

Requirements on data and format for
Zonal Authorisation and Re-Authorisation of plant protection products in Norway

“Completeness check”

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##

## How the document works

The applicant fills out the brown section of the tables and the zRMS answers in the red section of the tables. If the applicant experience that there is a data gap in the submitted documentation the applicant can highlight this with an “X” in the data gap section, if not this section is reserved the zRMS on the purpose for completeness check. Other missing data requirements that are justified can be explained with a “justification”.

**Table: Example of how to use the completeness check scheme.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Applicant** |  | **MS** |
| **Data point** | **Information, test or study** **(Example)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| x.x.1 | Data requirement 1 | Y |  |  | Y |  |
| x.x.2 | Data requirement 2 | N/NA | Not required | X | N | According to 284/2013 this is a data requirement. |

## General requirements

The application must meet the following criteria:

* Preferably to be submitted in Caddy.xml
* Using a maximum of 100 letters in the file directory (including the file name)
* Contain a cover letter including application form and description of number of CDs and a brief description of the content of each CD.
* Contain 3 copies of each CD
* Must be submitted on CD (not USB-stick e.g.)

The applicant must make sure that all national requirements are covered in the dossier and shall include this in the completeness check.

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Applicant** |  | **MS** |
| **Description of the document** | **Provided** | **Data gap** | **OK** | **Comment** |
| Application form in English and/or in the language in the relevant MS | Y/N/NA |  | Y/N |  |
| Covering letter, or printed first page of the application | Y/N/NA |  | Y/N |  |
| List of intended uses | Y/N/NA |  | Y/N |  |
| Norwegian GAP  | Y/N/NA |  | Y/N |  |
| Zonal core GAP, if relevant  | Y/N/NA |  | Y/N |  |
| Complete zonal GAP (indicating relevance for which Member State)  | Y/N/NA |  | Y/N |  |
| Proposal as to which Member State to act as zRMS | Y/N/NA |  | Y/N |  |
| Copy of conclusion of the Member State assessing equivalence, where relevant | Y/N/NA |  | Y/N |  |
| Justifications of steps taken to avoid animal testing and duplication of such testing | Y/N/NA |  | Y/N |  |
| Reasons for necessity for submission of tests and study reports | Y/N/NA |  | Y/N |  |
| Data for the identification of the plant protection product, including its composition and and declaration on co-formulants | Y/N/NA |  | Y/N |  |
| Data for the identification of the active substance(s), safener or synergist | Y/N/NA |  | Y/N |  |
| Letter of Access | Y/N/NA |  | Y/N |  |
| For Annex II -data  | Y/N/NA |  | Y/N |  |
| For Annex III –data | Y/N/NA |  | Y/N |  |
| Registration certificate | Y/N/NA |  | Y/N |  |
| Applicant | Y/N/NA |  | Y/N |  |
| Permanent representative | Y/N/NA |  | Y/N |  |
| Letter of authorisation  | Y/N/NA |  | Y/N |  |
| Temporary representative | Y/N/NA |  | Y/N |  |
| Permanent representative | Y/N/NA |  | Y/N |  |
| Draft Labels | Y/N/NA |  | Y/N |  |
| Master label in English | Y/N/NA |  | Y/N |  |
| NO label | Y/N/NA |  | Y/N |  |
| DK label  | Y/N/NA |  | Y/N |  |
| SE label | Y/N/NA |  | Y/N |  |
| FI label | Y/N/NA |  | Y/N |  |
| EE label (three Baltic states language label) | Y/N/NA |  | Y/N |  |
| LT label (three Baltic states language label) | Y/N/NA |  | Y/N |  |
| LV label (three Baltic states language label) | Y/N/NA |  | Y/N |  |
| Document K-III – individual test and study reports in accordance with the requirements specified in Annex III | Y/N/NA |  | Y/N |  |
| A list of references to new AnnexII data if applicable | Y/N/NA |  | Y/N |  |
| Draft Registration Report | Y/N/NA |  | Y/N |  |
| Comparative Assessment report (if A.S. is candidate for substitution) | Y/N/NA |  | Y/N |  |

## Draft registration report

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Applicant** |  | **MS** |
| **Description of the document** | **Provided** | **Data gap** | **OK** | **Comment** |
| Version of the Northern Zonal Guidance followed in the evaluation | Version |  |
| **Part A -** Risk management | Y/N/NA |  | Y/N |  |
| **Part B core - North** | Y/N/NA |  | Y/N |  |
| 0. Product Background, Regulatory Context and GAP information | Y/N/NA |  | Y/N |  |
| 1, 2, 4. Identity, Physical and chemical properties, further information | Y/N/NA |  | Y/N |  |
| 3. Efficacy data and information | Y/N/NA |  | Y/N |  |
| 5. Analytical methods | Y/N/NA |  | Y/N |  |
| 6. Mammalian toxicology  | Y/N/NA |  | Y/N |  |
| 7. Metabolism and residues  | Y/N/NA |  | Y/N |  |
| 8. Environmental fate  | Y/N/NA |  | Y/N |  |
| 9. Ecotoxicology | Y/N/NA |  | Y/N |  |
| 10. Assessment of the relevance of metabolites in ground water | Y/N/NA |  | Y/N |  |

## Part B National - North

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Applicant** |  | **MS** |
| **Description of the document** | **Provided** | **Data gap** | **OK** | **Comment** |
| **Member State** | MS |  |
| **Part A -** Risk management | Y/N/NA |  | Y/N |  |
| **Part B core - North** | Y/N/NA |  | Y/N |  |
| 0. Product Background, Regulatory Context and GAP information | Y/N/NA |  | Y/N |  |
| 1, 2, 4. Identity, Physical and chemical properties, further information | Y/N/NA |  | Y/N |  |
| 3. Efficacy data and information | Y/N/NA |  | Y/N |  |
| 5. Analytical methods | Y/N/NA |  | Y/N |  |
| 6. Mammalian toxicology  | Y/N/NA |  | Y/N |  |
| 7. Metabolism and residues  | Y/N/NA |  | Y/N |  |
| 8. Environmental fate  | Y/N/NA |  | Y/N |  |
| 9. Ecotoxicology | Y/N/NA |  | Y/N |  |
| 10. Assessment of the relevance of metabolites in ground water | Y/N/NA |  | Y/N |  |

## Part C – Confidential data

|  | **Applicant** |  | **MS** |
| --- | --- | --- | --- |
| **Data point** | **Description of the document** | **Provided** | **Data gap** | **OK** | **Comment** |
| 1.1 | Producer of the plant protection product and of the active substances | Y/N/NA |  | Y/N |  |
| 1.1.1 | Producer(s) of the preparation | Y/N/NA |  | Y/N |  |
| 1.1.2 | Producer(s) of the active substance(s) | Y/N/NA |  | Y/N |  |
| 1.1.3 | Statement of purity (and detailed information on impurities) of the active substance(s) | Y/N/NA |  | Y/N |  |
| 1.2 | Detailed quantitative and qualitative information on the composition of the preparation | Y/N/NA |  | Y/N |  |
| 1.2.1 | Composition of the plant protection product | Y/N/NA |  | Y/N |  |
| 1.2.2 | Information on co-formulants | Y/N/NA |  | Y/N |  |
| 1.2.3 | Description of formulation process | Y/N/NA |  | Y/N |  |
| 1.2.4 | Description of the analytical methods for the determination of relevant formulants | Y/N/NA |  | Y/N |  |
| 1.3 | Data on the formulants | Y/N/NA |  | Y/N |  |
| 1.3.1 | Material safety data sheets | Y/N/NA |  | Y/N |  |
| 1.3.2 | Available toxicological data for each formulant | Y/N/NA |  | Y/N |  |
| 2 | Statement of the regulatory status of formulants | Y/N/NA |  | Y/N |  |
| App. 1 | List of studies considered in support of the evaluation | Y/N/NA |  | Y/N |  |
|  | Confidential data and information, to include: | Y/N/NA |  | Y/N |  |
|  | Safety data sheets prepared in accordance with newest guidance (Regulation (EC) 1906/2006, 1272/2008, and 2015/830). | Y/N/NA |  | Y/N |  |
|  | File containing confidential data and information | Y/N/NA |  | Y/N |  |

## Part B – Section 0 Product background, regulatory context and GAP information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Applicant** |  | **MS** |
|  **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 1)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 0.1 | Introduction | Y/N/NA |  |  | Y/N |  |
| 0.1.1 | Reason for application | Y/N/NA |  |  | Y/N |  |
| 0.1.2 | Details of zRMS(s) and concerned MS | Y/N/NA |  |  | Y/N |  |
| 0.1.3 | Regulatory history of the active(s) | Y/N/NA |  |  | Y/N |  |
| 0.1.3.1 | Active substance 1 | Y/N/NA |  |  | Y/N |  |
| 0.1.3.2 | Active substance 2 | Y/N/NA |  |  | Y/N |  |
| 0.1.3.3 | Active substance 3 | Y/N/NA |  |  | Y/N |  |
| 0.1.4 | Regulatory history of the product (if relevant) | Y/N/NA |  |  | Y/N |  |
| 0.2 | zRMS conclusion | Y/N/NA |  |  | Y/N |  |
| App. 1 | All intended uses  | Y/N/NA |  |  | Y/N |  |

## Part B – Section 1, 2, 4 Identity of the plant protection product, Physical and chemical properties and Further information on the plant protection product

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 1)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| **Identity of the plant protection product** |
| 1.1. | Applicant (name, address, contact, telephone and telefax numbers) | Y/N/NA |  |  | Y/N |  |
| 1.2. | Producer of the preparation and of the active substance  | Y/N/NA |  |  | Y/N |  |
| 1.2.1. | Producer(s) of the preparation(name, address, contact, telephone and telefax numbers) | Y/N/NA |  |  | Y/N |  |
| 1.2.2. | Producer(s) of the active substance(s) (name, address, contact, telephone and telefax numbers) | Y/N/NA |  |  | Y/N |  |
| 1.2.3. | Statement of purity (and detailed information on impurities) of the active substance(s) | Y/N/NA |  |  | Y/N |  |
| 1.2.3.1 | Active substance 1 | Y/N/NA |  |  | Y/N |  |
| 1.2.3.2 | Active substance 2 | Y/N/NA |  |  | Y/N |  |
| 1.2.3.3 | Active substance 3 | Y/N/NA |  |  | Y/N |  |
| 1.3. | Trade name and producer’s code number(s), for the preparation  | Y/N/NA |  |  | Y/N |  |
| 1.4. | Detailed quantitative and qualitative information on the composition of the preparation | Y/N/NA |  |  | Y/N |  |
| 1.4.1. | Composition of the plant protection product Contents of : | Y/N/NA |  |  | Y/N |  |
| 1.4.1. | - Active substance(s) | Y/N/NA |  |  | Y/N |  |
| 1.4.1. | - Safener and synergists | Y/N/NA |  |  | Y/N |  |
| 1.4.1. | - Relevant impurities | Y/N/NA |  |  | Y/N |  |
| 1.4.2. | Information on the active substance(s) | Y/N/NA |  |  | Y/N |  |
| 1.4.2 | - ISO common name proposed or accepted for active substances, and synonyms | Y/N/NA |  |  | Y/N |  |
| 1.4.3. | Information on safeners, synergists and co-formulants | Y/N/NA |  |  | Y/N |  |
| 1.4.3. | - ISO common name proposed or accepted for formulants, and synonyms | Y/N/NA |  |  | Y/N |  |
| 1.5 | Type and code of the plant protection product | Y/N/NA |  |  | Y/N |  |
| 1.6 | Function (herbicide, insecticide *etc.*) | Y/N/NA |  |  | Y/N |  |
| **Physical, chemical and technical properties of the plant protection product** |
| 2.1 | Description of the physical state of the preparation (formulation) and its colour and odour | Y/N/NA |  |  | Y/N |  |
| 2.2.1 | Explosive properties of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.2.2 | Oxidizing properties of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.3.1 | The flash point of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.3.2 | The flammability of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.3.3 | The self-heating of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.4.1 | Acidity or alkalinity and pH value | Y/N/NA |  |  | Y/N |  |
| 2.4.2 | pH of a 1 % aqueous dilution, emulsion or dispersion | Y/N/NA |  |  | Y/N |  |
| 2.5.1 | Viscosity of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.5.2 | Surface tension of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.6.1 | Relative density of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.6.2 | Bulk or tap density of the preparation | Y/N/NA |  |  | Y/N |  |
| 2.7.1 | Stability after storage for 14 days at 54 °C | Y/N/NA |  |  | Y/N |  |
| 2.7.2 | Stability after storage for other periods and/or temperatures  | Y/N/NA |  |  | Y/N |  |
| 2.7.3 | Minimum content after heat stability testing | Y/N/NA |  |  | Y/N |  |
| 2.7.4 | Effect of low temperature on stability | Y/N/NA |  |  | Y/N |  |
| 2.7.5 | Shelf life following storage at ambient temperature | Y/N/NA |  |  | Y/N |  |
| 2.7.6 | Shelf life in months | Y/N/NA |  |  | Y/N |  |
| 2.8.1 | Wettability | Y/N/NA |  |  | Y/N |  |
| 2.8.2 | Persistent of foaming | Y/N/NA |  |  | Y/N |  |
| 2.8.3.1 | Suspensibility | Y/N/NA |  |  | Y/N |  |
| 2.8.3.2 | Spontaneity of dispersion | Y/N/NA |  |  | Y/N |  |
| 2.8.3.3 | Dispersion stability | Y/N/NA |  |  | Y/N |  |
| 2.8.4 | Degree of dissolution and dilution stability | Y/N/NA |  |  | Y/N |  |
| 2.8.5.1.1 | Particle size distribution/nominal size range of granules | Y/N/NA |  |  | Y/N |  |
| 2.8.5.1.2 | Wet sieve test | Y/N/NA |  |  | Y/N |  |
| 2.8.5.2.1 | Dust content | Y/N/NA |  |  | Y/N |  |
| 2.8.5.2.2 | Particle size of dust | Y/N/NA |  |  | Y/N |  |
| 2.8.5.3 | Attrition | Y/N/NA |  |  | Y/N |  |
| 2.8.5.4 | Hardness and integrity | Y/N/NA |  |  | Y/N |  |
| 2.8.6.1 | Emulsifiability | Y/N/NA |  |  | Y/N |  |
| 2.8.6.2 | Emulsion stability | Y/N/NA |  |  | Y/N |  |
| 2.8.6.3 | Re-emulsifiability | Y/N/NA |  |  | Y/N |  |
| 2.8.7.1 | Flowability | Y/N/NA |  |  | Y/N |  |
| 2.8.7.2 | Pourability (including rinsed residue) | Y/N/NA |  |  | Y/N |  |
| 2.8.7.3 | Dustability following accelerated storage | Y/N/NA |  |  | Y/N |  |
| 2.9.1 | Physical compatibility of tank mixes | Y/N/NA |  |  | Y/N |  |
| 2.9.2 | Chemical compatibility of tank mixes | Y/N/NA |  |  | Y/N |  |
| 2.10.1 | Adhesion to seeds | Y/N/NA |  |  | Y/N |  |
| 2.10.2 | Distribution to seeds | Y/N/NA |  |  | Y/N |  |
| 2.11 | Other/special studies | Y/N/NA |  |  | Y/N |  |
| **Further information on the plant protection product** |
| 4.1 | Packaging and compatibility with the preparation | Y/N/NA |  |  | Y/N |  |
| 4.1 | - Description and specification of the packaging and materials used in packaging, size, capacity, size of openings, types of closure and seals | Y/N/NA |  |  | Y/N |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Additional data on the physical, chemical and technical properties of the active substance | Y/N/NA |  |  | Y/N |  |
| A 2.1 | Active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 2.2 | Active substance 2 | Y/N/NA |  |  | Y/N |  |
| A 2.3 | Active substance 3 | Y/N/NA |  |  | Y/N |  |

## Part B – Section 3Efficacy Data and Information

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | **Applicant** |  | **MS** |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 7)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 3.1 | Summary and conclusions of zRMS on section 3: Efficacy |  |  |  |  |  |
| 3.2 | Efficacy data | Y/N/NA |  |  | Y/N |  |
| 3.2.1. | Preliminary tests | Y/N/NA |  |  | Y/N |  |
| 3.2.2 | Minimum effective dose tests | Y/N/NA |  |  | Y/N |  |
| 3.2.3 | Efficacy tests | Y/N/NA |  |  | Y/N |  |
| 3.3 | Information on the occurrence or possible occurrence of the development of resistance | Y/N/NA |  |  | Y/N |  |
| 3.4 | Adverse effects on treated crops | Y/N/NA |  |  | Y/N |  |
| 3.4.1 | Phytotoxicity to host crop | Y/N/NA |  |  | Y/N |  |
| 3.4.2 | Effects on the yield of treated plants and plant products | Y/N/NA |  |  | Y/N |  |
| 3.4.3 | Effects on the quality of plants and plant products | Y/N/NA |  |  | Y/N |  |
| 3.4.4 | Effects on the transformation processes | Y/N/NA |  |  | Y/N |  |
| 3.4.5 | Impact on treated plants or plant products to be used for propagation | Y/N/NA |  |  | Y/N |  |
| 3.5 | Observations on other undesirable or unintended side-effects | Y/N/NA |  |  | Y/N |  |
| 3.5.1 | Impact on succeeding crops | Y/N/NA |  |  | Y/N |  |
| 3.5.2 | Impact on other plants including adjacent crops | Y/N/NA |  |  | Y/N |  |
| 3.5.3 | Effects on beneficial and other non-target organisms | Y/N/NA |  |  | Y/N |  |
| 3.6 | Other/special studies | Y/N/NA |  |  | Y/N |  |
| 3.7 | List of test facilities including the corresponding certificates | Y/N/NA |  |  | Y/N |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |

##

Part B – Section 5
Analytical methods

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 2)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 5.1 | Conclusion and summary of assessment | Y/N/NA |  |  | Y/N |  |
| *5.2* | *Methods used for the generation of pre-authorization data* |  |  |  |  |  |
| 5.2.1 | *Analysis of the plant protection product* |  |  |  |  |  |
| 5.2.1.1 | Determination of active substance and/or variant in the plant protection product | Y/N/NA |  |  | Y/N |  |
| 5.2.1.2 | Description of analytical methods for the determination of relevant impurities | Y/N/NA |  |  | Y/N |  |
| 5.2.1.3 | Description of analytical methods for the determination of formulants | Y/N/NA |  |  | Y/N |  |
| 5.2.1.4 | Applicability of existing CIPAC methods | Y/N/NA |  |  | Y/N |  |
| 5.2.2 | Methods for the determination of residues | Y/N/NA |  |  | Y/N |  |
| 5.3 | *Methods for post-authorization control and monitoring purposes* |  |  |  |  |  |
| 5.3.1 | Analysis of the plant protection product | Y/N/NA |  |  | Y/N |  |
| 5.3.2 | *Description of analytical methods for the determination of residues of active substance 1* |  |  |  |  |  |
| 5.3.2.1 | Overview of residue definitions and levels for which compliance is required | Y/N/NA |  |  | Y/N |  |
| 5.3.2.2 | Description of analytical methods for the determination of residues in plant matrices | Y/N/NA |  |  | Y/N |  |
| 5.3.2.3 | Description of analytical methods for the determination of residues in animal matrices | Y/N/NA |  |  | Y/N |  |
| 5.3.2.4 | Description of methods for the analysis of soil | Y/N/NA |  |  | Y/N |  |
| 5.3.2.5 | Description of methods for the analysis of water | Y/N/NA |  |  | Y/N |  |
| 5.3.2.6 | Description of methods for the analysis of air | Y/N/NA |  |  | Y/N |  |
| 5.3.2.7 | Description of methods for the analysis of body fluids and tissues | Y/N/NA |  |  | Y/N |  |
| 5.3.2.8 | Other studies/ information | Y/N/NA |  |  | Y/N |  |
| 5.3.3 | *Description of analytical methods for the determination of residues of active substance 2* | Y/N/NA |  |  | Y/N |  |
|  | Include 5.3.3.1-7 as for active substance 1 |  |  |  |  |  |
| 5.3.4 | *Description of analytical methods for the determination of residues of active substance 3* | Y/N/NA |  |  | Y/N |  |
|  | Include 5.3.4.1-7 as for active substance 1 |  |  |  |  |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Detailed evaluation of submitted analytical methods | Y/N/NA |  |  | Y/N |  |
| A 2.1 | *Analytical methods for the active substance 1* | Y/N/NA |  |  | Y/N |  |
| A 2.1.1 | Methods used for the generation of pre-authorization data | Y/N/NA |  |  | Y/N |  |
|  | Analytical methods as described in data point 5.3.2.x for active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 2.1.2 | Methods for post-authorization control and monitoring purposes | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.1 | Analytical methods for the determination of residues in plant matrices | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.2 | Analytical methods for the determination of residues in animal matrices | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.3 | Analytical methods for the analysis of soil | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.4 | Analytical methods for the analysis of water | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.5 | Analytical methods for the analysis of air | Y/N/NA |  |  | Y/N |  |
| A 2.1.2.6 | Analytical methods for the analysis of body fluids and tissues | Y/N/NA |  |  | Y/N |  |
| A 2.2 | Analytical methods for the active substance 2 | Y/N/NA |  |  | Y/N |  |
|  | Include A 2.2.1-2 as for active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 2.3 | Analytical methods for the active substance 3 | Y/N/NA |  |  | Y/N |  |
|  | Include A 2.3.1-2 as for active substance 1 | Y/N/NA |  |  | Y/N |  |

## Part B – Section 6Mammalian Toxicology

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 3)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 6.2 | Toxicological Information on Active Substance(s)  | Y/N/NA |  |  | Y/N |  |
| 6.3 | Toxicological Evaluation of Plant Protection Product | Y/N/NA |  |  | Y/N |  |
| 6.4 | Toxicological Evaluation of Groundwater Metabolites | Y/N/NA |  |  | Y/N |  |
| 6.4.1 | Metabolite 1 | Y/N/NA |  |  | Y/N |  |
| 6.4.2 | Metabolite 2 | Y/N/NA |  |  | Y/N |  |
| 6.5 | Dermal Absorption | Y/N/NA |  |  | Y/N |  |
| 6.5.1 | Justification for proposed values - active substance 1 | Y/N/NA |  |  | Y/N |  |
| 6.5.2 | Justification for proposed values - active substance 2 | Y/N/NA |  |  | Y/N |  |
| 6.6 | Exposure Assessment of Plant Protection Product | Y/N/NA |  |  | Y/N |  |
| 6.6.1 | Selection of critical use(s) and justification | Y/N/NA |  |  | Y/N |  |
| 6.6.2 | Operator exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.2.1 | Estimation of operator exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.3 | Measurement of operator exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.4 | Worker exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.4.1 | Estimation of worker exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.4.2 | Refinement of generic DFR value | Y/N/NA |  |  | Y/N |  |
| 6.6.4.3 | Measurement of worker exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.5 | Bystander and resident exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.5.1 | Estimation of bystander and resident exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.5.2 | Measurement of bystander and/or resident exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.6 | Combined exposure | Y/N/NA |  |  | Y/N |  |
| 6.6.6.1 | Exposure Assessment of active substance 1 and active substance 2 in Product name/Product code | Y/N/NA |  |  | Y/N |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Detailed evaluation of the studies relied upon  | Y/N/NA |  |  | Y/N |  |
| A 2.1 | Statement on bridging possibilities | Y/N/NA |  |  | Y/N |  |
| A 2.2 | Acute oral toxicity | Y/N/NA |  |  | Y/N |  |
| A 2.3 | Acute percutaneous (dermal) toxicity | Y/N/NA |  |  | Y/N |  |
| A 2.3.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| A 2.4 | Acute inhalation toxicity | Y/N/NA |  |  | Y/N |  |
| A 2.4.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| A 2.5 | Skin irritation | Y/N/NA |  |  | Y/N |  |
| A 2.5.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| A 2.6 | Eye irritation | Y/N/NA |  |  | Y/N |  |
| A 2.6.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| A 2.7 | Skin sensitization | Y/N/NA |  |  | Y/N |  |
| A 2.7.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| A 2.8 | Supplementary studies for combinations of plant protection products | Y/N/NA |  |  | Y/N |  |
| A 2.9 | Data on co-formulants | Y/N/NA |  |  | Y/N |  |
| A 2.9.1 | Material safety data sheet for each co-formulant | Y/N/NA |  |  | Y/N |  |
| A 2.9.2 | Available toxicological data for each co-formulant  | Y/N/NA |  |  | Y/N |  |
| A 2.10 | Studies on dermal absorption | Y/N/NA |  |  | Y/N |  |
| A 2.11 | Other/Special Studies | Y/N/NA |  |  | Y/N |  |
| App. 3 | Exposure calculations | Y/N/NA |  |  | Y/N |  |
| A 3.1 | Operator exposure calculations | Y/N/NA |  |  | Y/N |  |
| A 3.1.1 | Calculations for active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 3.1.2 | Calculations for active substance 2 | Y/N/NA |  |  | Y/N |  |
| A 3.1.3 | Calculations for active substance 3 | Y/N/NA |  |  | Y/N |  |
| A 3.2 | Worker exposure calculations | Y/N/NA |  |  | Y/N |  |
| A 3.2.1 | Calculations for active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 3.2.2 | Calculations for active substance 2 | Y/N/NA |  |  | Y/N |  |
| A 3.2.3 | Calculations for active substance 3 | Y/N/NA |  |  | Y/N |  |
| A 3.3 | Bystander and resident exposure calculations | Y/N/NA |  |  | Y/N |  |
| A 3.3.1 | Calculations for active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 3.3.2 | Calculations for active substance 2 | Y/N/NA |  |  | Y/N |  |
| A 3.3.3 | Calculations for active substance 3 | Y/N/NA |  |  | Y/N |  |
| A 3.4 | Combined exposure calculations for active substance 1, active substance 2and active substance 3 | Y/N/NA |  |  | Y/N |  |
| App. 4 | Detailed evaluation of exposure and/or DFR studies relied upon  | Y/N/NA |  |  | Y/N |  |

## Part B – Section 7Metabolism and Residues

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 4)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 7.1.1 | Critical GAP(s) and overall conclusion | Y/N/NA |  |  | Y/N |  |
| 7.1.2 | Summary of the evaluation | Y/N/NA |  |  | Y/N |  |
| 7.1.2.1 | Summary for active substance 1 | Y/N/NA |  |  | Y/N |  |
| 7.1.2.2 | Summary for active substance 2 | Y/N/NA |  |  | Y/N |  |
| 7.1.2.3 | Summary for active substance 3 | Y/N/NA |  |  | Y/N |  |
| 7.1.2.3 | Summary for product code | Y/N/NA |  |  | Y/N |  |
| 7.2 | Active substance 1 | Y/N/NA |  |  | Y/N |  |
| 7.2.1 | Stability of residues | Y/N/NA |  |  | Y/N |  |
| 7.2.1.1 | Stability of residues during storage of samples | Y/N/NA |  |  | Y/N |  |
| 7.2.1.2 | Stability of residues in sample extracts | Y/N/NA |  |  | Y/N |  |
| 7.2.2 | Nature of residues in plants, livestocks and processed commodities | Y/N/NA |  |  | Y/N |  |
| 7.2.2.1 | Nature of residues in primary crops | Y/N/NA |  |  | Y/N |  |
| 7.2.2.2 | Nature of residues in rotational crops  | Y/N/NA |  |  | Y/N |  |
| 7.2.2.3 | Nature of residues in processed commodities | Y/N/NA |  |  | Y/N |  |
| 7.2.2.4 | Conclusion on the nature of residues in commodities of plant origin | Y/N/NA |  |  | Y/N |  |
| 7.2.2.5 | Nature of residues in livestock | Y/N/NA |  |  | Y/N |  |
| 7.2.2.6 | Conclusion on the nature of residues in commodities of animal origin | Y/N/NA |  |  | Y/N |  |
| 7.2.3 | Magnitude of residues in plants | Y/N/NA |  |  | Y/N |  |
| 7.2.3.1 | Summary of European data and new data suporting the intended uses | Y/N/NA |  |  | Y/N |  |
| 7.2.3.2 | Conclusion on the magnitude of residues in plants | Y/N/NA |  |  | Y/N |  |
| 7.2.4 | Magnitude of residues in livestock | Y/N/NA |  |  | Y/N |  |
| 7.2.4.1 | Dietry burden calculation | Y/N/NA |  |  | Y/N |  |
| 7.2.4.2 | Livestocke feeding studies | Y/N/NA |  |  | Y/N |  |
| 7.2.5 | Magnitude of residues in processed commidities (Industrial Processing and/or Household Preparation) | Y/N/NA |  |  | Y/N |  |
| 7.2.5.1 | Available data for all crops under consideration | Y/N/NA |  |  | Y/N |  |
| 7.2.5.2 | Conclusion on processing studies | Y/N/NA |  |  | Y/N |  |
| 7.2.6 | Magnitude of residues in representative succeeding crops  | Y/N/NA |  |  | Y/N |  |
| 7.2.6.1 | Field rotational cro studies | Y/N/NA |  |  | Y/N |  |
| 7.2.7 | Other/ special studies | Y/N/NA |  |  | Y/N |  |
| 7.2.8 | Estimation of exposure through diet and other measn | Y/N/NA |  |  | Y/N |  |
| 7.2.8.1 | Input values for the consumer risk assessment | Y/N/NA |  |  | Y/N |  |
| 7.2.8.2 | Conclusion on the consumer risk assessment | Y/N/NA |  |  | Y/N |  |
| 7.3 | Active substance 2 | Y/N/NA |  |  | Y/N |  |
| 7.4 | Active substance 3 | Y/N/NA |  |  | Y/N |  |
| 7.5 | Combined exposure and risk assessment | Y/N/NA |  |  | Y/N |  |
| 7.5.1 | Acute consumer risk assessment from combined exposure | Y/N/NA |  |  | Y/N |  |
| 7.5.2 | Chronic consumer risk assessment from combined exposure | Y/N/NA |  |  | Y/N |  |
| 7.6 | References | Y/N/NA |  |  | Y/N |  |
| App. 1 | Lists of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Detailed evaluation of the additional studies relied upon | Y/N/NA |  |  | Y/N |  |
| A 2.1 | Active substance 1 | Y/N/NA |  |  | Y/N |  |
| A 2.1.1 | Stability of residues | Y/N/NA |  |  | Y/N |  |
| A 2.1.2 | Nature of residues in plants, livestock and processed commodities | Y/N/NA |  |  | Y/N |  |
| A 2.1.3 | Magnitude of residues in plants | Y/N/NA |  |  | Y/N |  |
| A 2.1.4 | Magnitude of residues in livestock | Y/N/NA |  |  | Y/N |  |
| A 2.1.5 | Magnitude of residues in processed commidities (Industrial Processing and/or Household Preparation) | Y/N/NA |  |  | Y/N |  |
| A 2.1.6 | Magnitude of residues in representative succeeding crops | Y/N/NA |  |  | Y/N |  |
| A 2.1.7 | Other/special studies | Y/N/NA |  |  | Y/N |  |
| A 2.2 | Active substance 2 | Y/N/NA |  |  | Y/N |  |
| A 2.3 | Active substance 3 | Y/N/NA |  |  | Y/N |  |
| App. 3 | Pesticide Residue Intake Model (PRIMo) | Y/N/NA |  |  | Y/N |  |
| A 3.1 | TMDI calculations | Y/N/NA |  |  | Y/N |  |
| A 3.2 | IEDI calculations | Y/N/NA |  |  | Y/N |  |
| A 3.3 | IESTI calculations – Raw commodities | Y/N/NA |  |  | Y/N |  |
| A 3.4 | IESTI calculations – Processed commodities | Y/N/NA |  |  | Y/N |  |
| App. 4 | Additional information provided by the applicant | Y/N/NA |  |  | Y/N |  |
|  |  | Y/N/NA |  |  | Y/N |  |

## Part B – Section 8Fate and behaviour in the environment

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 5)** | **Provided** | **Justification** | **Data gap** | **OK** | **Comment** |
| 8.1 | Critical GAP and overall conclusions | Y/N/NA |  |  | Y/N |  |
| 8.2 | Metabolites considered in the assessment | Y/N/NA |  |  | Y/N |  |
| 8.3 | Rate of degradation in soil | Y/N/NA |  |  | Y/N |  |
| 8.3.1 | Aerobic degradtion in soil | Y/N/NA |  |  | Y/N |  |
| 8.3.1.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.3.1.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.3.1.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.3.2 | Anaerobic degradtion in soil | Y/N/NA |  |  | Y/N |  |
| 8.4 | Field studies | Y/N/NA |  |  | Y/N |  |
| 8.4.1 | Soil dissipation testing on a range of representative soils | Y/N/NA |  |  | Y/N |  |
| 8.4.1.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.4.1.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.4.1.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.4.2 | Soil accumuation testing | Y/N/NA |  |  | Y/N |  |
| 8.5 | Mobility in soil | Y/N/NA |  |  | Y/N |  |
| 8.5.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.5.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.5.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.5.3 | Column leaching | Y/N/NA |  |  | Y/N |  |
| 8.5.4 | Lysimeter studies | Y/N/NA |  |  | Y/N |  |
| 8.5.5 | Field leaching studies | Y/N/NA |  |  | Y/N |  |
| 8.6 | Degradation in the water/sediment systems | Y/N/NA |  |  | Y/N |  |
| 8.6.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.6.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.6.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.7 | Predicted Environmental Concentrations in soil (PECsoil) | Y/N/NA |  |  | Y/N |  |
| 8.7.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 8.7.2 | Active substance(s) and relevant metabolite(s) | Y/N/NA |  |  | Y/N |  |
| 8.7.2.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.7.2.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.7.2.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.7.2.4 | PECsoil of formulation | Y/N/NA |  |  | Y/N |  |
| 8.8 | Predicted Environmental Concentrations in groundwater (PECgw) | Y/N/NA |  |  | Y/N |  |
| 8.8.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 8.8.2 | Active substance(s) and relevant metabolite(s) | Y/N/NA |  |  | Y/N |  |
| 8.8.2.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.8.2.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.8.2.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.9 | Predicted Environmental Concentrations in surface water (PECsw) | Y/N/NA |  |  | Y/N |  |
| 8.9.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 8.9.2 | Active substance(s), relevant metabolite(s) abd the formuatin | Y/N/NA |  |  | Y/N |  |
| 8.9.2.1 | Active substance 1 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.9.2.2 | Active substance 2 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.9.2.3 | Active substance 3 and its metabolites | Y/N/NA |  |  | Y/N |  |
| 8.9.2.4 | PECsw/PECsed of formulation | Y/N/NA |  |  | Y/N |  |
| 8.10 | Fate and behaviour in air | Y/N/NA |  |  | Y/N |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Detailed evaluation of the new Annex II studies | Y/N/NA |  |  | Y/N |  |
| A 2.1 | Study 1 | Y/N/NA |  |  | Y/N |  |
| App. 3 | Additional information provided by the applicant (e.g. detailed modelling data) | Y/N/NA |  |  | Y/N |  |

## Part B – Section 9Ecotoxicology

|  |  | **Applicant** |  | **MS** |
| --- | --- | --- | --- | --- |
| **Data point** | **Information, test or study** **(according to OECD Dossier Guidance Document, Appendix 6, Part 6)** | **Provided** | **Justifi-cation** | **Data gap** | **OK** | **Comment** |
| 9.1 | Critical GAP and overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.1.1 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.1.1.1 | Effetcs on birds, Effects on terrestrial vertebrates othe rthan birds, Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) | Y/N/NA |  |  | Y/N |  |
| 9.1.1.2 | Effects on aqautic organisms | Y/N/NA |  |  | Y/N |  |
| 9.1.1.3 | Effects on bees | Y/N/NA |  |  | Y/N |  |
| 9.1.1.4 | Effetcs on athropods other than bees | Y/N/NA |  |  | Y/N |  |
| 9.1.1.5 | Effects on non-target soil meso- and macrofauna, Effects on soil microbial activity | Y/N/NA |  |  | Y/N |  |
| 9.1.1.6 | Effects on non-target terrestrial plants | Y/N/NA |  |  | Y/N |  |
| 9.1.1.7 | Effetcs ob other terrestrial organisms (flora and fauna) | Y/N/NA |  |  | Y/N |  |
| 9.1.2 | Grouping of intended uses for risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.1.3 | Consideration of metabolites | Y/N/NA |  |  | Y/N |  |
| 9.2 | Effects on birds | Y/N/NA |  |  | Y/N |  |
| 9.2.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.2.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.2.2 | Risk assessment for spray applicatins | Y/N/NA |  |  | Y/N |  |
| 9.2.2.1 | First-tier assessment (screening/generic focal species) | Y/N/NA |  |  | Y/N |  |
| 9.2.2.2 | Higher tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.2.2.3 | Drinkning water exposure | Y/N/NA |  |  | Y/N |  |
| 9.2.2.4 | Efffects of secondary poisoning | Y/N/NA |  |  | Y/N |  |
| 9.2.2.5 | Biomagnification in terrestrial food chains | Y/N/NA |  |  | Y/N |  |
| 9.2.3 | Risk asssessment for baits, pellets, granules, prills or treated seed | Y/N/NA |  |  | Y/N |  |
| 9.2.4 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.3 | Effects on terrestrial vertebrates other than birds | Y/N/NA |  |  | Y/N |  |
| 9.3.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.3.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.3.2 | Risk assessment for spray applicatins | Y/N/NA |  |  | Y/N |  |
| 9.3.2.1 | First-tier assessment (screening/generic focal species) | Y/N/NA |  |  | Y/N |  |
| 9.3.2.2 | Higher tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.3.2.3 | Drinkning water exposure | Y/N/NA |  |  | Y/N |  |
| 9.3.2.4 | Efffects of secondary poisoning | Y/N/NA |  |  | Y/N |  |
| 9.3.2.5 | Biomagnification in terrestrial food chains | Y/N/NA |  |  | Y/N |  |
| 9.3.3 | Risk asssessment for baits, pellets, granules, prills or treated seed | Y/N/NA |  |  | Y/N |  |
| 9.3.4 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.4 | Effects on other terrestrial vertebrate wildlife (reptiles and amphibians) | Y/N/NA |  |  | Y/N |  |
| 9.5 | Effects on aquatic organisms | Y/N/NA |  |  | Y/N |  |
| 9.5.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.5.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.5.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.5.3 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.6 | Effects on bees | Y/N/NA |  |  | Y/N |  |
| 9.6.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.6.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.6.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.6.2.1 | Hazard quotients for bees | Y/N/NA |  |  | Y/N |  |
| 9.6.2.2 | Higher-tier risk assessment for bees (tunnel test, field studies) | Y/N/NA |  |  | Y/N |  |
| 9.6.3 | Effects on bumble bees | Y/N/NA |  |  | Y/N |  |
| 9.6.4 | Effecst on solitary bees | Y/N/NA |  |  | Y/N |  |
| 9.6.5 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.7 | Effects on arthropods other than bees | Y/N/NA |  |  | Y/N |  |
| 9.7.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.7.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.7.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.7.2.1 | Risk assessment for in-field exposure | Y/N/NA |  |  | Y/N |  |
| 9.7.2.2 | Risk assessment for off-field exposure | Y/N/NA |  |  | Y/N |  |
| 9.7.2.3 | Additional higer-tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.7.2.4 | Risk mitigation measures | Y/N/NA |  |  | Y/N |  |
| 9.7.3 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.8 | Effects on non-target soil meso- and macrofauna | Y/N/NA |  |  | Y/N |  |
| 9.8.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.8.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.8.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.8.2.1 | First-tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.8.2.2 | Higher-tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.8.3 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.9 | Effects on soil microbial activity | Y/N/NA |  |  | Y/N |  |
| 9.9.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.9.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.9.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.9.3 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.10 | Effects on non-target terrestrial plants | Y/N/NA |  |  | Y/N |  |
| 9.10.1 | Toxicity data | Y/N/NA |  |  | Y/N |  |
| 9.10.1.1 | Justification for new endpoints | Y/N/NA |  |  | Y/N |  |
| 9.10.2 | Risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.10.2.1 | Tier-1 risk assessment (based on screening data) | Y/N/NA |  |  | Y/N |  |
| 9.10.2. | Tier-2 risk assessment (based on dose-response data) | Y/N/NA |  |  | Y/N |  |
| 9.10.2.3 | Higher-tier risk assessment | Y/N/NA |  |  | Y/N |  |
| 9.10.2.4 | Risk mitigatin measures | Y/N/NA |  |  | Y/N |  |
| 9.10.3 | Overall conclusions | Y/N/NA |  |  | Y/N |  |
| 9.11 | Effects on other terrestrial organisms (flora and fauna) | Y/N/NA |  |  | Y/N |  |
| 9.12 | Monitoring data | Y/N/NA |  |  | Y/N |  |
| 9.13 | Classification and labelling | Y/N/NA |  |  | Y/N |  |
| App. 1 | List of data considered in support of the evaluation | Y/N/NA |  |  | Y/N |  |
| App. 2 | Detailed evaluation of the new studies | Y/N/NA |  |  | Y/N |  |
| A 2.1 | Effects on birds and other terrestrial vertebrates | Y/N/NA |  |  | Y/N |  |
| A 2.1.1 | Effects on birds | Y/N/NA |  |  | Y/N |  |
| A 2.1.2 | Effects on terrestrial vertebrates other than birds | Y/N/NA |  |  | Y/N |  |
| A 2.1.3 | Effects on other terrestrial vertebrate wildlife (reptiles and amphbians) | Y/N/NA |  |  | Y/N |  |
| A 2.2 | Effects on aquatic species | Y/N/NA |  |  | Y/N |  |
| A 2.2.1 | Acute toxiticy to fish, aquatic invertebrates, or effects on aqauatic algae and macrophytes | Y/N/NA |  |  | Y/N |  |
| A 2.2.2 | Additional long-term and chronic toxicity studies on fish, aqautic invertebrates and sediment dwelling organisms | Y/N/NA |  |  | Y/N |  |
| A 2.2.3 | Further testing on aquatic species | Y/N/NA |  |  | Y/N |  |
| A 2.3 | Effects on arthropods | Y/N/NA |  |  | Y/N |  |
| A 2.3.1 | Effects on bees | Y/N/NA |  |  | Y/N |  |
| A 2.4 | Effects on non-target soil meso- and macrofauna | Y/N/NA |  |  | Y/N |  |
| A 2.4.1 | Earthworms | Y/N/NA |  |  | Y/N |  |
| A 2.4.2 | Effects on non-target soil meso- and macrofauna (other than earthworms) | Y/N/NA |  |  | Y/N |  |
| A 2.5 | Effecst on soil nitrogen transformation | Y/N/NA |  |  | Y/N |  |
| A 2.6 | Effects on terrestrial non-target higher plants | Y/N/NA |  |  | Y/N |  |
| A 2.6.1 | Sumamry of screening data | Y/N/NA |  |  | Y/N |  |
| A 2.6.2 | Testing on non-target plants | Y/N/NA |  |  | Y/N |  |
| A 2.6.3 | Extended laboratory studies on non-target plants | Y/N/NA |  |  | Y/N |  |
| A 2.7 | Effects on other terrestrial organisms (flora and fauna) | Y/N/NA |  |  | Y/N |  |
| A 2.8 | Monitoring data | Y/N/NA |  |  | Y/N |  |