AT Experiences with the Zonal Evaluation Process (2)

Christian Prohaska
Austrian Agency for Health and Food Safety (AGES)
CEUREG 2012, Vienna

Overview

- 1 – New annex II Data
- 2 – Article 62
- 3 – Classification and Labelling
- 4 – 4 procedures

New Annex II data

New Annex II data

- When are new Annex II data to be considered?
- Procedure described in GD SANCO/10328/2004 rev 7
- As a matter of principle to be evaluated for re-newal of the active substance only (use LoEPs!)

  Unless:
  - new data show adverse risk assessment (no safe use!) – to be evaluated by RMS
  - to show a safe use (e.g. for other uses than representative uses) to be evaluated by zRMS
  - ADI/ARfD/AOEL -> Standing Committee!

Article 62 of Reg. 1107/2009

Article 62 of Reg. 1107/2009

Sharing of vertebrate studies (Article 62) is not such a completely new approach…

And we are under the ethical obligation to follow it

Article 62 of Reg. 1107/2009

Article 13, para 7 of **Dir. 91/414 EEC**

(a) applicants for authorization of plant protection products shall, before carrying out experiments involving vertebrate animals, enquire of the competent authority of the Member State to which they intend making application:

— whether the plant protection product for which an application is to be made is the **same** as a plant protection product for which authorization has been granted

Article 62, para 4 of **Reg. 1107/2009**

Where the prospective applicant and the holder or holders of the relevant authorisation of plant protection products containing the same active substance, safener or synergists, or of adjuvants cannot…

— means: not the same PPP, but a PPP containing the same active substance,….(i.e. the PPP must be **comparable**)

Article 62 of Reg. 1107/2009

Sharing of tests and studies involving vertebrate animals

1.

Testing on vertebrate animals for the purposes of this Regulation shall be undertaken only where no other methods are available. Duplication of tests and studies on vertebrates undertaken for the purposes of this Regulation shall be avoided in accordance with paragraphs 2 to 6.

Article 62 of Reg. 1107/2009

2.

Member States shall not accept duplication of tests and studies on vertebrate animals or those initiated where conventional methods (*explanation*: calculation method) described in Annex II to Directive 1999/45/EC could reasonably have been used, in support of applications for authorisations. Any person intending to perform tests and studies involving vertebrate animals shall take the necessary measures to verify that those tests and studies have not already been performed or initiated.

Article 62 of Reg. 1107/2009

3.

The prospective applicant and the holder or holders of the relevant authorisations shall make every effort to ensure that they share tests and studies involving vertebrate animals.

The costs of sharing the test and study reports shall be determined in a fair, transparent and non-discriminatory way. The prospective applicant is only required to share in the costs of information he is required to submit to meet the authorisation requirements.

Article 62 of Reg. 1107/2009

4.

If no agreement - the prospective applicant shall inform the competent authority of the Member State referred to in Article 61(1). The failure to reach agreement, shall not prevent the competent authority of that Member State from using the test and study reports involving vertebrate animals for the purpose of the application of the prospective applicant.

Article 62 of Reg. 1107/2009

Implications for zonal assessments?

List of studies to be provided by the authorities (according to Article 60) on request

- legally binding only for products first registered according to 1107/2009 (remark: without a study list implementation of Article 62 difficult!)
- request for a study list preceed the application
- How many weeks/months do the zRMS and cMS need to check if there is a comparable product and to prove data protection?

Article 62 of Reg. 1107/2009

Implications for zonal assessments?

To be further considered

- For testing of comparability, the exact composition of the PPPs must be known
- How to prepare the dRR (3rd party/generic/costumer is this time not to blame, he does not have access to studies…)? Use the evaluation of the cMS prepared originally for the national authorisation (if available in English)?
- Change of C & L criteria with CLP -> a detailed previous evaluation by cMSs would be necessary… or the zRMS needs to evaluate the studies
- All cMSs have to have access to the vertebrate studies of the specific product, in order to allow them to comment and support the authorisation

Article 62 of Reg. 1107/2009

Implications for zonal assessments?

Exemptions to obligatory application of Art 62?

- If the studies were generated to support other regulatory regimes e.g. for the US market)
- Studies generated prior to 14 June 2011 (submitting a justification demonstrating generation in good faith and no other approach were available at that time)
- What about studies showing worse effects (e.g. C & L)? Refuse those studies?

Article 62 of Reg. 1107/2009

Draft guidance on data protection and Article 62 provisions (prepared by UK)

- Article may apply to all studies conducted on vertebrate animals, with the exception of field bird and mammal "monitoring" type studies

- MS to inform the data owner of the name and address of the *prospective* applicant (standard letter attached) – how to identify a *prospective* applicant? Until application is received in the MS?

Article 62 of Reg. 1107/2009

Draft guidance (continued)

- Prospective applicant and data owners to make "*every effort*" to ensure that they share vertebrate tests and studies

  - MS will not become involved in considering whether "*every effort*" has been made
  - Potential applicant to inform MS that they failed to reach agreement when they submit their application
  - Time between accepting the application and issuing the authorisation should be sufficient for access negotiations
  - If access negotiations are prolonged, MS may issue the authorisation without LoA to vertebrate studies

C & L and risk assessment

C & L and risk assessment

- C & L of active -> C & L of product (e.g. CMR)

- Active substances are in various stages considering Classification and Labelling:
  - ATP available
  - no ATP available
  - no decision by ECHA yet
  - CLH Annex VI report already submitted to ECHA
  - proposal by PRAPeR meetings available only
  - new studies to be considered
  - ….

C & L and risk assessment

Implications for zonal assessments

- The same product may be classified differently in individual MS

- Influence to the relevance assessment of possible groundwater metabolites

- New Scientific Opinion of PPR Panel (EFSA): "*Scientific Opinion on Evaluation of the Toxicological Relevance of Pesticide Metabolites for Dietary Risk Assessment*", published in July 2012
  C & L of the active to be considered for metabolites in food commodities

->need for harmonisation

C & L and risk assessment

Solution possible?

- Draft Position Paper – to use the most recent evaluation (no agreement between MSs)

- Self classification vs. classification by the MSCA
  (see letter from COM to ECPA by 25 April 2012 – MSCA´s responsibility)

Further challenges

- Harmonisation of risk assessment
  (aim to keep the national addenda as limited as possible)

- MRL setting (EFSA and COM procedure to be considered)

- Efficacy and core assessment
  - What is useful to be included into the core assessment?
  - What belongs to national addenda? – draft GD UK/FR
  - All EPPO zones to be covered by the biological dossier?

- Timelines for first approval of an active substance, MRL-setting, Classification and Labelling and registration of a PPP to be synchronized….

4 Procedures

1. Approval of a.s. according to REG 1107/2009

2. Harmonised MRLs according to REG 396/2005

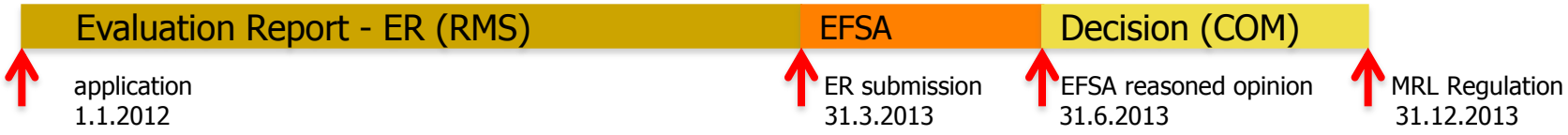
3. 1st authorisation of a PPP according to REG 1107/2009

4. Harmonised C & L according to REG 1272/2008

4 Timelines

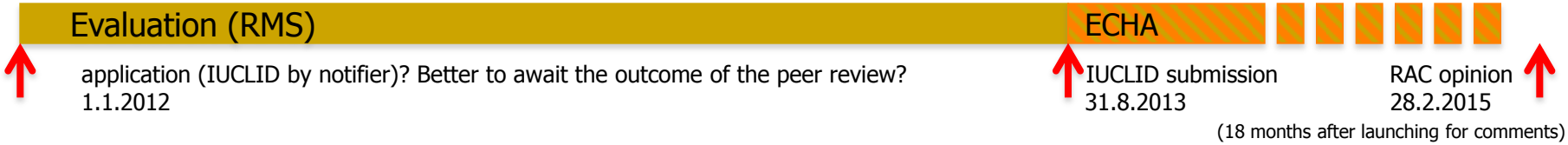
1. Approval of a.s.

2. Harmonised MRLs



3. Authorisation of PPP

4. C & L



4 formates

1. Approval of a.s.: DAR (OECD formate)
2. Harmonised MRLs: Evaluation Report
3. 1st authorisation of a PPP: (d)RR
4. Harmonised C & L: IUCLID

Recommendations/summary

- Avoidance of new Annex II data unless necessary
- Clear procedure for Article 62
- Improvement of risk harmonisation
- 4 procedures to be considered!!!!

What a nightmare!