

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) ⁷
- 1.3 *Identity of the MPCA* (Dossier Documents J, K-active substance and L-active substance)
 - 1.3.1 Name and address of applicant(s)
 - 1.3.2 Producer: name and address of each plant where MPCA is produced
 - 1.3.3 Name and species description
 - 1.3.4 Composition of material used for manufacturing of formulated products (MPCP(s))
 - 1.3.5 Accession numbers
- 1.4 *Identity of the MPCP* (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 ⁷
- 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)

⁷ 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**

- 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 *Biological, physical and chemical properties*
- 2.1.3 *Details of uses and further information*
- 2.1.4 *Classification and labelling*
- 2.2 *Methods of analysis*
- 2.3 *Impact on human and animal health*
- 2.3.1 Effects having relevance to human and animal health arising from exposure to the MPCA or to impurities contained in the active substance or to their transformation products
- 2.3.2 Impact on human or animal health arising from exposure to the MPCA or to impurities contained in it
- 2.4 *Residues (not normally required)*
- 2.5 *Fate and behaviour in the environment*
- 2.6 *Effects on non-target species*
- 2.6.1 Effects on terrestrial vertebrates

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**

- 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)

- 2.7 *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
- 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
- 2.7.8 Compatibility with other pesticide products which may be used sequentially or in tank-mix with the proposed product

Overall Conclusions

- Appendix 1 Standard terms and abbreviations
- Appendix 2 Specific terms and abbreviations
- Appendix 3 Compilation of scientific, 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 MPCA or MPCP
- 4.2 Biological properties of the MPCA and physical, chemical and technical properties of the MPCP
- 4.3 Data on application and further information
- 4.4 Classification, packaging and labelling
- 4.5 Methods of analysis
- 4.6 Toxicology
- 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 *Biological properties*
- A.3 *Further information*
- A.4 *Classification, packaging and labelling*
- A.5 *Methods of analysis*
- A.6 *Toxicology*
- 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 MPCA

B.1.2 Identity of the MPCP

B.1.3 References relied on

B.2 *Biological, physical, chemical and technical properties*

B.2.1 Biological properties of the MPCA

B.2.2 Physical, chemical and technical properties of the MPCP

B.2.3 References relied on

B.3 *Data on application and further information*

B.3.1 Data on application relevant to the MPCA

B.3.2 Data on application relevant to the MPCP

B.3.3 Summary of data on application

B.3.4 Further information on the MPCA

B.3.5 Further information on the MPCP

B.3.6 References relied on

B.4 *Proposals for classification and labelling*

B.4.1 Proposals for the classification and labelling of the MPCA

B.4.2 Proposals for the classification and labelling of MPCP

B.4.3 References relied on

B.5 *Methods of analysis*

B.5.5 Evaluation and assessment

B.5.6 References relied on

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

B.6 *Toxicology*

B.6.2 Acute toxicity (infectivity and toxicity)

B.6.3 Short-term toxicity

B.6.4 Genotoxicity

B.6.8 Further toxicological studies

B.6.9 Medical data and information

B.6.10 Summary of mammalian toxicology

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.8 *Environmental fate and behaviour*

B.8.4 References relied on

B.9 *Ecotoxicology data and assessment of risks for non-target species*

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.9.11 References relied on

**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**

B.10 *Efficacy*

- B.10.1 Effectiveness against target organisms, or with respect to the effect achieved (level, consistency and duration)
- B.10.2 Possible occurrence of the development of resistance
- 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.10.8 Compatibility with other pesticide products which may be used sequentially or in tank-mix with the proposed product
- B.10.9 References relied on

Appendix 1 Standard terms and abbreviations

Appendix 2 Specific terms and abbreviations

Appendix 3 Compilation of scientific, 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 MPCA
 - C.1.3 Detailed specification of the MPCP
 - 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