

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

The caveat set out in paragraph 4.1.1 should be inserted to form the first element of Level I of each Monograph prepared.

- 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 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

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 2 and Level 3**

- 1.3.8 Method or methods of manufacture ⁷
- 1.3.9 Specification of purity of the active substance
- 1.3.10 Identity of isomers, impurities and additives ⁷
- 1.3.11 Analytical profile of batches ⁷

- 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 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)
- 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
- 2.2.3 Analytical methods for residue 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 active substance or to impurities contained in the active substance or to their transformation products
- 2.3.2 Toxicological end point for assessment of risk following long-term dietary exposure - ADI
- 2.3.3 Toxicological end point for assessment of risk following acute dietary exposure - ARfD (acute reference dose)
- 2.3.4 Toxicological end point for assessment of occupational and bystander risks – AOEL / MOE
- 2.3.5 Drinking water limit
- 2.3.6 Impact on human or animal health arising from exposure to the active substance or to impurities contained in it

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**

- 2.4 *Residues*
 - 2.4.1 Definition of the residues relevant to MRLs
 - 2.4.2 Residues relevant to consumer safety
 - 2.4.3 Residues relevant to worker safety
 - 2.4.4 Proposed MRLs and compliance with existing MRLs
 - 2.4.5 Proposed import tolerances and compliance with existing import tolerances
 - 2.4.6 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs

- 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

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

2.7 *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 Tank mixing recommendations

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
- 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*
- 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**

- B.5.2 Analytical methods (residue) for plants, plant products, foodstuffs of plant and animal origin, feedingstuffs
- B.5.3 Analytical methods (residue) soil, water, air
- B.5.4 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.6.1 Absorption, distribution, excretion and metabolism (toxicokinetics)
 - B.6.2 Acute toxicity including irritancy and skin sensitization
 - B.6.3 Short-term toxicity
 - B.6.4 Genotoxicity
 - B.6.5 Long-term toxicity and carcinogenicity
 - B.6.6 Reproductive toxicity
 - B.6.7 Delayed neurotoxicity
 - 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
 - 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*
 - B.7.1 Metabolism, distribution and expression of residues in plants
 - B.7.2 Metabolism, distribution and expression of residues in livestock
 - B.7.3 Definition of the residue
 - B.7.4 Use pattern

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.7.5 Identification of critical GAPs
- B.7.6 Residues resulting from supervised trials
- B.7.7 Effects of industrial processing and/or household preparation
- B.7.8 Livestock feeding studies
- B.7.9 Residues in succeeding or rotational crops
- B.7.10 Proposed pre-harvest intervals for envisaged uses, or withholding periods, in the case of post-harvest uses
- B.7.11 MRLs in OECD countries
- B.7.12 Proposed MRLs and justification for the acceptability of those MRLs
- B.7.13 Proposed Import tolerances and justification for the acceptability of those residues
- B.7.14 Basis for differences, if any, in conclusions reached having regard to established or proposed CAC MRLs
- B.7.15 Estimates of potential and actual dietary exposure through diet and other means
- B.7.16 Summary and evaluation of residue behaviour
- B.7.17 References relied on

- B.8 *Environmental fate and behaviour*
- B.8.1 Route and rate of degradation in soil
- B.8.2 Adsorption, desorption and mobility in soil
- B.8.3 Predicted environmental concentrations in soil (PEC_s)
- B.8.4 Fate and behaviour in water
- B.8.5 Impact on water treatment procedures
- B.8.6 Predicted environmental concentrations in surface water and in ground water (PEC_{sw}, PEC_{gw})
- B.8.7 Fate and behaviour in air
- B.8.8 Predicted environmental concentrations in air (PEC_a)
- B.8.9 Definition of the residue
- B.8.10 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 C**

- B.9 *Ecotoxicology data and assessment of risks for non-target species*
- B.9.1 Effects on birds
- B.9.2 Effects on aquatic organisms
- B.9.3 Effects on other terrestrial vertebrates
- B.9.4 Effects on bees
- B.9.5 Effects on other arthropod species
- B.9.6 Effects on earthworms
- B.9.7 Effects on other soil non-target macro-organisms
- B.9.8 Effects on soil non-target micro-organisms
- B.9.9 Effects on other non-target organisms (flora and fauna) believed to be at risk
- 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.10.2 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 Tank mixing recommendations
- 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