Pesticides and Gene Technology
4. November 2015

Requirements for applications and dossiers in the Northern Zone

Submission of application and documentation

The application and documentation must include the following:

- Cover letter including description of number of CDs and a brief description of the content of each CD
- Application scheme
- Active substance dossier (if not previously submitted)(incl. study reports)
- Product dossier – study reports and dRR for all sections
- Justification for new data submitted
- GAP and label/use instruction

The application and documentation must meet the following criteria:

- Must be submitted on CD with 3 copies of each CD
- Preferably submission in Caddy.xml format
- When possible, using a maximum of 100 letters in the file directory (including the file name)

The submitted documentation must be structured and intuitive to navigate through. The folder structure must be simple and the naming of folders and documents must be clear and reflect the content.

Further down are recommended structure for the documentation.

Dossier content:

- Assessment based on latest active substance endpoints
- Assessments based on guidance in place at dossier submission.
- The sections of the dRR must be targeted and transparent.
- Only information and data relevant for the concerned countries/North Zone should be presented.

The GAP should cover the Northern Zone for zonal applications and the EU-countries for inter-zonal applications.

Recommended structure for the documentation

Caddy.xml format (dRR format according to SANCO/6895/2009):

- Part A - Risk Management
- Part B - Data Evaluation and Risk Management
  - Section 1 - Identity, physical and chemical properties and further information
    - Section 1/001 - [Product code/name] - Part B Section 1
  - Section 2 - Analytical methods
    - Section 2/001 - [Product code/name] - Part B - Section 2
  - Section 3 - Mammalian toxicology
    - Section 3/001 - [Product code/name] - Part B - Section 3
  - Section 4 - Metabolism and Residues
    - Section 4/001 - [Product code/name] - Part B - Section 4
  - Section 5 - Environmental fate
    - Section 5/001 – [Product code/name] - Part B - Section 5
  - Section 6 - Ecotoxicological studies
    - Section 6/001 - [Product code/name] - Part B - Section 6
  - Section 7 - Efficacy data and information
    - Section 7/001 - [Product code/name] - Part B - Section 7
  - Section 8 - Assessment of the relevant metabolites in groundwater
    - Section 8/001 - [Product code/name] - Part B - Section 8
  - Part C - Confidential Information
    - Confidential Part C/001 - [Product code/name] - Part C
    - Confidential Part C/002 - Safety data sheet –
- Part K - Individual test and study reports *(should following the structure of the dRR)*
  - KIIIA 1 - Identity of the Plant Protection Product
  - KIIIA 2 - Physical, Chemical and Technical Properties of the
  - KIIIA 3 - Data on Application
  - KIIIA 4 - Further Information on the Product
  - KIIIA 5 - Methods of Analysis
  - KIIIA 6 - Efficacy Data and Information (including Value Data)
  - KIIIA 7 - Toxicological Studies and Exposure Data and Information
  - KIIIA 8 - Metabolism and Residues Data
  - KIIIA 9 - Fate and Behaviour in the Environment
  - KIIIA 10 - Ecotoxicological studies on the plant protection product
  - KIIIA 12 - Assessment of the relevant metabolites in groundwater

Caddy.xml format (dRR format version 2015):

- Part A - Risk Management
- Part B - Data Evaluation and Risk Management
  - Section 0 - Product Background, Regulatory Context and GAP information
    - Section 0/001 - [Product code/name] - Part B Section 0
  - Section 1, 2, 4 - Identity, physical and chemical properties and further information
    - Section 1, 2, 4/001 - [Product code/name] - Part B Section 1, 2, 4
  - Section 3 - Efficacy data and information
    - Section 3/001 - [Product code/name] - Part B Section 3
  - Section 5 - Analytical methods
    - Section 5/001 - [Product code/name] - Part B - Section 5
  - Section 6 - Mammalian toxicology
    - Section 6/001 - [Product code/name] - Part B - Section 6
  - Section 7 - Metabolism and Residues
    - Section 7/001 - [Product code/name] - Part B - Section 7
  - Section 8 - Environmental fate
    - Section 8/001 – [Product code/name] - Part B - Section 8
  - Section 9 - Ecotoxicology
    - Section 9/001 - [Product code/name] - Part B - Section 9
  - Section 10 - Assessment of the relevance of metabolites in groundwater
    - Section 10/001 - [Product code/name] - Part B - Section 10
  - Part C - Confidential Information
    - Confidential Part C/001 - [Product code/name] - Part C
    - Confidential Part C/002 - Safety data sheet – [xxx]
- Part K - Individual test and study reports *(should following the structure of the dRR)*
  - KIIIA 0 - Product Background, Regulatory Context and GAP information
  - KIIIA 1 – Identity
  - KIIIA 2 - Physical, Chemical and Technical Properties of the plant protection product
  - KIIIA 3 - Efficacy Data and Information (including Value Data)
  - KIIIA 4 - Further Information on the Product
  - KIIIA 5 - Methods of Analysis
  - KIIIA 6 - Toxicological Studies and Exposure Data and Information
  - KIIIA 7 - Metabolism and Residues Data
  - KIIIA 8 - Fate and Behaviour in the Environment
  - KIIIA 9 - Ecotoxicological studies on the plant protection product
  - KIIIA 10 - Assessment of the relevant metabolites in groundwater

Folder structure (dRR format according to SANCO/6895/2009):

1. Admin (Cover letter, application form)
2. dRR
    a. Part A
    b. Part B
        i. dRR section 1 (Identity, physical and chemical properties and further information)
        ii. dRR section 2 (Analytical methods)
        iii. dRR section 3 (Mammalian toxicology)
        iv. dRR section 4 (Metabolism and Residues)
        v. dRR section 5 (Environmental fate)
        vi. dRR section 6 (Ecotoxicological studies)
        vii. dRR section 7 (Efficacy data and information)
        viii. dRR section 8 (Assessment of the relevant metabolites in groundwater)
    c. Part C
        i. dRR Part C
        ii. Other confidential documents
    d. Part K (KIIIA test and study reports)
        i. Section 1 (Identity, physical and chemical properties and further information)
        ii. Section 2 (Analytical methods)
        iii. Section 3 (Mammalian toxicology)
        iv. Section 4 (Metabolism and Residues)
        v. Section 5 (Environmental fate)
        vi. Section 6 (Ecotoxicological studies)
        vii. Section 7 (Efficacy data and information)
        viii. Section 8 (Assessment of the relevant metabolites in groundwater)
3. GAP (Master GAP, GAP for each country)
4. Label (Master label, country specific labels)
5. Letter of Access (if relevant)
6. Additional documents

Folder structure (dRR format version 2015):

1. Admin (Cover letter, application form)
2. dRR
    a. Part A
    b. Part B
        i. dRR section 0 (Product Background, Regulatory Context and GAP information)
        ii. dRR section 1, 2, 4 (Identity, physical and chemical properties and further information)
        iii. dRR section 3 (Efficacy data and information)
        iv. dRR section 5 (Analytical methods)
        v. dRR section 6 (Mammalian toxicology)
        vi. dRR section 7 (Metabolism and Residues)
        vii. dRR section 8 (Environmental fate)
        viii. dRR section 9 (Ecotoxicology)
        ix. dRR section 10 (Assessment of the relevant metabolites in groundwater)
    c. Part C
        i. dRR Part C
        ii. Other confidential documents (e.g. SDS)
    d. Part K (KIIIA test and study reports)
        i. Section 0 (Product Background, Regulatory Context and GAP information)
        ii. Section 1 (Identity)
        iii. Section 2 (Physical and chemical properties)
        iv. Section 3 (Efficacy data and information)
        v. Section 4 (Further information)
        vi. Section 5 (Analytical methods)
        vii. Section 6 (Mammalian toxicology)
        viii. Section 7 (Metabolism and Residues)
        ix. Section 8 (Environmental fate)
        x. Section 9 (Ecotoxicology)
        xi. Section 10 (Assessment of the relevant metabolites in groundwater)
3. GAP (Master GAP, GAP for each country)
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