

## APPENDIX 4

### SUGGESTED ORDER FOR THE PREPARATION OF EACH OF THE FOUR LEVELS AND THE THREE ANNEXES OF THE MONOGRAPHS TO BE PREPARED BY REGULATORY AUTHORITIES

#### Level 1

- 1 *Statement of subject matter and purpose for which the monograph was prepared*
- 1.1 *Purpose for which the monograph was prepared* (Dossier Document A)
- 1.2 *Summary and assessment of information relating to the collective provision of dossiers* (Dossier Document B)<sup>7</sup>
- 1.3 *Identity of the active substance* (Dossier Documents J, K-active substance and L-active substance)
  - 1.3.1 Name and address of applicant(s)
  - 1.3.2 Common name and synonyms
  - 1.3.3 Chemical name
  - 1.3.4 Manufacturer's development code number
  - 1.3.5 CAS, EEC and CIPAC numbers
  - 1.3.6 Molecular and structural formulae, molecular mass
  - 1.3.7 Manufacturer or manufacturers of the active substance
  - 1.3.8 Method or methods of manufacture<sup>7</sup>
  - 1.3.9 Specification of purity of the active substance
  - 1.3.10 Identity of isomers, impurities and additives<sup>7</sup>
  - 1.3.11 Analytical profile of batches<sup>7</sup>

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<sup>7</sup> If confidentiality in accordance with the legislative provisions of the country to which application is made has been claimed and accepted, the information concerned should not be included. Instead a reference should be included to the relevant paragraphs of Annex C in which the information concerned is included.

**Appendix 4**      **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Regulatory Authorities - Level 1 and Level 2**

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- 1.4      *Identity of the plant protection product* (Dossier Documents J, K-active substance, L-active substance, K-formulation and L-formulation) (to be included for each preparation for which documentation was submitted)
  - 1.4.1      Current, former and proposed trade names and development code numbers
  - 1.4.2      Manufacturer or manufacturers of the plant protection product
  - 1.4.3      Type of the preparation and code
  - 1.4.4      Function
  - 1.4.5      Composition of the preparation <sup>7</sup>
  
- 1.5      *Uses of the plant protection product* (Dossier Documents C, D and E) (to be included for each preparation for which documentation was submitted)
  - 1.5.1      Field of use
  - 1.5.2      Effects on harmful organisms
  - 1.5.3      Summary of intended uses
  - 1.5.4      Information on registrations in OECD countries

**Level 2**

- 2      ***Reasoned statement of the overall conclusions drawn by the regulatory authority***
  - 2.1.1      *Identity*
  - 2.1.2      *Physical and chemical properties*
  - 2.1.3      *Details of uses and further information*
  - 2.1.4      *Classification and labelling*
  
- 2.2      *Methods of analysis*
  - 2.2.1      Analytical methods for analysis of the active substance as manufactured
  - 2.2.2      Analytical methods for formulation analysis

**Appendix 4**      **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Regulatory Authorities - Level 2 and Level 3**

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- 2.3      *Impact on human and animal health*
- 2.3.1    Effects having relevance to human and animal health arising from exposure to the active substance or to impurities contained in the active substance or to their transformation products
- 2.3.6    Impact on human or animal health arising from exposure to the active substance or to impurities contained in it
  
- 2.4      *Residues (not normally required)*
  
- 2.5      *Fate and behaviour in the environment*
- 2.5.1    Definition of the residues relevant to the environment
- 2.5.2    Fate and behaviour in soil
- 2.5.3    Fate and behaviour in water
- 2.5.4    Fate and behaviour in air
  
- 2.6      *Effects on non-target species*
- 2.6.1    Effects on terrestrial vertebrates
- 2.6.2    Effects on aquatic species
- 2.6.3    Effects on bees and other arthropod species
- 2.6.4    Effects on earthworms and other soil macro-organisms
- 2.6.5    Effects on soil micro-organisms
- 2.6.6    Effects on other non-target organisms (flora and fauna)
- 2.6.7    Effects on biological methods of sewage treatment
  
- 2.7      *Efficacy*
- 2.7.1    Effectiveness against target organisms, or with respect to the effect achieved
- 2.7.2    Possible occurrence of the development of resistance
- 2.7.3    Effects on the quality of plants or plant products

**Appendix 4**      **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Regulatory Authorities - Level 2 and Level 3**

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- 2.7.4    Effects on transformation processes
- 2.7.5    Effects on the yield of treated plants or plant products
- 2.7.6    Phytotoxicity to target plants or target plant products
- 2.7.7    Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation

*Overall Conclusions*

- Appendix 1      Standard terms and abbreviations
- Appendix 2      Specific terms and abbreviations
- Appendix 3      Compilation of chemical, common and code names and synonyms
- Appendix 4      Listing of end points

**Level 3**

- 3      ***Proposed decision with respect to the application***
- 3.1    Background to the proposed decision
- 3.2    Proposed decision
- 3.3    Rational for the postponement of the decision, or for the conditions and restrictions to be associated with any approval or registration, as appropriate

#### **Level 4**

- 4      ***Further information to permit a decision to be made, or to support a review of the conditions and restrictions associated with any approval or registration***
- 4.1    Identity of the active substance or formulation
- 4.2    Physical and chemical properties of the active substance and physical, chemical and technical properties of the formulation
- 4.3    Data on application and further information
- 4.4    Classification, packaging and labelling
- 4.5    Methods of analysis
- 4.6    Toxicology and metabolism
- 4.7    Residue data (not normally required)
- 4.8    Environmental fate and behaviour
- 4.9    Ecotoxicology
- 4.10   Efficacy

#### **Annex A**

- A      ***List of the tests and studies submitted and of information available***  
(Dossier Documents J, I, K-active substance, L-active substance, K-formulation and L-formulation and other information available to or brought to the attention of the regulatory authority)
- A.1    *Identity*
- A.2    *Physical and chemical properties*
- A.3    *Further information*
- A.4    *Classification, packaging and labelling*
- A.5    *Methods of analysis*
- A.6    *Toxicology and metabolism*
- A.7    *Residue data (not normally required)*
- A.8    *Environmental fate and behaviour*
- A.9    *Ecotoxicology*
- A.10   *Efficacy*

## Annex B

### B      *Regulatory authority's summary, evaluation and assessment of the data and information*

#### B.1      *Identity*

B.1.1      Identity of the active substance

B.1.2      Identity of the plant protection product

B.1.3      References relied on

#### B.2      *Physical and chemical properties*

B.2.1      Physical and chemical properties of the active substance

B.2.2      Physical, chemical and technical properties of the plant protection products

B.2.3      References relied on

#### B.3      *Data on application and further information*

B.3.1      Data on application relevant to the active substance

B.3.2      Data on application relevant to the plant protection product

B.3.3      Summary of data on application

B.3.4      Further information on the active substance

B.3.5      Further information on the plant protection product

B.3.6      References relied on

#### B.4      *Proposals for classification and labelling*

B.4.1      Proposals for the classification and labelling of the active substance

B.4.2      Proposals for the classification and labelling of preparations

B.4.3      References relied on

#### B.5      *Methods of analysis*

B.5.1      Analytical methods for formulation analysis

**Appendix 4**      **Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Regulatory Authorities - Annex B**

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- B.5.2 If required, analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feedingstuffs
- B.5.3 If required, analytical methods (residue) soil, water, air
- B.5.4 If required, analytical methods (residue) for body fluids and tissues
- B.5.5 Evaluation and assessment
- B.5.6 References relied on
  
- B.6 *Toxicology and metabolism*
- B.6.2 Acute toxicity including irritancy and skin sensitization
- B.6.8 Further toxicological studies
- B.6.9 Medical data and information
- B.6.10 Summary of mammalian toxicology and proposed ADI, ARfD, AOEL and drinking water limit, if required
- B.6.11 Acute toxicity including irritancy and skin sensitization of preparations
- B.6.12 Dermal absorption
- B.6.13 Toxicological data on non active substances
- B.6.14 Exposure data
- B.6.15 References relied on
  
- B.7 *Residue data (not normally required)*
- B.7.16 Summary and evaluation of residue behaviour
- B.7.17 References relied on
  
- B.8 *Environmental fate and behaviour*
- B.8.1 Assessment of fate and behaviour in soil
- B.8.2 Assessment of fate and behaviour in water
- B.8.3 Assessment of fate and behaviour in air
- B.8.4 References relied on
  
- B.9 *Ecotoxicology data and assessment of risks for non-target species*

**Appendix 4      Suggested Order for the Preparation of each of the Four Levels and the Three Annexes of the Monographs to be Prepared by Regulatory Authorities - Annex B**

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- B.9.1    Assessment of possible effects on birds
- B.9.2    Assessment of possible effects on aquatic organisms
- B.9.3    Assessment of possible effects on other terrestrial vertebrates
- B.9.4    Assessment of possible effects on bees
- B.9.5    Assessment of possible effects on other arthropod species
- B.9.6    Assessment of possible effects on earthworms
- B.9.7    Assessment of possible effects on other soil non-target macro-organisms
- B.9.8    Assessment of possible effects on soil non-target micro-organisms
- B.9.9    Assessment of possible effects on non-target plants
- B.9.10   Effects on biological methods of sewage treatment
- B.9.11   References relied on
  
- B.10    *Efficacy*
- B.10.1   Effectiveness against target organisms, or with respect to the effect achieved (level, consistency and duration)
  
- B.10.3   Effects on the quality of plants or plant products
- B.10.4   Effects on transformation processes
- B.10.5   Effects on the yield of treated plants or plant products
- B.10.6   Phytotoxicity to target plants or target plant products
- B.10.7   Impact on succeeding crops, adjacent crops and on treated plants or plant products used for propagation
  
- B.10.9   References relied on
  
- Appendix 1      Standard terms and abbreviations
- Appendix 2      Specific terms and abbreviations
- Appendix 3      Compilation of chemical, common and code names and synonyms



### Annex C

- C      *Confidential information and, where relevant, details of any task force formed for the purposes of generating tests and studies submitted*
- C.1    *Confidential information*
  - C.1.1    Detailed information on the manufacturing process or processes for the active substance
  - C.1.2    Detailed specification of the active substance
  - C.1.3    Detailed specification of the preparations
  - C.1.4    Other confidential information
- C.2    *Summary of information relating to any task forces that submitted tests and study reports*
  - C.2.1    Membership of each task force and contact point (Dossier Document B)
  - C.2.2    Contact point for each member of the task force
  - C.2.3    List of test and study reports submitted and information relative to the ownership of and rights of access to the test and study reports