BUNDESINSTITUT FÜR RISIKOBEWERTUNG

Bundesinstitut für Risikobewertung

Zonal assessments of PPP – German view on the harmonised approach in toxicology and exposure assessment

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Overview

- ➔ Background
- ➔ Approval of AS – authorisation of PPP
- ➔ Consideration of the state of science and technique and of guidance documents in the zonal procedure
- ➔ Optimisation of the procedure/decision making
- ➔ Activities on further harmonisation

Background

Aims/objectives of the Directive (EC) No 1107/2009

- .....

- Simplification and harmonisation of the procedures

- Reduction of the workload for applicators and authorities

- Harmonisation/standardisation of authorisation of PPP

Background

- **Current situation -**
  Simplification and harmonisation of the procedures ?

  - Procedures harmonised – comparable in all MS (zonal authorisation, mutual recognition, ...)

  - Strict timelines (unrealistic / unpracticable?)

Background

- **Current situation -**
  Reduction of the workload ?

  - Number of applications for authorisation in Germany is not reduced

  - Formal requirements on applicants and risk assessors are increased

  - Efforts for reporting of study evaluation, risk assessment, decision making and authorisation are increased

Background

- **Current situation -**
  Harmonisation/standardisation of authorisation of PPP ?

  - Harmonisation is ongoing but not really finalised

  - In the context of the development of science and techniques a never ending process

Approval of AS – Authorisation of PPP

Results of the approval of the AS are <u>one</u> basis for the authorisation of PPP.

For the human health risk assessement:

- **The toxicological reference values (ADI, AOEL and ARfD) should be used unchanged for the authorisation of PPP**

- **Values of dermal absorption can be used if the tested formulation is comparable to the intended formulation (justification is necessary)**

Approval of AS – Authorization of PPP

How to deal with studies to be generated and confirmatory data required with the approval of AS ?

Case by case decision :

- **Studies/data not relevant for the risk assessment of the intended uses of PPP – authorisation possible**

- **Studies/data relevant for the risk assessment of the intended uses of PPP but unacceptable risks can be excluded under realistic worst case conditions – authorisation possible**

- **Studies/data relevant for the risk assessment of the intended uses of PPP but unacceptable risks cannot be excluded under realistic worst case conditions – authorisation not possible**

Consideration of the state of science and technique and of guidance documents in the zonal procedure

All available guidance documents noted (accepted) by Commission and Member States have to considered by applicants and authorities in the zonal procedure of PPP.

- **Revised versions of guidance documents after the approval of AS**

- **New guidance documents after the approval of AS**

Complete overview of all current available guidance documents is missing.

Optimisation of the procedure/decision making

What can we do now?

Applicants:

- **Complete applications with concrete references to all points of data requirements for AS and PPP**

- **References of studies submitted in other procedures and available evaluation of studies are allowed, if the studies or evaluations can be used for the intended PPP (approval procedure or other zonal procedures ...)**

Optimisation of the procedure/decision making

What can we do now?

Authorities / risk assessors:

- **Comprehensible and transparent evaluation of studies, risk characterisation and risk assessment of PPP and intended uses according to all current available guidance documents in the Registration Report**

- **Necessary for the acceptance of the Registration Reports by the other MS**

dRR Guidance document SANCO/6895/2009 rev. 1, 09 Oktober 2009 under revision now!

Activities on further harmonisation

From the view of risk assessors – general point:

- **Improvement of the direct information exchange between experts/risk assessors of the MS in the zonal procedure**

- **Discussion of concrete questions and open points for the assessment of a PPP or of a use application (e.g. input parameters for exposure modelling, ...)**

- **Data base / compilation of open points and single problem solutions in preparation of a common generalisation (czSC, izSC, PAI, ???)**

Activities on further harmonisation

From the view of risk assessors – Assessment of co-formulants and their consideration in the risk assessment:

- **Data requirements ?**
- **Safety data sheet (relevance and content)**
- **Use of data/information from other sources (notification or registration under REACH, ...)**

Activities on further harmonisation

From the view of risk assessors – Specific points for the near future?

- **Harmonisation of the uses at EU-level**
- **Interpretation of cut off-criteria**
- **Interpretation of negligible exposure/risk**
- **Cumulative risk assessment**
- **Comparative assessment**

Vision of an ideal procedure / decision making?

- Complete application with a full data package to all data requirements of AS and PPP

- Evaluation of studies, risk characterisation, exposure estimation and risk assessment according to all current available guidance documents

- Comprehensive and transparent decision making / authorisation of PPP based on the risk assessment

Acceptance of the decision will be given by applicants, by authorities, by farmers, by public and ……

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Thank you very much for your attention

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