

Pesticides and Biocides

18. November 2020

# 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/ instructions for use

The application and documentation must be submitted on CD. The applicant is encouraged to submit the dossier in Caddy XML format and to use 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.

General rules for preparing product dossiers:

* + Assessment must be based on latest active substance endpoints
	+ Assessments must be 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/Northern Zone must be presented.
	+ National requirements must be met.

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 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 follow 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 version 2015):

1. Admin (Cover letter, application form)
2. dRR
	1. Part A
	2. Part B
		1. dRR section 0 (Product Background, Regulatory Context and GAP information)
		2. dRR section 1, 2, 4 (Identity, physical and chemical properties and further information)
		3. dRR section 3 (Efficacy data and information)
		4. dRR section 5 (Analytical methods)
		5. dRR section 6 (Mammalian toxicology)
		6. dRR section 7 (Metabolism and Residues)
		7. dRR section 8 (Environmental fate)
		8. dRR section 9 (Ecotoxicology)
		9. dRR section 10 (Assessment of the relevant metabolites in groundwater)
	3. Part C
		1. dRR Part C
		2. Other confidential documents (e.g. SDS)
	4. Part K (KIIIA test and study reports)
		1. Section 0 (Product Background, Regulatory Context and GAP information)
		2. Section 1 (Identity)
		3. Section 2 (Physical and chemical properties)
		4. Section 3 (Efficacy data and information)
		5. Section 4 (Further information)
		6. Section 5 (Analytical methods)
		7. Section 6 (Mammalian toxicology)
		8. Section 7 (Metabolism and Residues)
		9. Section 8 (Environmental fate)
		10. Section 9 (Ecotoxicology)
		11. Section 10 (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