02	Traub, M.	2012	AE C509607: Aerobic degradation in four European soils Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-00958, Edition Number: M-431784-01-1 Date: 2012-04-17 GLP/GEP: yes, unpublished	N	Y	Metabolite not exceeding 5% AR in soil but potentially required to assess the behaviour in soil of succeeding metabolite NC20645	Task Force Ethofumesate	Submitted for the purpose of renewal (2014)
KCA 7.1.2.1.2 /03	Traub, M.	2012	Ethofumesate-carboxylic acid (as potassium salt: AE C639175): Aerobic degradation in four European soils Eurofins-GAB GmbH, Niefern-Oeschelbronn, Germany Bayer CropScience, Report No.: S11-03264, Edition Number: M-432551-01-1 Date: 2012-05-22 GLP/GEP: yes, unpublished	N	Y	Required according to new metabolite identification triggers.	Task Force Ethofumesate	Submitted for the purpose of renewal (2014)
KCA 7.1.2.1. 2/01	Malekani, K.	2013	NC8493 (A METABOLITE OF ETHOFUMESATE) - AEROBIC RATE OF DEGRADATION IN THREE SOILS United Phosphorus Ltd., 13845.6134 Smithers Viscient, Massachusetts, USA GLP: yes Published: no	N	Y	Required since a metabolite in new photolysis study.	UPL	Submitted for the purpose of renewal (2014)

Necessary? & Protected? data

- Necessary & justification:

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status	Vertebrate study Y/N	Data protection claimed Y/N	Justification if data protection is claimed	Owner
KCA 5.2.1/1	[REDACTED]	2000 a	Oral LD50 study in albino rats with Pendimethalin (AC 92553)	Yes	Yes	New data for AIR3 renewal	BASF
KCA 5.2.2/1	[REDACTED]	2000 a	Dermal LD50 study in albino rats with Pendimethalin (AC 92553)	Yes	Yes	New data for AIR3 renewal	BASF



Sharing data

- Vertebrate data: clear, Article 62
- Do I have an obligation to share? Yes. a right to share? Yes.
- Non-vertebrate data: Article 61, but not clear
- Art. 61.3: The applicant for the renewal and the data owner shall take all reasonable steps to reach agreement on the sharing of **any** test and study reports protected under Art. 59, in a fair, transparent and non-discriminatory way.
- Art. 62: “a fair share of the cost”.
- It is not about the cost of the studies! Refusal to share is about preventing competition.



Sharing data

- Taskforces agree to share, between themselves.
- New applicants wanting to join:
 - Often rejected without explanation, or
 - “You have no data to contribute”, or
 - “it is too late in the process to allow you to join”.
- “non-discriminatory”? Why is this word in the text?
 - Refusal to join a Task Force: data kartel?
- “transparent”?
- “fair”? If rejection without (justified) motivation is considered fair, then what is “unfair”?



When?

- Art. 61 aims to avoid duplication of studies, but is based on a sequential process.
 - First authorisation by data owner
 - After patent expiry, generic approaches data owner
 - Data sharing negotiation, agreement, Letter of Access
 - Generic application, with LoA
- Renewal is a simultaneous process.
 - Data owner = notifier
 - After renewal:
 - Data owner submits within 3 months
 - Generic submits within 3 months



When?

- Art. 61 aims to avoid duplication of studies, but is based on a sequential process.
- Renewal is a simultaneous process.
- Are there obligations/expectations for the data sharing negotiation process?
 - When to start?
 - EFSA conclusions? Not a good indicator (*see Cat. 1 studies: Data identified by EFSA as data gaps but which are not reflected in the regulation renewing the approval of the active substance*)
 - Publication Review Report? No list of necessary studies...
 - “shall take all reasonable steps to reach agreement on sharing”. When are all reasonable steps exhausted? When to start generating unnecessary and unwanted duplicative data?



Data sharing, is Art. 61 taken seriously?

- What was the purpose of the “list of necessary studies”?
- What was the purpose of Art. 61?
- Does the practice reflect the purpose?

