NZSC
Northern Zone Steering Committee

GUIDANCE DOCUMENT ON WORK-SHARING IN THE NORTHERN ZONE IN THE AUTHORISATION OF PLANT PROTECTION PRODUCTS - ver 14

Version 14. This guidance document replaces the version 13 of June 2025 and can be voluntarily applied from June 2026. The document must be applied from the dates given in the table starting on page 2. Changes to the previous version are highlighted in yellow.

Editing log – Guidance Document on Works-sharing in the Northern zone in the Authorisation of Plant Protection Products

Date	Revision	Issues	Responsible	Implementation date
January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products	DK + expert groups	
July 2011	1.0	First revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products	DK + expert groups	1 July 2011
April 2013	2.0	Second revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in following Sections: 3. Procedures 4.1 Identity 4.2 Toxicology 4.3. Residues 4.5. Environmental fate and behaviour 4.6. Ecotoxicology	FI + expert groups	1 October 2013
April 2014	3.0	Third revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in following Sections: 3. Procedures	Steering group	2 May, 2014
		4.1 Identity	expert group	1 August 2014
		4.2 Toxicology	expert group	2 January 2015
		4.3. Residues	expert group	1 August 2014
		4.5. Environmental fate and behaviour	expert group	2 January, 2015
		4.6. Ecotoxicology	expert group	2 January 2015
April 2015	4.0	Fourth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in following Sections:		
		3. Procedures	Steering group	1 July 2015
		4.2 Toxicology	expert group	1 January 2016
		4.5. Environmental fate and behaviour	expert group	1 January 2016
		4.6. Ecotoxicology	expert group	1 January 2016
April 2016	5.0	Fifth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections:		
		3. Procedures	Steering group	1 May 2016
		4.2 Toxicology 4.3 Residues 4.4 Efficacy 4.5 Environmental fate and behaviour 4.6 Ecotoxicology	Expert group	1 October 2016
May 2017	6.0	Sixth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections: 3. Procedures 4.1 Identity 4.2 Toxicology 4.3 Residues 4.4 Efficacy 4.5 Environmental fate and behaviour 4.6 Ecotoxicology	Steering group and expert group	1 November 2017
May 2018	7.0	Seventh revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections: All sections	Steering and expert groups	1 November 2018
June 2019	8.0	Eighth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections:	Steering and expert groups	1 November 2019

Date	Revision	Issues	Responsible	Implementation date
		All sections		
June 2020	9.0	Ninth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections: All sections	Steering and expert groups	1 November 2020
June 2021	10.0	Tenth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections: All sections	Steering and expert groups	1 November 2021
July 2023	11.0	Eleventh revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections: All sections	Steering and expert groups	1 November 2023
September 2023	11.1	Changes of the 11th revision due to some missed comments. Also some minor corrections have been made. The changes are highlighted in turquoise and are in section: • 17.1.2.1 • 18.2.1.1 • 18.2.3 • Table 6 • Table 7 • 19.6 • 21.3.3 • 21.3.4 • 22.6 • 22.8 • 22.1 • Appendix III, IV, V, VI, XI	Expert groups	1 November 2023
July 2024	12.0	Twelfth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in following sections: 5.Before submission of an application 6. Application 6.5 Interzonal uses 18. Toxicology 18.2.5 Risk mitigation measures 19. Residues 21. Environmental Fate and Behaviour 21.1 Soil 21.2 Ground water 21.2.2 Substance input data 21.2.5 National requirements for PECgw simulations 21.3 Surface water 21.3.1 Input parameters 21.3.2 Application dates 21.3.3 Surrogate crops 22. Ecotoxicology 22.3 Risk assessment for uses in protected structures 22.6.1 Mixture toxicity assessment 22.9 Earthworms and other soil organisms 22.11 Risk assessment of metabolites 22.12 Use of non-testing methods (e.g. QSAR) as higher tier refinement for metabolites Appendix V. Summary of national requirements Appendix VI. List of mitigation options available in the Member States in the Northern zone Appendix VII. Template for Aquatic Risk Assessment including mitigation measures	Steering and expert groups	1 November 2024

Date	Revision	Issues	Responsible	Implementation date
		Appendix IX. Acute inhalation toxicity – for spray application		
June 2025	13.0	Thirteenth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes are highlighted in yellow. Changes are made in the following sections and their subsections: • 17.1 Identity of the plant protection product • 17.2 Physical, chemical and technical properties of the plant protection product • 18.1 Acute Toxicity • 18.2 Exposure Assessment • 18.3 Dermal Absorption • 19.3 Livestock feeding studies • 19.4 Studies on industrial processing and/or household preparation • 19.6 Estimation of Exposure through Diet and Other Means • 19.7 Comparability, extrapolation, group tolerance and data requirements for pesticides resi-dues in food and raw agricultural commodities • 21 Environmental Fate and Behaviour • 21.1 Soil • 21.2 Ground water • 21.3 Surface water • 21.4 Monitoring data • 22 Ecotoxicology • 22.2 Non-professional use/Home gardens • 22.5 Birds and mammals • 22.8 Non-target arthropods • 22.9 Earthworms and other soil organisms • 22.10 Non-target terrestrial plants • 22.12 Use of non-testing methods (e.g. QSAR) as higher tier refinement for metabolites • Appendix III, IV, V, VI, IX and X Furthermore, a new section (6.5) has been added regarding specific requirements for microbial plant protection products. The former section 6.5 is now 6.6. In addition to the above, minor adjustments, including abbreviations, have been made to ensure a consistent and unified appearance of the Guidance Document. The table numbering has been updated to correspond with the sections they belong to.	Steering and expert groups	1 November 2025
June 2026	14.0	14th revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes are highlighted in yellow. Changes are made in the following sections and their subsections: • Table 4.1 • 6.4. Format and requirements for an application • 7. Proposal for new endpoints in the risk assessment • 12.1 Amendment of authorisation • 17. Identity, physical chemical properties and analytical methods • 17.1 Identity of the plant protection product • 17.2 Physical, chemical and technical properties of the plant protection product • 18. Toxicology	Steering and expert groups	1 November 2026

Date	Revision	Issues	Responsible	Implementation date
		• 18.1.1 Step-wise approach for assessment of acute toxicity including skin and eye irritation and skin sensitisation • 18.1.2 Endpoint specific notes • 18.1.3 Use of silico methods (e.g. QSAR • 18.2.1 Professional use (Operator, Worker, Bystander and resident exposure) • 18.2.2 Non-professional use • 18.2.5 Risk mitigation measures • 21. Environmental Fate and Behaviour • 21.1. Soil • 21.2 Groundwater • 21.3 Surface water • 22. Ecotoxicology • 22.5 Birds and mammals • 22.5.1 Geometric mean • 22.5.2 Willow warbler in late growth stages of maize [Chapter deleted] • 22.5.3 Mixture toxicity assessment [Chapter deleted] • 22.5.2 Tier 1 refinement options • 22.6 Aquatic ecosystems • 22.7 Bees • 22.8 Non-target arthropods • 22.9.4.2 Refined PEC [Chapter deleted] • 22.11 Risk assessment of metabolites • Appendix V. Summary of national requirements • Appendix VII. Template for Risk Assessment including mitigation measures [Appendix deleted] In addition, minor corrections, including updating of links, have been made. The appendix numbering has been updated to correspond with the sections they belong to.		

The correct reference for the NZ work sharing GD: Northern Zone, 2026. Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products. Version 14, June 2026.

Content

1. Legal Status

This document does not intend to produce legally binding effects and by its nature does neither prejudice any measure taken by a Member State (MS)/country within the Regulation (EC) No 1107/2009 or previous implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC, nor prejudice any case law developed with regard to these provisions. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in MSs.

2. Introduction

This document describes a procedure for the submission and assessment of applications for authorisation, re-authorisation and amendments of plant protection products following approval of an active sub-stance under Regulation (EC) No 1107/2009 in the Northern Zone (NZ) and thereof an inclusion in Regulation (EU) No 540/2011.

The NZ Guidance document has been agreed by the responsible competent authorities in Denmark, Estonia, Finland, Iceland, Latvia, Lithuania, Norway and Sweden. The document is based on the EU Guidance documents on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 – rev. 11, January 2021) and Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/13170/2010 – rev. 11, January 2021). The intention is that it should be used in the context of zonal evaluations of applications for authorisation of plant protection products in order to reduce the workload for both applicants and authorities and to promote the harmonisation in the NZ. The procedures in this document will be applied for re-authorisation of products containing active substances with a re-approval date from 1 January 2016.

For applications of new authorisations submitted after 1 March 2021 the provisions of the EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010 – rev. 11, January 2021) applies.

The document might be updated once a year to take into account developments and practical experience of the procedures, new data requirements and/or guidance on risk assessment and risk mitigation.

Since the preparation of dossiers may have started before the details in this guidance document were known to applicant’s flexibility will be applied, regarding what is put into the core part of the dossier and what should be included in the national addenda. Therefore, a period of implementation will be given, until the latest version of this guidance must be followed, see editing log for implementation date.

The latest updates of the guidance document can be voluntarily followed already after its publication. See table on page 2 for specific implementation dates. Note that it can be different implementation periods in different sections, due to the characteristics of the changes.

3. Procedures

In summary, the procedure is as follows:

The applicant submits the application to all MSs where they wish to gain/maintain authorisation. One lead country in the zone – the zonal Rapporteur Member State (zRMS) will complete the evaluation of a core dossier on behalf of the concerned Member States (cMS) in the zone.

The MSs, as well as the applicant, within the zone will have the possibility to comment on the core assessment with focus on essential parts, e.g., areas of particular attention pointed out in the approval regulation, areas of importance for the final decision, and new studies submitted to address data gaps identified in the review report.

The zRMS will then finalize the assessment with received comments taken into account and make it available via CIRCABC. The MSs within the zone will be notified via e-mail. The cMS will then complete their national assessments based on the zRMS core assessment taking into consideration national requirements, risk assessment schemes and national options for risk mitigation when relevant. The final assessment including the commenting table will be submitted to the applicant.

The procedures for new applications and re-authorisations are further described in this document.

4. Zonal steering committee

The zonal steering committee is formed from representatives of the competent authorities of each MS in the zone and from the EFTA countries Norway and Iceland. Contact points are listed in in Appendix IV.

The steering committee has online conferences approximately every second month and face-to-face meetings at least once a year. The steering committee is normally chaired by one country for one year on a rotational basis, see Table 4.1 for chair. Chairs are responsible for drafting the agendas of the meeting of the steering committee, minutes of the meetings as well as to coordinate the update of this document. The chair of the steering committee is also the primary contact point for the Central- and Southern zones and the primary NZ representative at workshops, conferences etc.

Table 4.1 Incoming chairs year 2026–2032

Year	Country*
2026	Latvia
2027	Lithuania
2028	Estonia
2029	Sweden
2030	Norway
2031	Denmark
2032	Finland

*Iceland is excluded

4.1 Coordination group

The coordination group is a subgroup under the steering committee.

The coordination group has approximately four online conferences per year, with two per half year.

The responsibility of the coordination group is to coordinate updating of the list of applications with agreed zRMS and timelines.

5. Before submission of an application

Applicants are encouraged to prepare a single dossier that just covers the intended uses in the zone and to harmonise GAPs as much as possible. This will allow a 'risk envelope' approach to the assessment, whereby only the worst-case exposure scenarios for each area of the risk assessment are evaluated, with other 'less risky' scenarios being deemed acceptable. Different formulations may be covered by the same risk assessment if bridging studies and scientific justifications are available.

Guidance on the 'risk envelope' approach is available at the EU level as detailed in:

https://food.ec.europa.eu/document/download/bcef38e1-ff75-4f7e-b6c2-6863110f0c3b_en?filename=pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf.

Applicants are encouraged to make early contact with the preferred zRMS regarding applications for label extensions and new authorisations. Regarding renewal authorisations, the process for allocation of zRMS is initiated by the Steering Committee. Contact points for MSs are listed in Appendix IV.

Applicant's preference for choice of zRMS will be taken into consideration, but the decision regarding the zRMS allocation will be made by Steering Committee in the NZ based on the following:

- the identity of the original RMS for the evaluation of the active substance
- the relevance/importance of the products in each country
- the availability of resources

The applicant will be informed of the appointed zRMS. All communication regarding the application should be made with the zRMS, unless it concerns national addenda only relevant for cMS.

5.1 Pre-notifications

All applicants are requested to submit a notification, to all cMSs, at the latest 6 months before submission of the dossier for new applications, mutual recognition and label extensions. The notification form is available at the Commission's web site (see Appendix I).

Before making a pre-notification for new authorisations and major label extensions, please contact the preferred zRMS to discuss a time slot for the application.

The applicant should request Cat 4 data in the cover letter, which is sent to the zRMS, with copy to the cMS.

Please note, a precise estimate of submission date will facilitate the work-sharing and increase our possibility to keep the evaluation timelines.

For any questions related to pre-submission issues of applications, applicants are recommended to contact the contact point in each respective MS (for contact details, please see Appendix III).

6. Application

6.1 Submission of renewal of authorisation

An application for renewal of authorisation shall be submitted to the appointed zRMS within 3 months from when the decision of the re-approval of the active substance applies. An application shall be sent to all cMSs in the zone.

EU Guidance document on Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/2010/13170 (or later version)) should be followed as well as the NZ guidance document. For issues related to specific national requirements (specified in Appendix V) the applicant should contact the respective country.

6.2 Submission of a new product authorisation

The applicant should submit an application to all MSs within the zone where they wish to gain authorisation. Together with the application a zRMS has to be proposed. For applications for a new product authorisation the EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010) should be followed as well as the NZ guidance document.

6.3 Submission of label extension

The applicant should submit an application to all MSs within the zone where they wish to gain a label extension. Together with the application a zRMS has to be proposed.

6.4 Format and requirements for an application

Guidance documents accepted on EU-level are applicable in the NZ from the implementation date of each guidance, whether the guidance is mentioned in this document or not. If the NZ has done any exemptions from these guidance documents, they are noted in this guidance document.

The application and documentation should be in English and submitted on CD or by file share services.

The application should contain:

1. A core draft Registration Report (dRR) based on the following:
   - Assessment based on adopted active substance endpoints.
   - Assessments based on guidance in place at submission of the application.
   - The sections of the dRR must be targeted and transparent.
   - Only information and data relevant for the concerned countries/ NZ should be presented.
   - If applicable national addenda as indicated in Appendix V. Addenda addressing national requirements for cMSs should also be submitted to the zRMS. zRMS should also receive all national part A. The template for the dRR is to be found on the Commissions webpage: dRR templates for chemical plant protection products with report - v202011 | Food Safety
   - An assessment should be conducted using the worst-case use(s)/scenarios following the risk envelope approach according to SANCO/11244/2011. Uses with similar characteristics can be assessed group-wise. The risk assessment for different groups can be simplified by assessing the worst-case group. It should be noted that this may result

in different grouping in the different sections and under sections of the dRR.

2. **Cover letter**, including a brief summary of the application content and a brief summary describing how the documentation is organised.
3. **The application form**, available at each authority's website.
4. **Studies and study reports**: Applicants are required to submit a full dossier according to the data requirements for products that is valid for the application[1]. Preferably organised in an intuitive structure with folder and file names reflecting the content, see Appendix VII for a recommended structure. File directory should not exceed 100 letters, including the file name.

   Further guidance on data requirements can be found in EU Guidance document on the interpretation of the transitional measures for the data requirements for chemical active substances and plant protection products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509 /2013).

   Duplication of vertebrate studies shall not be accepted by MS according to Article 62 (2). This is also applicable for vertebrate studies generated in a regulatory jurisdiction outside the EU. If other alternative means exist (e.g. calculations according to the CLP regulation), which have been evaluated to properly address the effects investigated in a vertebrate study, they shall be used instead.
5. **Completeness check scheme**
6. **GAP tables** – complete with all intended uses in the zone, which also appoints which use is relevant for which country. The GAP should cover the NZ for zonal applications and the EU-countries for interzonal applications.
7. **Labels**, all labels should also be submitted to the zRMS.
   1. National labels in national languages
   2. Master label in English containing a description of the use in the whole zone.
8. **Active substance dossier** (if not previously submitted) (incl. study reports) - in accordance with the requirements specified in Regulation (EU) No 283/2013 (or (EU) No 545/2011 for AIRII substances).
9. **Justification** for new data submitted and use of vertebrate studies.
10. **Complete reference list**
    1. All studies required to support the application, i.e. both product and active substance data should be included in the list in Appendix 4 of Part A

[1] Please note that Commission Regulations (EU) 2022/1439, 2022/1440, and 2022/1441 regarding data requirements for microorganisms and plant protection products containing microorganisms, as well as the uniform principals for evaluation shall apply from 21 November 2022. However, until 21 November 2024 applications for authorisation of plant protection products containing microorganisms can follow the data requirements in Part B of the Annex to Regulation (EU) No 284/2013 as it stood before the changes in Regulations 2022/1439, 2022/1440 and 2022/1441.

2. A justification if data protection is claimed. The justification shall confirm that the study is necessary, and that no data protection period have been granted previously in a specific MS or at EU level or if data protection granted is still valid, as required in Article 59.3 of the Regulation.

11. **Confidentiality claim** – use template in appendix 10 of the EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010).

6.5 Microbial Plant Protection Products

Applications for a microbial plant protection product should follow the data requirements and assessment guidelines described in "Evaluation Manual for the Authorisation of Microbial pesticides according to Regulation (EC) No 1107/2009" and "Explanatory Notes for the Implementation of the Data Requirements on Micro-organisms and Plant Protection Products Containing Them in the Framework of Reg. (EC) No 1107/2009".

6.6 Interzonal uses

The EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010) should be followed.

The IZSC has developed a guidance on requirements for the interzonal use in greenhouses. The implementation dates for the guidances (excel sheet and working document) are 1 September 2024. The guidances can be found at CIRCABC PPP zonal portal, in the interzonal steering committee folder[2].

7. Proposal for new endpoints in the risk assessment

Proposal of new data (endpoints) shall be in accordance with Guidance Document on the Evaluation of New Data on an Active Substance Submitted Post (Renewal Of) Approval - SANCO/10328/2004 – rev 10

8. Data gaps identified in active substance evaluation

The IZSC has agreed on the way applicants and MSs need to deal with data gaps mentioned in the EFSA conclusion when preparing the assessment of a plant protection product (PPP) based on the concerned active substance (a.s.). The paper

[2] PPP Zonal – Bibliotek (europa.eu)

can be found at CIRCABC PPP zonal portal[3]. However, it should be acknowledged that the way of handling EFSA data gaps varies according to the situation. Consequently, for each of the cases described in the paper, a harmonised procedure has been agreed. Data gaps of active substances and metabolites first identified in the authorisation procedure of PPP are not covered.

9. Administrative prolongations of authorisations

If the approval of the active substance is prolonged, the products can be prolonged accordingly, plus 1 year (according to Article 32).

- SE, LV and EE will require a letter of intent from the applicant and will charge a fee.
- LT will require a letter of intent from the applicant and FI will require an email of intent from the applicant but will not charge a fee.
- NO and DK prolongs the authorisations automatically and does not charge a fee.

In case no application for renewal of an authorisation will be submitted, the product will expire at the date of renewal of approval of the active substance. Periods of grace for retail, sale and use can be granted, according to Article 46.

10. Renewal according to Article 43

For renewals according to Article 43 in Regulation (EC) No 1107/2009 an application for renewal of the product authorisation shall be submitted within 3 months from when the renewal of the approval of an active substance should be applied.

It is not possible to apply for renewal of an authorisation through mutual recognition. Products that previously have been authorised through mutual recognition must be renewed by zonal applications.

The renewal for products containing more than one active substance is done in accordance with the EU Guidance Document stating that:

- If the period between the renewal of the first active substance and the expiry of the second active substance is within 12 months at the time of application, the evaluation of the renewal of authorisation of both active substances should be coordinated and only one dossier needs to be submitted at the deadline of the second a.s.

[3] https://circabc.europa.eu/ui/group/0b40948d-7247-4819-bbf9-ecca3250d893/library/05a3402f-54fd-496c-8fe2-435d2a8d75f7/details.

- If the initial period between the renewals of 2 a.s. is within 12 months, however approval of one or both a.s. is extended by EC regulation due to the delay in evaluation of a.s. at EU level, date of application of the product dossier for Article 43 authorization should be considered based on the available realistic date of renewal of approval of a.s. (availability of EFSA conclusion, etc). If it is not realistic that renewal of approval of both a.s. will be in 12-month period, the application for reauthorization of the product according to the Article 43 shall be submitted within 3 months from the renewal of the approval of first active substance. Borderline cases will be discussed and decided upon by the NZ steering committee. The zRMS will inform the applicant of the decision.

Even if the evaluation of two or more active substances can be coordinated one application per active substance has to be submitted, within the timelines specified in the regulation.

If the product contains more than one active substance and only one of them has been renewed, the evaluation should mainly focus on the substance being renewed. This means that there should not be new/modified endpoints or modelling data for the active substances that has not been renewed. However new data and new modelling data may be required as new guidance has to be applied and thus require refinements and assessment of data concerning the other substance(s).

An application for renewal shall contain the information stated in 6.4. unless it is agreed with zRMS that the complete dossier should be submitted later.

The zRMS notifies the applicant on the receipt of the application and agrees on a date for the submission of a complete dossier for renewal.

10.1 Updates and harmonization of the use of the products in connection with the renewals

According to the EU guidance document regarding renewals of product authorisations pursuant to Article 43, only already authorised uses in the individual MSs and amendments, resulting from changes in the evaluation of the active substance and changes due to new guidance should be assessed for applications for renewal in accordance with Article 43. The NZ requires that the assessment submitted for Article 43 renewals is in accordance with technical guidance in force at the time of application submission.

The NZ will consider changes and amendments to the GAP in connection with the renewals if the following conditions are fulfilled:

1. Changes and amendments in uses that fall within the Risk Envelope

2. Changes are covered by the efficacy and MRL data previously evaluated in the context of national authorisations.
3. Non-significant formulation changes, for further information see Section 17.1.

Uses that are new for the zone will not be accepted as part of the application for renewal. Such an application shall be submitted as an application for amendment, and it will be decided case by case when this application for amendment can be submitted.

- Changes, including amendments of the GAP, must be agreed with zRMS and subsequently with cMS at the same time as the pre-notification. Otherwise, the application may be rejected.
- If changes/updates related to formulations and new MSs etc. are not acceptable for renewals, then companies should submit applications for authorisation of "new" products including new dossiers.

10.2 Category 4 data

According to EU guidance on Article 43, category 4 (Cat. 4) data is data which are directly related to new guidance in place at the time of submission or to a new/revised endpoint decided at the time of the renewal of the approval of the active substance (endpoints as listed in the supporting information to the EFSA conclusions) and for which the time is too short from the publication of the EFSA conclusion to produce the requested study.

If there is a need to develop data related to the above, the applicant needs to justify the lack of data by the fact that it could not anticipate this request before publication of the EFSA conclusions. Proof of, or commitment to, initiation of the study and an expected finalisation date must be provided. Such information may be related to either active substance or formulated product data requirements. However, data falling under the scope of Article 38 (new source of technical material) cannot be considered according to this paragraph.

This justification should be sent to the appointed zRMS together with the pre-notification, preferably in connection to a pre-submission meeting. Before submission of the application, it has to be agreed that the data is considered as Cat. 4 data, and when the data should be submitted. If no agreement has been reached, a later submission of the data is per default not accepted, hence the product authorisation may not be prolonged awaiting the missing data. zRMS should inform the cMSs in the zone.

Missing data not identified as Cat. 4 data prior to submission of the application will not be accepted as Cat. 4 data.

Cat. 4 data will be discussed and decided upon by the NZ steering committee. The zRMS will inform the applicant of the decision.

Within 3 months after the date of application of the approval of the active substance in question (DoA according to the renewal regulation), the applicant shall submit a formal application for renewal and that application should include:

1. Cover letter.
2. List of Cat. 4 studies to be submitted with the full dossier.
3. Indication of the time when the Cat. 4 studies will be finalised.

The zRMS will notify the applicant on the receipt of the application and an agreement on the date for the submission of a complete dossier for renewal. The dRR and full dossier (as requested in 3.6.1) shall be submitted 3 months after Cat. 4 data is finalised, at the latest.

11. Applications for mutual recognitions

The EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010), should be followed. Some MS in the zone have also developed national Guidance documents on mutual recognitions, e.g., Sweden.

In all cases the following requirements must be fulfilled for mutual recognitions:

1. A copy of the authorisation granted by the reference MS as well as a translation of the authorisation into an official language of the MS receiving the application (depending on the MS a translation into English could be sufficient)
2. Submission of the dossier (study reports) that was submitted to the reference MS.
3. The assessment which is being referred to should fulfil the current requirements concerning form and detail (e.g., Registration Report (RR)).
4. Part A of the reference MS.
5. National requirements must be addressed.
6. Compliance with the national agricultural and environmental standards
7. National risk management measures must be considered.

12. Withdrawal and amendment of an authorisation based on zonal evaluations

12.1 Amendment of authorisation

Amendments shall be dealt with according to the zonal procedure, if applicable. EU Guidance documents on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010) should be followed and Appendix 1 in in that guidance states which kind of applications that should be sent for commenting. The NZ does always require an application for all amendments i.e., a notification is not accepted as suggested in SANCO/12638/2011. Please consult Section 17.1 for more information regarding formulation changes.

Different types of amendments require various information and/or documentation to be submitted, and relevant sections of the latest RR should be updated accordingly. Depending on the changes, revised sections or addenda should be submitted, supported by the new information or data relied on. **The format should be agreed with zRMS before submission**. Table 12.1 below shows which sections of the dRR need to be revised. All changes in the revised sections of the latest RR, including the revised reference list, should be highlighted in a different colour for transparency reasons. It is not allowed to make other changes than those required for the applied amendment.

Table 12.1 Type of amendment and section submission.

Type of amendment	Sections and information that should be revised and submitted (section numbers are according to the new dRR-format)
Non-significant formulation change, e.g. adding alternative co-formulant	An updated part C. An updated Part B1, B2, B4 or relevant addenda if applicable. See Section 17.1 for additional information that should be submitted. The detailed complete composition of the co-formulants needs to be submitted to all cMS to make commenting possible.
Significant formulation change	An updated part C An updated part B1, 2, 4 or addenda Updates/addenda of other necessary part B, e.g analytical methods (method specificity), tox, efficacy etc. An updated part A, when the change leads to an altered classification of the product. See Section 17.1 for additional information that should be submitted. The detailed complete composition of the co-formulants needs to be submitted to all cMSs to make commenting possible.
Change or addition of source of active substance	An updated part C (including status on equivalence related to renewal of active substance and possible update of reference specification must be included).
Change or addition of source of product	An updated section, as it was originally submitted, part B1 or part C
Label extensions (crops, pests etc.)	Part A Updates/addenda for relevant part B's, depending on the amendment (e.g. efficacy, toxicology, fate, residues, ecotox, analytical methods for residues if not addressed at EU level). Only necessary assessment relevant for the amendment, should be inserted in the respective Part B's. Studies under evaluation in the a.s. renewal and/or product studies according to the new data requirements (Regulation 284/2013) should not be included in an amendment. For further information see appendix 4 of guidance document SANCO/13169/2010
Administrative changes (authorisation holder, name of product etc.)	National application only No updated dRR necessary
Other changes (e.g. CLP, packaging)	Updates/addenda for relevant part Bs, depending on the amendment. An updated part A when the classification is changed.

12.2 Grace period according to Article 46

EU Guidance documents on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010) is applicable.

13. Timelines

13.1 Application for re-authorisation of products (Article 43)

The allocation of the zonal RMS for the products within the NZ is initiated during the re-evaluation process (AIR-programs) of the active substances. The work is coordinated by one of the NZ's MSs. The holder of the product authorisation will be notified of the zonal RMS for their product before the finalisation of the active substance evaluation.

It is highly recommended to have a pre-submission meeting before submission of an application for re-authorisations. It is also recommended, prior to application of re-authorisation, to notify the zRMS and cMS regarding:

- Category 4- data. See Section 10.2 Category 4 data.
- Supported GAP and indication of amendments of the GAP (to be agreed in pre-submission meetings with zRMS)
- Indication of which parts of the risk assessment need updating (to be agreed in pre-submission meetings with zRMS)
- A "data matching list" according to the Commission guidance document (Template for Submission Demonstrating Access to a Complete Package According to Regulation (EU) 283/2013 and for the Data Matching Step, SANTE/2016/11449 7 December 2016

A scheme of the process is given in Figure 1 Scheme of the process for re-authorisations.

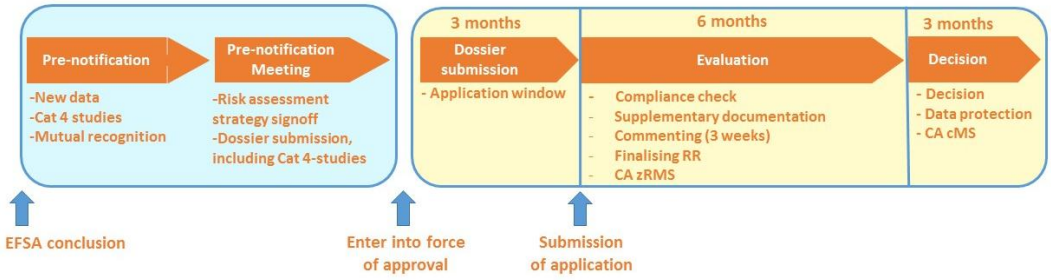


Figure 1 Scheme of the process for re-authorisations

13.2 New product authorisations

A decision on who will act as zRMS will be taken based on proposed zRMS by the applicant as well as available resources and priorities set in each MS. The evaluation of the product and the proposed uses should be organised by the zRMS as an individual project, setting specific deadlines and allocating in advance the necessary resources for the fulfilment of the obligations.

A six week period is given for the zRMS to check the completeness of the application. The zRMS will conduct the evaluation within 6.5 months. In case further information/studies are required a maximum six-month period is given to the applicant to complete the application, clock stop. When the dRR is finalised (revision 0) it will be uploaded on CIRCABC and sent to the other MSs in the zone and the applicant for commenting. A six weeks commenting period is provided.

The zRMS prepares a reporting table (see Appendix II) with all received comments and the zRMS response including a remark on whether the comment has been accepted or not. The RR (revision 1) is finalised taken the accepted comments into consideration and the report is uploaded on CIRCABC together with the reporting table. A notification is sent to the MSs within the zone that the evaluation is finalised and the outcome of the zRMS decision. The other cMSs should take a decision within 120 days (excluding clock-stop time, if any left) of receipt of the RR and the copy of the certificate of registration in the zRMS. A scheme of the process for new product is given Figure 2 below.

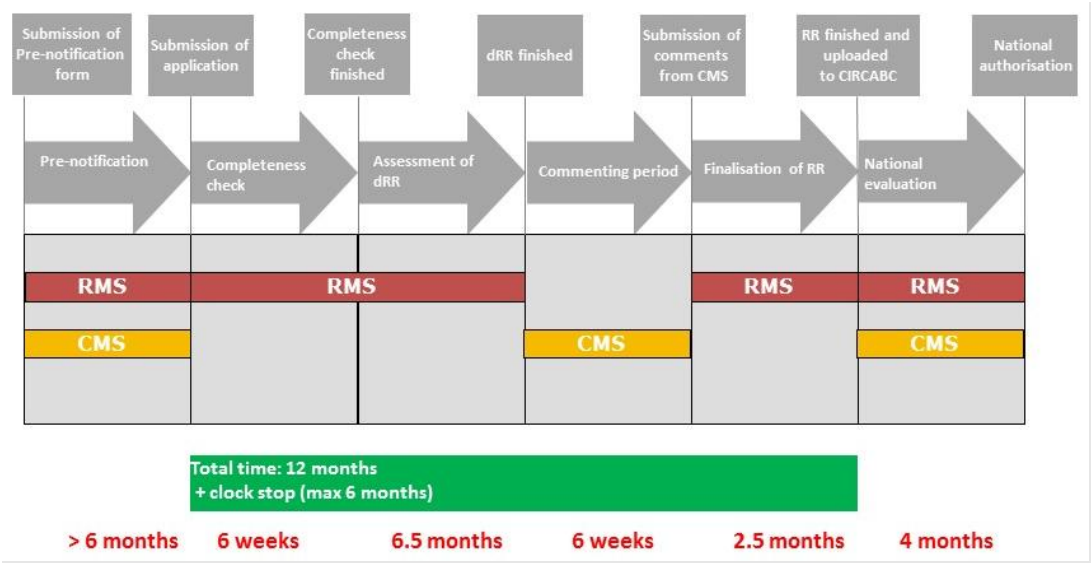


Figure 2 Scheme of the process for assessment of applications for new product authorisations

13.3 Authorisation of low-risk products

The authorisation procedure for low-risk plant protection products is the same as for conventional plant protection products, but with different timelines. All provisions relating to authorisations under Regulation (EC) No 1107/2009 shall apply.

The zRMS shall decide whether the requirements for authorisation are met within 120 days from receiving the application for authorisation of a low-risk product. This period may be extended by maximum of 6 months if further information is requested. In addition, the timelines can be suspended if the procedure in Article 38 (assessment of equivalence) is necessary. cMS shall at the latest within 120 days of

the receipt of the assessment report and the copy of the authorisation of the MS examining the application decide on the application.

For further guidance, please consult Section 8 of EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010).

13.4 Mutual recognition

The timelines for an application for mutual recognition is 120 days.

13.5 Amendment of authorisation

The same procedure (1 year evaluation plus possibly extended by up to 6 months) for applications for amendment of an existing authorisation e.g., extension of use, change of conditions of use, change of composition is applied, although where no technical risk assessment is involved, shorter timelines may apply.

E.g. minor assessments taking a maximum of 6 months for the zRMS, including the commenting period of 3 weeks.

The final evaluation of these amendments should be made available as soon as possible, in order for cMS to finalise their evaluation. The other MS should make their decision within 120 days at the latest, preferably shorter depending on the amendment.

14. Completeness check

For each application a completeness check is carried out using the completeness check form that can be found on each NZ MS's home page. In the completeness check, the zRMS will check that documentation addressing all relevant parts considered necessary for an assessment of the core dossier has been submitted. Completeness check of the national addenda is the responsibility of the respective country. The result of the completeness check of the national addenda will be reported to the zRMS. No evaluation of new studies or in-depth assessment of risk assessments will be conducted at this stage. Only complete applications are admitted for detailed evaluation.

For incomplete applications a 4-week period is given in general to complete the dossiers. Additional time may be given under certain circumstances. The zRMS should inform the other MSs about incomplete dossiers and the new deadline for submitting complete dossiers. All new data submitted to the zRMS shall also be sent to the cMS preferably in one complete sending including all requirements during the evaluation before commenting period.

For a dossier accepted as complete, subsequent areas of clarification could be needed and should be resolved between the applicant and the zRMS during the core assessment period. If the application is refused or rejected, the other competent authorities of the zone should be informed of the outcome as soon as possible. Besides bilateral consultations among experts, other competent authorities should refrain from working on the national submission until the zRMS core assessment is completed.

15. Commenting procedures for zonal evaluations

cMSs should peer review the assessment made by the zRMS focusing on:

- Areas having an impact on decision making.
- Areas of concern pointed out in the inclusion regulation.
- New studies submitted to address data gaps identified in the review report.
- Studies covering data requirements for uses that have not been evaluated before.

Comments should be submitted using the form in Appendix II and must be submitted before the agreed deadline (see timelines, Section 13) in order to be taken into consideration by the zRMS. Bilateral discussions among experts during the evaluation are encouraged.

According to the EU-Guidance document on zonal evaluations and mutual recognition, withdrawal and amendment of authorisations under regulation (EC) No 1107/2009 (SANCO/13169/2010) and EU Guidance document on Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/13170/2010), the applicant shall be given the opportunity to comment on factual issues in the core assessment.

If there are different opinions on technical issues between the zRMS and the cMS, they shall try to reach a compromise bilaterally. If the issue concerns the whole zone, all MS of the zone shall be included in the discussion.

16. Decision making

The risk assessments and RR prepared by zRMS should be used by the cMSs in order to prepare the national regulatory decision. However, the outcome of the decision in each MS may vary due to national requirements, differences in climatic and agricultural conditions (use of different scenarios) and different options for risk mitigation measures. This means that an authorisation granted in one MS does not necessarily mean that an authorisation also will be granted in another. For further details on risk mitigation options in the NZ, see Appendix VI .

17. Identity, physical chemical properties and analytical methods

If applicable the latest version of the following guidance documents shall be used for the core assessment:

- Guidance document for the generation and evaluation of data on physical, chemical and technical properties of plant protection products under Regulation (EC) No. 1107/2009, SANCO/10473/2003.
- Manual on development and use of FAO and WHO specifications for pesticides. https://openknowledge.fao.org/items/a8c661cb-27e1-4748-8d39-13d6ffd6caea
- The International Code of Conduct on Pesticide Management, FAO. http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en/ /
- Manual of Tests and Criteria, United Nations https://unece.org/sites/default/files/2025-09/ST-SG-AC10-11-Rev8-Amend1e.pdf
- ECHA guidance on the application of the CLP criteria: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp.
- Technical Material and Preparations: Guidance for generating and reporting methods of analysis. SANCO/3030/99.
- Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830.
- Guidance document on the finalization of the reference specification for technical active substances after peer review. SANCO/6075/2009.
- Guidance document on Pesticide Residue analytical methods, Series on Pesticides, No.39, Series on Testing and Assessment; No.72; OECD 2007).
- EU Guidance document on the assessment of the equivalence of technical materials. SANCO/10597/2003.
- Guidance document on significant and non-significant formulation changes of the chemical composition of authorised plant protection products under Regulation (EC) No 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. SANCO/12638/2011.
- Technical guideline on the evaluation of extraction efficiency of residue analytical methods, SANTE/2017/10632.

Some of the guidance documents listed above are available on the EU Commission website:

https://food.ec.europa.eu/plants/pesticides/approval-active-substances-safeners-and-synergists/guidelines-active-substances-and-plant-protection-products_en

17.1 Identity of the plant protection product

All former and current trade names and available development code numbers of the plant protection product shall be provided. When trade names and code numbers refer to related or similar but not identical plant protection products, their composition and full details of the differences shall be provided. Each product code number shall be specific to a unique plant protection product.

The identity and content of the technical active substance (based on the applicant specified minimum purity), the content of pure active substance and, if relevant, the corresponding content of the variant (such as salt or ester) of the active substance in g/kg or g/L and % w/w shall be given.

The acceptability of active substance's identity of every manufacturing source notified in the formulation shall be given with the precise reference (title of document, RMS, month, year of issue) to the EU relevant document (DAR/RAR Vol 4 Annex C, addendum to the DAR/RAR Vol 4 Annex C, Equivalence assessment report).

The identity and content of safeners, synergists and co-formulants shall be given in Part C of the dRR. The detailed complete composition shall be provided for all co-formulants. The trade name and/or supplier, where available, shall also be provided. If alternative co-formulants are proposed, then the original co-formulant should be highlighted in **bold**. The original co-formulants correspond to those used in product batches for which a complete risk assessment was performed and relied on. Composition statements (see Section 17.1.1) and SDSs shall be provided for all co-formulants *i.e.*, the original and the alternative co-formulants. Each of the alternative co-formulants will be evaluated for equivalence against the original co-formulant. If the co-formulant is no longer manufactured, then an "old" SDS and an explanation would be sufficient. But if a co-formulant has changed its name, then a SDS of the co-formulant with the new name and a statement from the supplier of the co-formulant about the name change should be submitted. Chemical equivalence will be assessed on a case-by-case basis.

Plant protection products must not contain any unacceptable co-formulants listed in Commission Regulation (EU) No 2021/383 of 3 March 2021 (amending Annex III to Regulation (EC) No 1107/2009) unless they are considered as unintentional impurities in the formulation at a concentration below 0.1 % w/w or less than a relevant specific concentration limit.

17.1.1 Composition statement

The detailed complete composition shall be provided for all co-formulants. If the applicant does not have access to proprietary data of the co-formulants, then the applicant must contact the supplier and ask them to submit the data directly to the competent authority of zRMS and all cMS.

A composition statement must account for 100 % of the chemical components in the co-formulant. This takes into account impurities which would not be covered if only intentionally added components were listed.

The composition statements should contain the following information:

- Chemical names of all ingredients, including impurities ≥ 0.1 % (also components < 0.1 % must be reported if toxicologically relevant), stabilizers etc.
- Content declared in weight % and amounting to 100 % in total (preferably as nominal values rather than batch specific values)
- CAS and EC numbers of all components, as applicable and available
- Information on content of substances in Annex III to regulation 1107/2009 (also those present at concentrations below 0.1 %)

17.1.1.1 Polymers and UVCB substances

Additional information is required for co-formulants that are polymers or UVCB substances and for mixtures that contain such substances.

17.1.1.1.1 Polymers

A polymer is defined as in Regulation (EC) No. 1907/2006 Art. 3 (5). The following must be provided when relevant:

- **Polymer content** of the co-formulant.
- **Molecular weight characterisation:** Weight average molecular weight (Mw); Number average molecular weight (Mn); Polydispersity index (PDI = Mw/Mn); Minimum–maximum molecular weight range.
- **Starting materials and residuals:** Identification (IUPAC name, CAS number and EC number) of monomers and other reactants; Residual monomer and other reactant content.
- **Stabilizers, if present, and impurities:** Identification (IUPAC name, CAS number and EC number) and content.
- **For alkoxylated polymers:** degree of polymerisation/formylation/ethoxylation/propoxylation (molar ratio of monomers and number of repeating units in the polymer (determined by e.g. GPC). Indication of distribution range.
- **Representative chromatograms and chromatographic data** (e.g. GPC/SEC) showing the molecular weight distribution. Each modal peak in the chromatogram should be assigned the number of repeating unit and the corresponding molecular weight ranges. A summary table of the chromatographic data should also be provided.

17.1.1.1.2 UVCB substances

CAS number may cover multiple non-identical substances. Therefore, CAS number alone is insufficient identifier. UVCBs shall be characterised as far as technically

possible, using a combination of compositional and process-based information. At minimum, the following shall be provided:

- **Known constituents:** Identification (IUPAC name, CAS number, EC number) of all known and identifiable constituents, irrespective of concentration.
- **Quantitative information:** Nominal concentration ranges for constituents present at ≥ 10% (w/w) and known constituents < 10% (w/w).
- **Generic characterisation:** Constituents that cannot be identified individually must be described using generic chemical characterization (e.g. functional groups, carbon-chain distribution, origin or reaction type).
- **Constituents relevant for classification:** Clear identification and specification of constituents contributing to the hazard classification.
- **Additives:** Identification (IUPAC name, CAS number and EC number) and concentration of any additives of the substance.

Determining equivalence between UVCB substances can be challenging. If the above data is not sufficient to establish equivalence between the alternatives, the following information can be requested:

- **Manufacturing process and origin:** A sufficiently detailed description of raw materials (origin and key characteristics), a general description of the manufacturing or reaction process, and process parameters relevant for compositional variability or impurity formation shall be provided where available.

17.1.2 SDS of co-formulants

Up-to-date safety data sheets (SDS) pursuant to Article 31 of Regulation (EC) No 1907/2006 as amended by Regulation (EC) No 453/2010, Regulation (EU) No 2015/830 and Regulation (EU) 2020/878 shall be provided and references to them included in Part C of the dRR. The revision/print date of the SDS should be less than 2 years from the submission date of an application, and the SDS should be up to date regarding classification.

17.1.3 Amendment of the authorisation

17.1.3.1 Amendment of packaging

A zonal application for change of packaging (material, size) is encouraged. The national data requirements of some NZ countries are given in Appendix V.

17.1.3.2 Amendment of product composition

It is the MS in question that determines whether the amendment meets the criteria for a non-significant or significant formulation change. The assessment is performed by comparing the new formulation to the formulation for which a complete risk assessment was performed. For significant formulation changes, where the change is applied for in several MSs, the evaluation is made available for commenting to all

relevant NZ MSs. To harmonize the assessment within the NZ, evaluation of non-significant formulation changes might also be sent to all relevant NZ MSs for commenting.

For changes that do not fall within the scope of an amendment, *e.g.*, change in the content of the active substance or formulation type, a new application for authorisation according to Article 33 must be submitted.

17.1.3.2.1 Procedure for evaluating formulation changes in the NZ

Non-significant formulation changes are evaluated based on composition alone. When alternative sources for a co-formulant are applied for by an applicant, the MS will conduct an assessment to determine if the new alternatives are chemically equivalent to the co-formulant currently authorized in the PPP. According to SANCO/12638/2011, the chemical composition is not really changed in a non-significant formulation change, therefore, only very small differences in the concentration of the main or key components in a co-formulant will be considered acceptable in the equivalence assessment. For some components, e.g. polymers and UVCBs, identical CAS-number is not sufficient to conclude on chemical equivalence. A more detailed composition statement is then required, see 17.1.1. For such cases, additional physchem and technical data of the product may be requested. Testing is generally expected unless the applicant demonstrates that the alternative co-formulant does not negatively affect product quality, performance, stability, toxicological profile, or environmental profile. Waiving of testing requires solid scientific justification.

Examples:

- Same co-formulant from different suppliers
- Alternative source of the co-formulant (only very small differences in the concentration of the main or key components in a co-formulant will be considered acceptable in the equivalence assessment)
- Adding a marker substance for authentication

The application must contain:

- An updated Part C (including references to new SDS(s) in Appendix I)
- Complete, detailed composition(s) as well as up-to-date SDS(s) for all co-formulants relevant for the formulation change including the original (exchange of co-formulants) or currently authorized (addition of alternative co-formulants) co-formulant. Requirements regarding composition statement and SDS are specified in Section 17.1.1.

Significant formulation change is an evaluation performed to determine whether the formulation change affects the properties of the product (tox, ecotox, efficacy, physico-chemical) or triggers additional validation of the analytical methods. Depending on the extent of the formulation change, new studies may be required to

support and enable the comparison of properties between the new formulation and the formulation for which a complete risk assessment was performed and relied on. Examples:

- Change of a preservative
- Change of an antifoaming agent

The application must contain:

- An updated Part C (including references to new SDS(s) in Appendix I).
- An updated Part B1,2,4 or addenda, if needed.
- Updated/addenda of other relevant Part Bs, e.g., analytical methods, tox, efficacy etc.
- An updated Part A (e.g., when the classification is changed).
- Relevant studies to enable comparison of properties between the formulation for which the full risk assessment was performed and the new formulation, if needed.
- Complete, detailed composition(s) as well as up-to-date SDS(s) for all co-formulants relevant for the formulation change including the original co-formulants. Requirements regarding composition statement and SDS are specified in Section 17.1.1.

If the change is applied for in several MSs, then the composition information should be submitted to all relevant MSs.

17.2 Physical, chemical and technical properties of the plant protection product

The dRR should be a standalone document and the result of individual tests and study reports shall be reported in the Phys-Chem properties table for transparency.

If a theoretical assessment on the physical hazard has been performed based on the chemical structure of the individual components of the formulation, this assessment should meet the criteria set out in Appendix 6 of the United Nations' Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria. Then, the outcome of the assessment should be presented in Part B1,2&4, and a detailed theoretical assessment containing the active substances as well as all the co-formulants of the product in question shall be reported in Part C since it could contain confidential information.

An adjuvant can have a great influence on the physical and chemical properties of the formulation, especially technical characteristics. If the formulation has to be used with an adjuvant, then it should be clearly specified (e.g. by trade name) on the label and in the GAP. In this case, tests on relevant physical-chemical properties for the product mixed with the adjuvant in question are required. If there are available data from efficacy study (field test performed with product-adjuvant mix) that show

good physical compatibility and acceptable technical properties, then this will in most cases be sufficient for the physicochemical section. However, an explanation to justify that the efficacy study is relevant for actual real-life operating conditions should be provided, *e.g.* taking into consideration the differences in time scale between the efficacy study and actual real-life application.

Storage stability studies at both ambient and accelerated temperature are required, as extrapolation of accelerated storage data to set the shelf life of a product is not accepted in the NZ. The 2-year shelf-life study should be carried out in the same material as the commercial packaging, and the final results of the study must be available before the authorisation is granted (please refer to Appendix V for national requirements). The sizes of the tested package should be reported. The applicant must provide a statement regarding the validity of the stability studies for all packaging sizes not tested. Any risks associated with potential adverse findings observed in the stability studies must be addressed and potential relevant measures to be taken must be stated.

The storage condition for accelerated tests is 2 weeks at 54°C (± 2 °C); however, some preparations may not be stable under these conditions and alternative time/temperature regimes may be used. In such cases, alternative time/temperature regimes may be proposed but the choice must be supported by a reasoned, scientific justification.

For relevant impurities, refer to SANCO/10473/2003, page 18.

When tank mixing is recommended on the label, then the physical and chemical compatibility should be demonstrated, by ASTM E1518-05 method or equivalent, and reported. Alternatively, the acceptability of tank mixing may be based on evidence from a relevant field study evaluated in the efficacy section of the dRR. In this case, reference to the relevant efficacy study, as well as the list of compatible tank mix products, should be included in the Part B 1,2 and 4 (Phys-Chem section) under annex point 2.9. An explanation to justify that the efficacy study is relevant for the actual real-life operating conditions should be provided, e.g., taking into consideration the differences in time scale between the efficacy study and actual real-life application. Known non-compatibility shall be reported.

17.3 Methods of analysis

Study summaries and reference lists shall be provided for all analytical methods, and study reports of the methods relevant for the application shall be provided. If the method has been assessed and accepted at EU-level, this should be indicated with reference to its assessment.

- Validated methods, including those for the generation of data and for post authorisation control and monitoring, are to be provided for:

- Analysis of the formulation
- Relevant impurities
- Residue determination in food/feed of plant and animal origin, including extraction efficiency addressed where relevant
- Residue determination in the environmental matrices and body fluids and tissues

Generation of data for risk assessment. Both old and new submitted methods should be justified, and the validation of the methods should be provided with cross-references to the corresponding studies of the risk assessment (tox, ecotox, fate, residues or efficacy). The cross-references should be clearly indicated (see example below Table 17.1) under KCP 5.1.2 (dRR template Part B5 Section 5.2.2 Table 5.2.3).

Table 17.1 Example of cross-reference

Matrix type	Method type	Method LOQ	Principle of method	Author(s), year/missing/EU agreed
Water, test solution (Ecotoxicology)	Primary XXX	2 g/L	HPLC-UV	Author1; 20xx Study report no. X Author 2; 20XX Study report no. Y Used in support of study. Study/report no. A Study/report no. B

Validated methods should be provided for the analysis of formulation that is intended to be authorised. According to Commission Regulation (EU) No 284/2013, an analytical method for the determination of the relevant impurity (including those that are specified in the FAO specification) present in the formulation is a data requirement independently of whether it is formed or not during storage. The LOQ of the method shall be below the maximum concentration of the relevant impurity in the formulated product, unless a scientific statement is provided to justify a LOQ above the maximum concentration.

18. Toxicology

If applicable the latest version of the following guidance documents shall be used for the core assessment:

- Guidance Document on the Evaluation of New Active Substance Data Post Approval. SANCO/10328/2004.
- Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Regulation (EC) No 1107/2009. SANCO/221/2000
- EFSA (European Food Safety Authority), 2017. Guidance on dermal absorption. EFSA journal 2017; 15(6):4873, 60 pp.

https://doi.org/10.2903/j.efsa.2017.4873. The implementation follows SANTE/2018/10591.

- Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) NO 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC[4]. SANCO/12638/2011
- EFSA (European Food Safety Authority), 2022. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2022; 20(1):7032, 134 pp. https://doi.org/10.2903/j.efsa.2022.7032 (referred to as EFSA OPEX GD 2022). The implementation follows SANTE/10832/2015.
- Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009 (2019/C 229/01)
- Guidance on the Application of the CLP Criteria "Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures". The guidance on the application of the CLP criteria is now presented in five documents and especially related to toxicological section are:
    - Part 1 General principles for Classification and Labelling
    - Part 3 Health Hazards

Specific national requirements are listed for each country within the NZ in Appendix V: Summary of national requirements and Appendix VI: List of mitigation options available in the MSs in the zone.

18.1 Acute Toxicity

If the PPP applied for has been considered in the EU peer review process of the active compounds, it is not necessary to include a study summary in the dRR for evaluation. However, study summaries must be submitted if the toxicological classification (for any of the acute toxicity endpoints that are included in the data requirements) for the PPP is only dependent on study data and differs from the CLP[5] classification based on the toxicological profile of the individual ingredients in the product. Likewise, if the study was evaluated according to previous data requirements or OECD guidelines that do not apply anymore.

[4] See section 17.
[5] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing 67/548/EC and 1999/45/EC and amending Regulation (EC) No 1907/2006

18.1.1 Step-wise approach for assessment of acute toxicity including skin and eye irritation and skin sensitisation

A step-wise approach listed below should be applied by the applicant to avoid unnecessary animal testing. *Applicants can discuss their suggested approach in writing or at a pre-submission meeting with MS.*

According to the data requirements for PPPs (EC) 284/2013 (section 7.1.1-7.1.6), tests for toxicity shall be carried out, unless the applicant can justify an alternative approach under CLP. In the latter case, the toxicity of all components shall be provided or reliably predicted with a validated method. Consideration shall be given to the possible effects of components on the toxic potential of the total mixture.

Furthermore, according to preamble no. 40 in Regulation EC 1107/2009, "*The use of non-animal test methods and other risk assessment strategies should be promoted. Animal testing should be minimised and tests on vertebrates should be undertaken as a last resort"*[6] . Thus, to make use of all existing information for the toxicity assessment of the PPP, and to ensure that the use of vertebrates for this purpose is minimised, the applicant should provide sound and well elaborated reasoning (in the dRR Part B6 or Part C) for each of the endpoints. In addition, duplication of vertebrate tests is not accepted[7]. The procedure for classifying mixtures is a tiered i.e. a step-wise approach based on a hierarchy principle according to CLP-regulation (Annex I section 3.1.3.1, 3.2.1.2, 3.3.1.2 and 3.4.3) and depends on the type and amount of available data/information (see step-wise approach described below).

For vertebrate studies the **Technical Guidelines on Data Protection according to Regulation (EC) No 1107/2009** (2019/C 229/01) applies. See paragraphs 68, 69 and 70 for details.

Thus, existing vertebrate studies can be accepted in specific cases:

a) Vertebrate studies which were conducted or initiated prior to 14 June 2011; (Step 1 below) or
b) Cases where it can be proficiently demonstrated that validated alternative methods (Step 2-4 below) could not be reliably applied; or
c) Vertebrate studies should always be taken into account if they show a more adverse outcome than other methods (Step 5)

The same (*a-c*) apply for vertebrate studies conducted for regulatory regimes outside the EU (paragraph 69).

[6] According to the data requirements (Commission Regulation (EC) 283/2013 and 284/2013, Annex Introduction, Point 5) tests on vertebrate animals shall be undertaken only where no other validated methods are available.
[7] Regulation (EC) No 1107/2009, Chapter V, Article 62.

The information, predictions and calculations should be made systematically and transparently (Please see Appendix IX). The detailed information must be presented in the dRR Part C. Even if the applicant does not have access to all information on identity or toxicity of the components in the PPP, it is still the applicant's responsibility that sufficient information is submitted for the MS(s) to evaluate and draw a conclusion.

18.1.1.1 Step 1 - Available/existing test data according to validated and internationally accepted test methods or other data (e.g., human data from accident or poison centre databases etc.) for the whole mixture (not made for the current EU PPP application)

The applicant must include a justification for the submission of the study in the dRR.

Vertebrate studies conducted or initiated prior to 14 June 2011 are accepted as existing data. In addition, vertebrate studies can be accepted for applications if the study was previously accepted in a national authorisation procedure for the PPP (decided in each MS) or in the EU peer review of an active substance. An existing vertebrate study is considered valid if it complies with current scientific and technical knowledge.

18.1.1.2 Step 2 - Bridging principles

When the hazard assessment for the PPP applied for is based on data from another similar formulation, the principles of CLP (Annex I point 1.1.3) and SANCO/12638/2011 should be applied. A comprehensive bridging statement must be provided in the dRR Part C by the applicant. In cases where vertebrate studies are used for bridging purposes, the same acceptance criteria as specified in step 1 shall apply.

Moreover, a detailed comparison of the compositions (formulation applied for and formulation bridged to) should be stated in the dRR Part C and the percent variations in concentrations of co-formulants must be indicated.

18.1.1.3 Step 3 - *In vitro* tests

These are only relevant when OECD validated methods are available for the specific endpoint, and only when they are considered applicable for PPPs in the EU. The applicant must ensure that the substance or PPP mixture tested is within the applicability domain of the test method. Examples of relevant documents to consult:

Skin and eye irritation: latest versions of the OECD Integrated Approaches to Testing and Assessment (IATA) No. 203 and 263 for skin and eye irritation.

Skin sensitisation: OECD Guideline No. 497 on Defined Approaches on skin sensitisation

18.1.1.4 Step 4 - Calculation of classification

If an endpoint is addressed by CLP calculation, information is required for all relevant components (defined below) in the PPP. In case of ingredients with apparently unknown toxicity, the applicant should consider if information on the toxicity can be found from other available sources. As a first step, information on toxicity should be obtained from REACH/ECHA (harmonised classifications or RAC opinions[8]) and up-to-date SDSs[9]. If this is not available, please see Appendix IX for a suggested approach to gather relevant information from additional sources for a WoE approach. Justifications for the different sources of information must be provided by the applicant. Please note that this might not be accepted by every MS in the NZ.

The relevant components are:

- **For acute oral, dermal and inhalation toxicity**: CLP, Annex I, paragraph 3.1.3.3. (a): the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a reason to suspect that an ingredient present at a concentration of less than 1 % is still relevant for classifying the mixture for acute toxicity (see Table 1.1).
- **For skin and eye irritation:** CLP, Annex I, paragraph 3.2.3.3.1. and 3.3.3.3.1: the 'relevant ingredients' of a mixture are those which are present in concentrations of 1 % (w/w for solids, liquids, dusts, mists and vapours and v/v for gases) or greater, unless there is a presumption (e.g., in the case of corrosive ingredients) that an ingredient present at a concentration of less than 1 % can still be relevant for classifying the mixture for skin irritation/corrosion and eye irritation/ damage. Please note that many acids and bases, inorganic salts, aldehydes, phenols, and surfactants are corrosive or irritant at concentrations <1% (3.2.3.3.4.1 and 3.3.3.3.4.1., these may therefore be relevant at lower concentrations.
- **For skin sensitisation:** For this endpoint it must be considered that ingredients present in the PPP at the concentrations mentioned in Table 3.9 in the Guidance on the Application of the CLP Criteria[10] may have skin sensitising properties – refer also to Endpoint specific notes, 18.1.2. In certain cases[11], additivity may be scientifically justified and may be applied to skin sensitisers with the same mode of action (expert judgement needed).

[8] Note that some MSs do not accept RAC Opinions as a source for classification.
[9] Note that the SDS must comply with the newest version of ECHAs "Guidance on the compilation of safety data sheets" and the REACH regulation.
[10] Table 3.9 in Guidance on the Application of the CLP Criteria, version 5.0- November 2024
[11] 1.6.3.3.3 in Guidance on the Application of the CLP Criteria, version 5.0- November 2024

In contrast to the CLP regulation unknowns[12] are not accepted according to (EC) 284/2013 when alternative methods are used to predict the toxicity of a PPP. Many co-formulants are mixtures and all components must be considered when the calculation method is used unless the co-formulant / mixture has been tested. The applicant should provide a calculation of the classification from the information they have available. However, it is the responsibility of the applicant to ensure that the information about the co-formulants that is not available to the applicant (e.g., due to confidentiality), is provided by the supplier directly to the zRMS and cMS(s).

Note that the absence of information is not accepted as evidence of no toxicity, e.g., for acute oral toxicity endpoint, if no LD_{50} value can be found in the SDS and the REACH registration database or from other reliable sources, the toxicity is considered unknown by the MSs.

It may be possible to predict the toxicity of a co-formulant (or ingredient in a co-formulant) by route-to-route extrapolation (refer also to 18.1.2). For this approach, see the *OECD Guidance No. 237 on Considerations for Waiving or Bridging*. Please note that a comprehensive justification is required. It may also be possible to use the *in vitro* methods for prediction of the toxicity of ingredients in a mixture (see in step 3 above).

18.1.1.5 Step 5 - New test data according to validated and internationally accepted test methods for the whole mixture (made for the current EU PPP application)

Vertebrate studies, which do not comply with conditions in Step 1, should be considered as a last resort. This includes cases where it can be proficiently demonstrated that validated alternative methods could not be reliably applied. In addition, vertebrate studies should always be taken into account if they show a more adverse outcome than calculation of classification.

Prior to conduction of a new vertebrate study, for the current EU PPP application, the applicant must always engage in dialogue with the zRMS/cMS to see if this could be avoided. For endpoints where validated and internationally accepted test methods using signs of non-lethal toxicity are available, these should be preferred over standard acute toxicity test guidelines using mortality as endpoint.

18.1.2 Endpoint specific notes

Acute inhalation toxicity: Until a change in Regulation (EU) No 284/2013 (the data requirement) section 7.1.3, condition i) or a harmonised EU interpretation is established, acute inhalation toxicity should always be addressed if the product in any state is to be sprayed.

[12] CLP, Annex I, section 3.1.3.6.2.2

A core evaluation for this end-point must contain the following:

- Animal studies, if these exist (refer to 18.1.1.1 and 18.1.1.5).
- CLP-calculation (refer to Appendix VIII) and in case of unknown acute inhalation toxicity, a pre-evaluation (refer to Appendix X).

Some MS may have other/alternative requirements, see Appendix V for further details on national approaches on how to deal with this data requirement. The requested information according to Appendix V should be added to a national addendum.

Skin and eye irritation: For skin and eye irritation, please note that in cases where the additivity approach does not apply the approach described in CLP section 3.2.3.3.4.3 and 3.3.3.3.4.3 must be considered.

Acute dermal toxicity - Route to route extrapolation from acute oral toxicity data:

- When co-formulants have an acute oral toxicity with LD50 > 2000 mg/kg bw – NZ MSs will accept route to route extrapolation to acute dermal toxicity, in accordance with point 16 in OECD Guidance No. 237 on Considerations for Waiving or Bridging.
- When co-formulants have an acute oral toxicity with LD_{50} 300 - 2000 mg/kg bw – route to route extrapolation to acute dermal toxicity should be adequately justified and will be evaluated case by case (referring also to OECD Guidance No. 237 on Considerations for Waiving or Bridging).
- When co-formulants have an acute oral toxicity with LD_{50} < 300 mg/kg bw, and there is not enough information to conclude on the acute dermal toxicity, point 17 in OECD Guidance No. 237 on Considerations for Waiving or Bridging could apply. If extrapolation from acute oral toxicity to acute dermal toxicity is accepted (i.e. a co-formulant classified with Category 2 oral toxicity would be classified Category 2 dermal toxic), then a converted ATE, from the corresponding GHS category, is derived for acute dermal toxicity and used in CLP calculation.

Skin sensitisation:

In absence of a specific concentration limit (SCL) or classification as Skin Sens. 1A, information on skin sensitisation shall be provided for co-formulants/ingredients present ≥ 1%[13]. Therefore, adequate, reliable and conclusive information on skin sensitising properties should be provided for a co-formulant/ingredient present in the PPP, at or above the generic concentration limit (GCL). Thus, absence of information on skin sensitisation for co-formulants/ingredients present < 1 %[13] can

[13] Finland applies the lower limit of < 0.1 % for acceptance of unknown skin sensitisation potential. See Appendix V for Finland's approach for addressing skin sensitisation.

be accepted, as long as there is no indications of same mode of action, in relation to skin sensitisation, for two or more co-formulants/ingredients.

18.1.3 Use of *silico methods* (e.g. QSAR)

If the applicant relies on (Q)SAR assessment for a given endpoint, the most recent version of OECD (Q)SAR model reporting formats (QMRF), and (Q)SAR prediction reporting format (QPRF) and (Q)SAR result reporting format (QRRF) shall be submitted according to the (Q)SAR Assessment Framework (QAF)[14]. The OECD QSAR Toolbox (available in QSAR Toolbox) is the preferred software for QSAR predictions.

18.2 Exposure Assessment

Assessments regarding exposure of operators, workers, bystanders and residents are obligatory. The exposure assessments shall cover the worst-case conditions for all types of intended uses within the NZ.

In those cases where refinement is needed by adding personal protective equipment (PPE), all tiers of the assessment should be presented.

For products containing more than one active substance, cumulative risk assessment of operator/worker/bystander/resident exposure should be conducted. In the first-tier, combined exposure is calculated as the sum of the component exposures (as % of the AOELs) without regard to the mode of action or mechanism/target of toxicity. Further refinement of the cumulative risk assessment is needed if the sum of the predicted exposure as % of the AOELs exceeds 100 % (i.e. exceeds 1 of the Hazard Index). Such refinements should be justified taking into consideration:

- The EFSA opinions on grouping of pesticides for cumulative risk assessment on the basis of their toxicological properties and/or
- The most appropriate critical NOAEL and specific AOEL.

According to Regulation (EC) No 1107/2009 safeners, synergists, co-formulants and adjuvants[15] shall be included in the risk assessment. Until detailed rules and the date of application are established, a hazard assessment should be performed.

MSs do not have the resources to evaluate new models. Applicants are therefore advised to use the models that are specified in this guidance document. Also, the Applicants are encouraged to share new models and results from field studies with

14 See the *(Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure - Activity Relationship models, predictions, and results based on multiple predictions, OECD Series on Testing and Assessment, No. 386 and OECD (2024), (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure Activity Relationship models and predictions - Second edition, OECD Series on Testing and Assessment No. 405.*

15 See Appendix V for national requirements for Norway on adjuvants.

EFSA/COM in order to facilitate the development and harmonisation of exposure models.

Relevant approaches developed by EFSA should be applied when available.

18.2.1 Professional use (Operator, Worker, Bystander and resident exposure)

18.2.1.1 The EFSA OPEX online calculator

The EFSA OPEX online calculator covers exposure scenarios for outdoor uses (falling into a category for which standardised exposure assessment can be applied) and greenhouse uses. The online calculator is based on the previous EFSA GD Exposure calculator and a greenhouse model for indoor uses (Greenhouse AOEM (BfR, 2020)), see EFSA OPEX GD 2022 for more details at:

Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products |EFSA (europa.eu)

Besides being updated with the new underlying data and the crop grouping etc., if the input parameters have changed (see Table 18.1) these should be provided in the dRR Part B6 for all product applications.

- EFSA OPEX online calculator is available at R4EU Portal - Sign in (https://r4eu.efsa.europa.eu/app/opex-dev), where registering an account is needed to perform the exposure calculations.

For operator and worker exposure during seed treatment and sowing, respectively, Seed Tropex model is acceptable.

Table 18.1. The following input parameters should be provided in the dRR Part B6 in all product applications using the EFSA OPEX online calculator.

Data entry on page 1 in the OPEX online calculator under "Product"	**Data entry on page 2 in the OPEX online calculator under "Active Substances"**	**Data entry on page 3 in the OPEX online calculator under "Application Scenarios"**	**Data entry on page 4 in the OPEX online calculator under "Intended Use"**
Product name	Name of active substance	Crop type (after the selection is made, there is a list of crops included under the particular type)	Experimental DFR and/or DT50 values (if other than default)
Formulation type	Nominal/pure concentration of active substance	Indoor/Outdoor scenario	N.A.
Use of water-soluble bags	AOEL/AAOEL	Re-entry activity	N.A.
Product category	Vapour pressure (if other than default 0.001 Pa) MW if SVC is to be calculated	Application rate (L or kg/ha product)	N.A.
N.A.	Dermal absorption of the concentrated product	No. of applications and days in between (if more than one application is chosen)	N.A.
N.A.	Dermal absorption of the diluted product* at the concentration used in the original dermal absorption study (the absorption is *pro rata* corrected automatically when necessary)	Both Min and Max water volume per hectare	N.A.
N.A.	Oral absorption	Buffer strip (2-3 m, 5 m or 10 m)	N.A.
N.A.	Inhalation absorption	Drift reduction (0 % or 50 %)	N.A.
* For default values, see EFSA Guidance on dermal absorption 2017, use the lowest concentration (highest spray dilution) for the proposed use.			

Default air concentration values are applied for the active substance with low vapour pressure (below 5 x 10^{-3} Pa) and for the active substance with moderate vapour pressure (between 5 x 10^{-3} Pa and 1 x 10^{-2} Pa). For the active substance with vapour pressure below 10^{-5} Pa or ≥ 10^{-2} Pa, the saturated vapour concentration (SVC) can be calculated, see OPEX GD 2022.

Please include the downloaded 'zip-folder' containing the input data, the reports ("General report" and "Registration Report") with all uses and a

summary of critical GAP when submitting the applications for authorisation of plant protection products.

One can also create reports under the menu "Summary" where a summary of the results is presented. This must be provided with the application. Please include tables from the report "Registration Report" (from EFSA OPEX online calculator) of the representative risk assessments (demonstrating the estimated exposure for all exposed groups for the critical GAP), in the Appendix 3 of dRR Part B6.

- If the application rate (L product/ha) for the same use has been given as an interval in the GAP table, the exposure calculations for the highest application rate in the interval covers the lower application rates. In exceptional (disproportional) cases, it may be necessary to perform additional exposure calculations for the lower application rates.
- For all models a default body weight of 60 kg should be used.
- Initially, the assessment shall be made with the assumption that the operator is not using any PPE. However, regular workwear (consisting of coveralls or long-sleeved shirt and trousers is assumed. See Table 18.4 for an overview of the tiered approach, use of PPE and other risk mitigation measures applicable in the NZ MSs.
- When normal and dense scenarios are applicable:
  It must be clearly stated in the outdoor (relevant for orchard and canefruit/high berries) and indoor (relevant for all scenarios) use application if a crop is considered normal or dense i.e., crops where contact with the treated crop cannot be avoided while spraying. The dense scenario is default for indoor uses, if the normal scenario is used it must be adequately justified. For outdoor scenarios in the Northern Zone, the normal scenario applies for orchards and canefruit/high berries in general, unless the specific crop is expected to belong under the dense scenario i.e. dense foliage and narrow paths.

General considerations:

Acute risk assessment for operator and bystander exposure can be performed only when the AAOEL values for active substances are established at EU level. See EU Pesticides Database - Active substances (europa.eu).

Please note that for application methods outside the applicability domain of the EFSA OPEX online calculator, scientifically justified *ad hoc* methods must be used for the exposure estimation, e.g handheld application to grassland or in case of active substance vapour pressure $\geq 10^{-2}$ Pa. Please note that, as a starting point, EFSA OPEX calculator can perform an SVC-calculation for active substances with vapour pressures $\geq 10^{-2}$ Pa, when MW and vapour pressure are entered. Other *ad hoc* methods may be needed if AOEL/AAOEL is exceeded using the SVC approach.

18.2.1.2 Greenhouse and Tunnel (indoor) use

The EFSA OPEX online calculator offers the option to calculate exposure for more specific uses than previously, e.g., normal or dense crops, high or low crops and various application types. This must be taken into account in the application for authorisation of PPP.

- It must be clearly stated in the application if a crop is considered normal or dense i.e., crops where contact with the treated crop cannot be avoided while spraying (dense is default, normal must be adequately justified).
- Crops grown at a height >0.6 m above ground level are considered high crops, thus, if plants are grown on tables or in racks, the exposure calculations must reflect this. If the application exclusively concerns a low crop this must be specified.
- For automated boom sprayers the handheld scenario should be used as a tier 1 approach for the exposure assessment. Justified *ad hoc* approaches can be used as tier 2.

Bystander/resident exposure is now included in the EFSA OPEX online calculator and must be addressed. A justification must be provided if waived.

The applicant must ensure that the critical GAP is justified.

Please note that for application methods outside the applicability domain of the EFSA OPEX online calculator, scientifically justified *ad hoc* methods must be used for the exposure estimation, this includes low volume mist and roof fogger equipment (Operator and bystander/residents), drip irrigation (all groups) and active substances with a vapour pressure $\geq 10^{-2}$ Pa.

18.2.1.3 Warehouse fogging or fumigation

In case of warehouse fogging or fumigation, no harmonised exposure model is available. Operator, worker and bystander/resident exposure assessment will be case-by-case and special conditions of use or special risk mitigation measures may be required. In addition, a field study measuring the concentration in the air before expected worker re-entry or the concentration in the air outside the warehouse during/after ventilation may be required.

18.2.1.4 Worker Exposure - re-entry interval

If worker exposure during the re-entry activities (e.g., inspection, harvesting, reaching, picking, cutting, sorting etc.) exceeds the AOEL, even when wearing protective gloves and workwear, a re-entry interval can be used as a risk mitigation measure.-The EFSA OPEX online calculator allows calculations regarding re-entry, both for outdoor and indoor scenarios, only after the application solution has dried. A re-entry interval is defined as the specific time-point post application (in hours or days), after which the worker exposure level(s) are lower than the AOEL, considering different clothing and PPE cases. The acceptability of the calculated re-entry interval for the worker should be examined on a case-by-case basis. Acceptability of a re-entry interval, as a risk mitigation measure, as well as time restriction on the use of protective gloves and workwear is decided on by each MS (for details see Table 18.4 and Appendix VI).

A noteworthy fact is that irrespective of the calculated re-entry interval, the individual MS have national requirements of non-calculated default waiting period(s), which is the time interval after indoor application until re-opening of the greenhouse/tunnel/warehouse etc. These are of different lengths with possible additional requirement of ventilation (for details see Appendix VI).

18.2.1.5 Bystander & Resident Exposure

For risk assessment of bystander and residents, the following approach, exposure calculations and input parameters are acceptable:

- **As a Tier I** for resident. For PPPs with no potential acute systemic toxicity, the longer-term risk assessment for residents covers the risk assessment for bystanders. If the estimated resident exposure (either the individual pathways (75th percentile) or the sum of the mean value from each pathway) exceeds the AOEL, increasing buffer zones and the use of drift-reducing nozzles could be considered as risk mitigation measures (RMM) (see Table 18.4).
- No fully detailed higher-tier risk assessment schemes are currently available; however, some risk management options could be considered for ad-hoc approaches for controlling risk or conducting a more refined assessment, e.g., using experimental data on active substances air concentration or including data on saturated vapour concentration.

For tunnel uses the EFSA OPEX online calculator outdoor scenario should be used, as it is considered the worst-case bystander and resident exposure scenario.

Recreational exposure

A risk assessment for recreational exposure is necessary for application of a PPP on a golf course, turf, other sports lawns or amenity turf/grassland areas (covers all

exposure scenarios) where members of the public are likely to have access[16,17]. Additionally, for application of a PPP on golf courses, turfs, lawns, grassland etc. an assessment of acceptable re-entry interval (see Section 18.2.1.4) has to be submitted in the core dRR. However, acceptability of a re-entry/waiting period will be decided on by each MS.

18.2.2 Non-professional use

The values for inhalation rates, body weights and body surface areas that are proposed in the EFSA OPEX online calculator, on non-dietary exposure, can also be applied in the risk assessment of non-professional uses. For low application rates, the EFSA OPEX online calculator may however overestimate the exposure (it should be noted that the EFSA OPEX online calculator does not calculate below 1.5 kg/ha).

In general, the areas that can be treated by a non-professional user per day are smaller than those treated during professional applications. A reduction factor (e.g., a factor of 10 for an area size of 1000 m^2) can be applied on the final exposure result from the EFSA OPEX online calculator (potential exposure without workwear). However, as gardens can differ significantly in size and can be of national characteristics, refer to Appendix V for eventual refinements on national level.

18.2.2.1 Operator exposure - (non-professional)

The following exposure models are acceptable:

- Manual-Knapsack data for 1 ha/day of the EFSA OPEX online calculator (potential exposure without workwear), adjusted for lower amounts i.e., divided by 10 as Tier 1, can be applied for exposure assessment during application (liquids, granules, powder). Available on R4EU Portal - Sign in (https://r4eu.efsa.europa.eu/app/opex-dev).
- UK POEM
- German model (75th percentile). Available on: Anwendersicherheit - Deutsches Modell (Safeguarding the Health of Operators - German Model) - BfR
- Dutch model (greenhouses). Available on: Calculation models Human Toxicology | Board for the Authorisation of Plant Protection Products and Biocides
- PHED
- Puffer pack model (Amateur/home garden user exposure models (for space sprays, surface sprays and dustable powder applications.xls)). Available on: https://www.hse.gov.uk/pesticides/data-requirements-handbook/operator-exposure.htm

[16] See Appendix V for restrictions in Norway for the use of PPPs on areas accessible for the public.
[17] In the EFSA OPEX GD Online Calculator choose golf course, turf and other sports lawns to assess the risk of recreational exposure.

- UK Trigger Spray model. (Amateur/home garden user exposure models (for space sprays, surface sprays and dustable powder applications.xls)). Available on: https://www.hse.gov.uk/pesticides/data-requirements-handbook/operator-exposure.htm

The assessment of products for non-professional (home & garden) use should consider the type of formulation, condition/location of use, method of application, type and size of container. The choice of exposure model should be justified in the dRR Part B6, and will be evaluated on a case-by-case basis. For a product applied both upwards and downwards outdoor using hand-held equipment, the EFSA OPEX online calculator can be used with a reduction factor for smaller area or it can be assessed according to the German or UK POEM model. The reduction factor is calculated as follows:

$$Reduction\ factor = \frac{estimated\ garden\ size\ hectar}{1\ hectar}$$

Relevant tiered approach to exposure evaluation should follow Table 18.2 below. The use of personal protective equipment to reduce exposure to an allowable level is not acceptable for non-professionals because of the risk of inappropriate handling due to lack of knowledge in this group. It should be noted that user conditions of higher tier exposure assessments may affect the user conditions stipulated in the national product authorization.

Table 18.2 Models and input values for a tiered exposure assessment of non-professional users.

		EFSA OPEX online calculator	UK POEM Solids/ liquids	German model Solids/ liquids	Dutch green-house	UK Trigger[d] Ready-To-Use	PHED Solids	Puffer-pack[d] Solids
Low crop 1st tier	Work rate ha/day	1ha[b]	0.1ha	N.A	0.1 ha		0.1ha	N.A
	Exposure duration	N.A	2h	N.A	N.A	2h	N.A	1h
Low crop 2nd tier[a]	Work rate ha/day	1ha x reduction factor[c]	0.01ha[b]	N.A	0.01 ha	N.A	N.A	N.A
	Exposure duration	N.A	0.5h[b]	N.A	N.A	0.5h[b]	N.A	0.5h[b]
High crop 1st tier	Work rate ha/day	1ha[b]	N.A	1 ha[b]	0.1 ha	N.A	N.A	N.A
High crop 2nd tier[a]	Work rate ha/day	1ha x reduction factor[c]	N.A	0.1ha	0.01 ha	N.A	N.A	N.A

[a] FI will assess 2nd tier on a case-by-case basis.
[b] default value
[c] reduction factor for smaller area = estimated garden size [ha]/1 ha. Please refer to Appendix V for eventual refinements on a national level
[d] default work rate is ~0.01 ha/day

18.2.3 Worker Exposure (non-professional)

Worker exposure in home gardens always needs to be addressed. For non-professional uses EFSA OPEX online calculator may be used, and eventual

refinements are evaluated on national level. The transfer coefficients, for potential exposure from the plant surface to the clothes or skin of the worker, in the EFSA OPEX GD 2022 also apply to non-professional work tasks in general, except for workwear and workwear plus gloves, as this kind of protection level cannot be ensured for non-professionals. A combination of operator and worker exposure might be considered relevant if both tasks are performed by the same person and within a short period timeframe. This will be handled on case-by-case basis. Worker exposure is not always considered relevant by some MSs (please refer to Appendix V for national requirements).

- The use of personal protective equipment to reduce exposure is not acceptable for non-professional worker.
- Working time should be reduced to 2 hours for all re-entry activities.
- For granule applications, no direct exposure with granules is expected, but contact with residues in the soil is relevant. The respective calculation from the EFSA OPEX GD 2022 can be used to assess the exposure.

18.2.3.1 Bystander & Resident Exposure – (non-professional)

For non-professional uses EFSA OPEX online calculator is used as a worst-case scenario. It should be noted that spray drift data for hand-held equipment is not available, and that default vapour concentrations from the EFSA OPEX GD 2022 were obtained for large, treated fields. Entry into treated crops can however be assumed to be similar for professional and non-professional uses. Private lawns are assessed as recreational exposure by some MSs (please refer to Appendix V for national requirements).

Eventual refinements are evaluated on national level.

- For granule application or use of plant rodlet via soil insertion, spray drift is not relevant.
- Risk mitigation measures, as for example the use of use of buffer strip or drift reducing equipment, is not an option for non-professional uses.

18.2.4 Field studies

A brief summary describing the field study and the main parameters, including study design, application rate and specific application equipment, PPE, the frequency and duration of pesticide handling and the weather conditions should be included in the dRR Part B6. An overview of the Norther Zone acceptance criteria for field studies has been given in Table 18.3**.**

A justification should be provided in the dRR (Part C if confidential) if the field study is performed with a different product, active substance or use. Accepted variations to the applied product and use are described below in the requirements. Furthermore, a comparison of relevant physical/chemical parameters for the applied

and tested products and/or active substance should be included, and deviations should be justified in the dRR. Fulfilment of acceptance criteria will be assessed on a case-by-case basis.

18.2.4.1 Human exposure

In general, where no standardised **first-tier method** for operator, worker, resident and bystander exposure assessment is available and a PPP application scenario is not covered by the exposure models and provisions mentioned above, an appropriate ***ad hoc* method** must be applied. This includes conducting field measurements in order to obtain more accurate and specific exposure data as well as deriving the exposures at the 75th and 95th percentiles for longer term and acute exposures, respectively. Field studies should be performed according to official guidance documents or test guidelines listed in table J.1, and acceptance criteria listed in appendix J (EFSA OPEX GD 2022) and Table 18.3.

It should be noted that user conditions of field studies might affect the user conditions stipulated in the national product authorization.

18.2.4.2 Dislodgeable foliar residue and dissipation of active substance on the foliage

Default values of dislodgeable foliar residue (DFR; 3 µg a.s./cm^2 of foliage/kg a.s. applied/ha), dissipation rate (DT50; 30 days) or turf transferable residue (TTR; a percentage of the applied application rate, for products applied as liquid sprays, 5%, and for products applied as granules, 1%) should be used as a **first-tier approach** in the exposure assessment. In case of unacceptable exposure, when using default values, DFR, TTR and/or DT50 from higher tier field studies may be used, if the acceptance criteria listed in the EFSA OPEX GD 2022 (i.e., section 2.5.2.2, 2.5.2.3 and appendix J) are fulfilled. Field studies should be performed according to official guidance documents or test guidelines listed in table J.1 and acceptance criteria listed in appendix J (EFSA OPEX GD 2022) and Table 18.3.

Table 18.3. Acceptance criteria for field studies in the NZ.

Parameter	Criteria	Exposure applicability
Number of studies/sites	< 3 sites[1]: use of default value 3-9 sites: use of maximal experimental DFR value or DT50[2] ≥ 10 sites: geometric mean of experimental DFR or DT50 value[2] Test sites should have different locations to cover variation in environment and agronomic practices. The data shall include all outliers in the data set as they represent realistic use.	DFR TTR DT50
No. of replicates (within a study)	3 replicates[3] per field plot[4]: use of maximal DFR value	DFR TTR DT50

Parameter	Criteria	Exposure applicability
	≥ 4 replicates per field plot: use of mean DFR value If SD ≥ 25 %: mean DFR + SD For the determination of DT50, a minimum of 3 replicates per time point is required. In order to obtain representative samples from a field plot, it must be divided into at least 3 subplots[5]. Replicate samples should be taken from the different subplots of a field plot to ensure representative sampling. Relevant field plot size variates from crop to crop and should be large enough to allow application of the plant protection product in a manner which reflects routine use and such that sufficient representative sample(s) can be obtained without bias[6].	
No. of replicates (within a study) – Operator, Worker, bystander and residents	Operator and Workers: ≥ 10 subjects (mannequins) are required for each task performed. Bystander/residents: ≥ 10 subjects (mannequins) of each type (adult and child) are required at each distance.	Human exposure
Extrapolation between plant protection products and different uses	○ Same active substance(s) ○ Similar formulation[7] ○ Same crop[8] ○ Higher or equal application rate ○ Similar growth stage ○ Similar application and growth conditions ○ Similar irrigation pattern and application technique relevant to NZ GAP	DFR TTR DT50
Extrapolation between plant protection products and different uses	○ Same or similar active substance[9] ○ Similar formulation[7] ○ Similar crop and growth stage[10] ○ Higher or equal application rate ○ Similar application technique relevant to NZ GAP ○ The study shall cover all relevant product and packaging parameters including (but not limited to) closed mixing and loading systems, water soluble bags, neck opening, container size	Human exposure
Climatic conditions	Study sites are considered relevant if study conditions are comparable to conditions in NZ (EPPO zones: Maritime and North-East). Another option is to apply Köppen–Geiger criteria to demonstrate	DFR TTR DT50 Human exposure

Parameter	Criteria	Exposure applicability
	representativeness in relation to NZ climatic conditions. If worst case conditions can be demonstrated, e.g. slower dissipation, a study from a different climatic zone may be accepted. Relevance will be assessed case-by-case.	
Fitting of data	In general, single first-order fitting) with assessment of goodness-of-fit[11].	DT50
Analytical methods	Analytical methods should be validated in accordance with requirements in the respective reference documents listed in OPEX GD, table J.1.	DFR TTR DT50 Human exposure

[1] A test site is the geographical location of the field study defined by unique geo-climatic conditions and agronomic practices under which the plant protection product will be used.
[2] Maximum or geometric mean of all DFR, DT50, TTR or human exposure values derived from each study.
[3] A replicate sample corresponds to total leaf punches with a surface area of 400 cm^2 (double-sided)
[4] A field plot is the experimental unit/field at the defined site from which samples are taken. One or several field plots and one control plot should be established at the site.
[5] A subplot is a sub-division of a field plot.
[6] See further description in OECD test guideline No. 509
[7] See further description in Appendix XI.
[8] Extrapolation to crops within the same crop group or with high similarity to the crop in the specific use may be accepted case-by-case. See further description in Appendix XI.
[9] If conducted with another active substance, then the active substances should have similar relevant physical chemical parameters such as vapour pressure.
[10] Measurements should be conducted under conditions as similar as can be reasonably expected from the NZ GAP.
[11] Criteria are listed in FOCUS 2014 (FOCUS Work Group on Degradation Kinetics, Version 1.1., 18 December 2014) and EFSA 2019 (EFSA supporting publication 2019; EN-1673, 117 pp) and summed up in Appendix XI.

18.2.4.3 Requirements to seed treatment field studies

An operator exposure seed treatment field study should be specific to the circumstances in which the product will be used or provide a refinement of the Seed TROPEX model using more realistic parameters to the particular scenario under evaluation. The study should be performed according to OECD Guidance No. 9 and follow GLP standards (OECD guideline No. 6). In addition, the study should always cover the same seed treatment method and monitor the same work tasks as would be expected by the type of seed and formulation, by label instructions and by relevant parameters in the NZ GAP. The field study should cover that type of treatment facility (e.g. (semi-) industrial treatment, treatment on farm and mobile treatment) for which the product is applied for.

Treatment of the seeds should be performed with a product having the same formulation type and similar adhesion to the seeds. The seeds must be identical to the seeds specified in the NZ GAP table.

Regarding worker exposure, the same sowing method as expected by the type of seed and formulation, by label instructions and by relevant parameters in the NZ GAP should be covered by the field study. During sowing, the crop and active substance do not need to be the same. However, product must have similar adhesion

to the seed and dustiness to make sure that the exposure conditions to the product may be considered comparable. The seed should have similar size and surface.

18.2.5 Risk mitigation measures

Table 18.4 gives an overview of the acceptable risk mitigation measures in each of the MSs in the NZ. Information on risk mitigation measures for workers such as acceptability of a re-entry interval, determined by the EFSA OPEX online calculator, and national requirements for waiting period(s) can be obtained in Summary of national requirements Appendix V and Appendix VI.

Concerning label requirements, there are different approaches. In some countries, the need for use of workwear and gloves is not mentioned on the label since this is part of the professional training and also standard equipment under other regulations (worker protection). Other countries state the PPE to be used on the label as the risk assessment is done by the regulators of PPP and thus can be more specific.

Buffer zones and drift reducing equipment are the risk mitigation measures for the health risk assessment. However, not all MSs in the NZ are ready to accept these risk mitigation measures i.e it may be not accepted or only partly accepted with time, when more experience has been gained, and MS legislation will be changed accordingly. The use of buffer strip and drift reducing equipment should be stated on the label if required as risk mitigation measures.

Table 18.4 NZ approach[18] of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator.

Operator	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmonised**
Tiered approach Workwear (mix/load+appl) + 1. No PPE 2. Gloves mix/load 3. Gloves mix/load+appl	Y	Y	Y	Y	Y	Y	Y	Y
RPE	Y	Y	Y	Y	Y	Y	Y	Y
Head protection (Incl. hood and eye/face protection)	Y	Y	Y	Y	Y	Y	Y	Y
Closed cab	Y	Y	Y	Y	Y	Y	Y	Y
Drift reducing equipment	Y	Y	Y	Y	Y	Y**	Y	Y
Rain suit (dense crop) for greenhouse only	Y#	Y#	CbC	CbC	Y#	CbC	CbC	N
Protective clothing (Certified protective coverall)	Y	Y	Y	Y	Y	Y	Y	Y
Residents/ bystanders	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmonised**
Buffer strip	Y	Y	Y	Y	Y	Y	Y	Y
Drift reducing equipment	Y	Y	Y	Y	Y	Y	Y	Y
Both buffer strip + drift red.	Y	Y	Y	Y	Y	Y**	Y	Y
Workers/ Greenhouse	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmonised**
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear +	Y	Y	Y	Y	Y	Y	Y	Y

[18] See Appendix V for National Requirements and Appendix VI for mitigation options available in the member states in the NZ.

1. No PPE 2. Gloves								
Re-entry interval for each tier, as well as further RMM if above AOEL at tier 2.	Y	Y	Y	Y	CbC[#]	CbC	CbC[#]	N
Field use	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmonised**
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear + 1. No PPE 2. Gloves	Y	Y	Y	Y	Y	Y	Y	Y
Re-entry interval for each tier, as well as further RMM if above AOEL at tier 2.	Y	Y	Y	Y	CbC[#]	CbC	Y[#]	N
CbC: Case-by-Case; RMM: risk mitigating measures; RPE: respiratory protective equipment **Experience is needed before changing legislation. #Please see details in Appendix VI.								

18.3 Dermal Absorption

Full summaries of studies on the dermal absorption that have not previously been evaluated within an EU peer review process should be submitted. The dermal absorption values of studies that have previously been evaluated should demonstrate that they were derived in accordance with the latest Guidance on Dermal Absorption.

If the dermal absorption study is performed on a similar product, a scientifically based bridging statement should be included in the dRR Part B6. The bridging statement should include a comparison of the composition of the two products (in Part C) and take into consideration a possible difference in the dilution rates. The criteria for when two formulations can be considered similar are listed in the latest Guidance on Dermal Absorption.

If the use of default dermal absorption values, as defined in the above-mentioned Guidance, indicates acceptable use for all exposure groups without the use of PPE in the exposure assessment accepted by the MS, the applicant could refrain from performing a dermal absorption study or from bridging to a similar product.

New dermal absorption studies should preferably be conducted using human skin in vitro according to the EFSA GD on dermal absorption (EFSA Journal 2017;15(6):4873). It is recommended that such studies are submitted in combination with the BfR template.

Variation in dermal absorption data is overall considered to reflect the natural variation between humans and therefore all data points should be kept in the data set. However, if valid reasons for excluding a possible outlier are evident, they should be clearly stated in the study summary text. Outliers should not be excluded on statistical grounds alone. Statistics in some cases can be used as a supplement. In such cases, clear statistical criteria to define outliers to be considered for removal

should be provided, taking into account the tendency of absorption data to be skewed. Since statistical criteria are context specific, different statistical methods could be acceptable. However, they should be justified, and the data set should fulfil the assumptions for that specific test.

18.4 Formulation Changes

Evaluation of significant formulation changes[19] as indicated by SANCO/12638/2011 should consider:

- the need of a new dermal absorption study on the basis of the type and function of the co-formulant that is being changed as indicated in the dermal absorption GD section 6.2 'Use of data on similar formulations'. A new study will not be required if the applicant can demonstrate acceptable exposure when using default values.
- hazard assessment of the end-points eye and skin irritation and sensitisation based on the classification of the co-formulant.

18.5 Assessment of the relevance of metabolites in groundwater and toxicity data relevant to the consumer risk assessment

A groundwater metabolite is considered to be of concern when the concentration is above 0.1 µg/L. In some cases, the NZ FOCUS scenarios may predict higher concentrations of groundwater metabolites than the EU FOCUS scenarios. Hence, a relevance assessment must be performed.

The assessment of the relevance of the metabolites in groundwater *should* cover all the requirements in the Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater (SANCO/221/2000). The full relevance assessment is to be presented in the core dRR, Part B section 6 and 10.

If new active substance data is submitted, these data shall be evaluated in accordance with *Guidance document on the evaluation of new active substance data post (renewal of) approval (SANCO/10328/2004).*

19. Residues

The applicant should write a separate dRR for the NZ only instead of a core dRR for whole EU. The GAP and the residue data should reflect the intended use in the NZ.

[19] Refer to the physical/chemical section for the evaluation of formulation changes and what is considered as a significant change.

Headlines not mentioned in this guidance document should be dealt with in accordance with the Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009).

The following guidance documents should be used for the core assessment for the NZ in accordance with Commission Communication in the framework of the implementation of Commission regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ, C95/1).

If applicable the latest version of the following guidance documents shall be used for the core assessment:

- Technical Guideline on the Evaluation of Extraction Efficiency of Residue Analytical Methods" SANTE/2017/10632 rev.5 of 11 May 2023
- Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32. OECD (2009).
- Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66). OECD (2011).
- Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96. OECD (2008).
- Guidance Document on the Definition of Residues. Environment, Health and Safety Publications. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31. OECD (2009).
- Data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin. Appendix D, SANTE/2019/12752 - revision1 - 10 May 2023.
- MRL Calculator EU. OECD (2015)
- EFSA 2023. Guidance on the assessment of pesticide residues in rotational crops.
- Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey. SANTE/11956/2016 rev. 9. 14 September 2018.
- Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater (SANCO/221/2000).
- Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830 Rev. 2, 14 February 2023. (Supersedes SANCO/3029/99 EU, rev. 4 and SANCO/825/00 EU, rev. 8.1.)
- Information note on Article 20 of Regulation (EC) No 396/2005 as regards processing factors, processed and composite food and feed. SANTE/10794/2021, rev. 1. 19/05/2025
- EFSA technical report "Recommendations on the use of the proportionality approach in the framework of risk assessment for pesticide residues" (EFSA supporting publication 2018:EN-1503)

- Residues trials and MRL calculations. Proposals for a harmonised approach for the selection of the trials and data used for the estimation of MRL, STMR and HR, EFSA 2015.
- Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 7 and Series on Pesticides No. 39. OECD (2007).
- OECD TEST GUIDELINES No. 501, 502, 503, 504, 506, 507, 508, 509.

Specific national requirements are specified for each country in Appendix V.

19.1 Stability of residues

Information on storage stability shall be included as well as the storage period between harvest and analysis in the residue trials. Alternatively, indicate whether the analyses have been performed within the period given for storage stability.

19.2 Studies on metabolism in plants or livestock

Insert brief summary of metabolism, distribution and expression of residue data in plants and livestock or cross reference to EU review. It shall be mentioned in which commodities and animals the metabolism studies are performed. Also, unresolved problems/items from the EFSA conclusion report shall be mentioned as well as how they are solved, e.g. new studies.

Residue definitions currently in place for both monitoring and risk assessment shall be mentioned and a reference included. If there is a conversion factor from the residue definition for monitoring to risk assessment the factor shall be stated.

19.2.1 Residue trials (supervised field trials)

Supervised field trials from Northern residue zone, defined in guidance document SANTE/2019/12752, rev01, should be used. Insert at least a brief summary of residue trials for all uses (e.g. summary schemes) including

- Report No. and Location including Postal Code
- Commodity/Variety
- Date of 1. Sowing or Planting, 2. Flowering, 3. Harvest
- Application rate per treatment (g as/hl & water l/ha & g as/ha)
- Method of treatment
- Dates of treatment(s) or no of treatment(s) and last date
- Spray interval (days)
- Growth stage expressed as BBCH at last treatment or date
- Portion analysed
- Residues (mg/kg). In some cases, when dealing with metabolites or degradation products, the residue level may be expressed as "mg equivalent/kg," indicating the total residue expressed as the amount of the parent pesticide it would be equivalent to.
- PHI (days)

- Remarks

Include also a statement of the validity of the analytical methods used and explain extrapolation between crops (according to the guidance document SANTE/2019/12752, rev01). Indicate if the methods include analysis of all substances included in the residue definition for both monitoring and risk assessment.

Residue trials are not necessary when herbicides are used on the ground in orchards and bush berries if no consumable part of the crops has been formed. According to SANTE/2019/12752, rev01 “for crops harvested after blossom (such as fruits or fruiting vegetables) a significant part of the consumable crop is present from full blossom (BBCH 65) onwards”.

Walk-in tunnels and temporary coverings are not considered as permanent structure and are therefore considered as outdoor conditions and should be supported with field residue trials.

Calculated rounded MRLs in the OECD calculator exceeding current MRLs is not acceptable. The exception would be if the current MRL is based on the same dataset, but an older version of the calculator was used when the MRL was set.

Honey trials are not dependent on climatic zones and therefore studies from all EU are accepted.

Residue trials are not required if the product will be used on crops for seed production only, provided that these seeds will not be used for human consumption or animal feed.

19.3 Livestock feeding studies

Insert brief summary of livestock feeding studies. If studies are not necessary (see guidance document SANCO/7031/VI/95 and https://food.ec.europa.eu/document/download/d5c1e80e-57cb-4924-bb09-3a677a3418f0_en?filename=pesticides_mrl_guidelines_animal_intake_mrl_2015_en.pdf) an explanation shall be given.

19.4 Studies on industrial processing and/or household preparation

Insert brief summary of studies on industrial processing and/or household preparation. If studies are not necessary (see guidance document SANCO/7035/VI/95) an explanation shall be given.

Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities can also be used in the evaluation. OECD Test No. 508

19.5 Studies for residues in representative succeeding crops

Insert brief summary of studies for residues in representative succeeding crops. If studies are not necessary (see guidance document SANCO/7524/VI/95) an explanation shall be given. The EFSA Guidance on pesticide residues in rotational crops as endorsed by SCoPAFF, Section Phytopharmaceuticals – Pesticide Residues on 23-24 September 2024, with an application date of 01 April 2025. Further advice on the application of this GD in the NZ should be included in future.

19.6 Estimation of Exposure through Diet and Other Means

It should be demonstrated that the uses of the evaluated plant protection product do not have any harmful effect on human including vulnerable population subgroups, or animal health, directly or indirectly through food and feed.

The assessment of residues on and in food or feed should include calculation of the acute and chronic exposure in relation to toxicological reference values and endpoints for all relevant residue species. Also known cumulative and synergistic effects can be considered where the scientific methods accepted by the European Food Safety Authority to assess such effects are available.

The chronic dietary exposure should be evaluated by calculation of the theoretical maximum daily intake (TMDI) using the most recent version of the EFSA PRIMo model and all existing MRL values. If these calculations result in an ADI exceedance, refinements should be done using supervised trial median residue (STMR) values from the supervised residue trials. Further refinements could sometimes be relevant.

The short-term exposure should also be performed using the most recent version of the EFSA PRIMo model, based on the MRL values for the crops included in the application. If the calculations result in an ARfD exceedance, refinements could be done using highest residues (HR) from the supervised residue trials. The most recent version has been endorsed by SCoPAFF and implemented for use in the evaluation of pesticides.

In case new national data are to be employed for the NESTI and NEDI assessments, such national requirements shall be specified for each country in Appendix V Summary of national requirements.

19.7 Comparability, extrapolation, group tolerance and data requirements for pesticides residues in food and raw agricultural commodities

The rules for comparability, extrapolation, group tolerance and data requirements for pesticides residues in food and raw agricultural commodities, described in guidance document SANTE/2019/12752, rev01, should be used.

The extrapolation results from trials in sugar beets to fodder beets and vice versa can be accepted.

Outdoor and indoor data are required, but applicant should also consider different coverings. The applicant should verify that the worst-case situation has been covered. If the residue data indicates that MRL may be exceeded, more information could be needed.

The extrapolation rules apply also for establishing of the zero residue situation (guidance document SANTE/2019/12752, rev01).

19.8 Residue issues related to renewal of products (Article 43)

Concerning residues/MRL it is only possible to add a crop if this crop can be extrapolated from a crop already authorized. E.g., rye can be included if wheat is already included provided that the GAP for rye is the same as for wheat.

20. Efficacy

The guidance on requirements for efficacy data is available at:

https://agro.au.dk/samarbejde/vejledning-vedr-krav-til-effektivitetsdata/

Specific national requirements are specified for each country in Summary of national requirements

20.1 Efficacy issues related to renewal of products (Article 43)

- Applicants are strongly encouraged to submit a BAD (Biological Assessment Data). Trial reports should be submitted and if a BAD is not submitted, the applicant is obliged to provide information on the origin of the data summarized in the various tables/figures of the dRR. The dRR should be a concise summary of the BAD and if a BAD is not submitted, it is a concise summary of the supporting data.

- For amendment of uses (label extensions) with in an article 43-application, see Section 10.1.
- The applicants are required to provide an overview of the current authorisations in the NZ either as a table inserted in the dRR or by providing the current GAP tables (in English) for each of the concerned countries in the zone. Labels in local language are not sufficient documentation.
- The countries in the NZ belong to two EPPO zones (Maritime and North-East) and if the applicant applies for authorisation in both zones, efficacy data from both zones should be submitted. However, as mentioned in the EPPO Standard P1/241 Guidance on Comparable Climate '*data from other zones may in any case be considered acceptable if the actual prevailing conditions are comparable*'. It is up to the applicant to justify that data from one EPPO zone is acceptable for registration in the other EPPO zone. Data from other zones than the Maritime and the North-East zone should not be included in the dRR.
- Dose extrapolation of +/- 10% are accepted without further justification. Other extrapolations should be justified in the dRR. Concerning acceptable extrapolations between pest species and crops, the applicant should consult the Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the NZ and the Annex 1 thereof. Link presented above.
- If the active substance is a candidate for substitution, the starting point for Comparative Assessment (CA) is efficacy. CA is a national issue and not a zonal issue and the data/justification for maintaining the product on the market should be included in the National Addenda, and not in the core assessment. Comparative assessment dossier should be submitted according to the Guidance document on Comparative Assessment and Substitution of Plant Protection products in accordance with Regulation (EC) No 1107/2009 (SANCO/11507/2013) by applicant. All MSs do their own CA assessment and decision nationally.

21. Environmental Fate and Behaviour

Disclaimer:

- This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases, specific national guidance must be consulted additionally. Specific national requirements are presented in Appendix V.
- EU-guidance documents should be followed from the implementation date of the specific guidance document. Any deviations from the EU-guidance that is stated in the NZ guidance document should be followed from the implementation date of the NZ guidance document.

Many of the specific national requirements are to be included in the core assessment as outlined below. However, if authorisation is not applied for in a specific country the specific national requirements do not need to be addressed.

If applicable the latest version of the following guidance documents shall be used for the core assessment:

- Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council Regulation (EC) No 1107/2009, SANCO/221/2000[20].
- Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration: Based on the official guidance document of FOCUS Degradation Kinetics in the context of 91/414/EEC and Regulation (EC) No 1107/2009, SANCO/10058/2005.
- Generic Guidance for Surface Water Scenarios: Based on official guidance document of FOCUS Surface Water Scenarios in the context of 91/414/EEC and Regulation (EC) No 1107/2009, SANCO/4802/2001.
- FOCUS groundwater scenarios in the EU review of active substances. SANCO/321/2000.
- Generic Guidance for Tier 1 FOCUS Ground Water Assessments: Based on the reports of the FOCUS Groundwater Scenarios workgroup (finalised in 2000), the FOCUS Ground Water Work Group (as noted in 2014) and the FOCUS Work Group on Degradation Kinetics (finalised in 2009) as modified by EFSA $DegT_{50}$ guidance (as noted in 2014).
- EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain $DegT_{50}$ values of active substances of plant protection products and transformation products of these active substances in soil.[21] EFSA Journal 2014; 12(5):3662.
- Guidance document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments. SANCO/12184/2014.
- Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach", SANCO/11244/2011.
- Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments, SANTE/12586/2020. *The NZ will assess, on a case-by-case basis, whether or not to accept aged sorption endpoints* ***if they were agreed at EU level*** *as refinements for groundwater modelling.*

[20] Note that this guidance is not accepted by DK (see Appendix V). For the assessment of groundwater exposure in DK, please see the Danish national guidance document.
[21] Please note the interception values, which should be used for all submissions.

- EFSA Guidance Document for Scientific guidance on soil phototransformation products in groundwater – consideration, parameterisation and simulation in the exposure assessment of plant protection products. EFSA Journal 2022; 20(3):7119

Applicants need to pay attention to the following points during the assessment:

- For **non-professional use** (home gardens), substantial differences exist between the MSs (see Appendix V). Exposure estimations are case-by-case decisions.
- **US EPA's Golf course adjustment factors (GCAF)** are accepted in Finland, Norway and Sweden for tees, greens, fairways, and roughs[22]. GCAFs are used to refine the area that is sprayed and the following factors are accepted: tees and greens - 0.05; fairways - 0.29; roughs- 0.66. Denmark has their own assessment factors: tees and greens - 0.10; fairways and roughs - 0.90.
- The **risk envelope** approach is acceptable for calculation of PEC_{soil}, while PEC_{gw} and PEC_{sw} modelling is more complex. The risk envelope approach may only be used for calculation of PEC_{gw} and PEC_{sw} in cases where worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised should be modelled.
- For **granulates**, the interception shall be set to 0 % for PEC calculations for all crops.
- Interception for special uses not covered by the guidance (e.g. plants are incorporated into the soil after dessication, spot application) will be assessed on a case by case basis.
- The Interzonal Steering Committee has developed an interim approach for **uses in protected crops (protected structures)**[23]. This interim approach should be applied for uses in professional greenhouses (low-and high technology). For more information on requirements for the interzonal core risk assessment for soil, groundwater, surface water and sediment, and air please refer to the working document and excel sheet stated in Section 6.6.

  Please note that the core assessment is considered as worst-case scenario that could be further refined at national level. It is therefore important that information on cultivation system is clear as well as other presumptions regarding the standard on the professional greenhouse. The risk assessment for uses in other protected structures than low-and high technology professional greenhouses are evaluated as field uses at zonal level.

[22] For golf-courses, modelling with run-off scenario R1 is not needed for Finland, since no appropriate surrogate crop is parameterised for R1 for this particular use.
[23] PPP Zonal - Library (europa.eu)

21.1 Soil

The Nordic PEC_{soil} calculator (tool and user manual available at https://www.kemi.se/en/pesticides-and-biocides/plant-protection-products/apply-for-authorisation-for-plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products) shall be used for the NZ. In the core assessment, a screen shot of the user interface showing all results and inputs for the parent and all metabolites shall be presented. Only the results from the Finnish temperature scenario, which is pre-implemented into the PEC_{soil} calculator, are accepted.

A worst case DT_{50}lab (normalized) should preferably be used as a first option. As a second alternative, a DT_{50}field (normalised) can be used. If field studies are used for PEC_{soil} calculations, it must be scientifically justified that these are representative with regards to soil conditions (among others, with regard to soil type, pH, organic C) and climate (see Table 21.1). EFSA Guidance Document for evaluating laboratory and field dissipation studies (2014)[24] should be used to select the proper DT_{50} value.

Table 21.1. Key properties for climate and agricultural soils in the NZ MSs

Member state	Soil properties		Climate	
	pH	Org. C %	Annual average air temperature (ºC)	Annual precipitation (mm)
Denmark[3]	5.1 -7.8(10)	Below 10 (Ap layer)	7.6- 8.7(3)	523 – 829(3)
Estonia[2]	4-7	Below 10 (Ap layer)	4.9-7.1	578 - 766
Finland[9]	4.7 – 6.5	Below 10 (Ap layer)	ca. 4.3	627 – 650
Latvia[4]	4.5 – 7	1.5 – 5 (Ap layer)	5.2 - 7.4	600 - 850
Lithuania	4.5 -7.5(7)	N.A.	4.5-8.2(8)	521-853(8)
Norway[1]	5 – 7	1.5 - 4.0 (Ap layer)	3.8 - 8.1	699 - 1405
Sweden	5.7-7.6(5)	1.3-5.4(5)	4.4-7.7(6)	530-759(6)

1) Data from VKM (2015). Degradation and mobility of pesticides in Norwegian soils. Opinion of the Panel on Plant Protection Products of the Norwegian Scientific Committee for Food Safety. VKM Report 2015: 34, ISBN: 978-82-8259-189-8, Oslo, Norway. Available online: www.vkm.no. pH given as pH_{H2O}.
2) Average annual air temperature (°C) and precipitation (mm) 1981-2010. Climate data from http://www.ilmateenistus.ee/?lang=en.
3) *From Cappelen, J. (2002): Danish climatological normal 1971-2000, for selected stations. Technical report 02-12, Danish Meteorological Institute (DMI).
4) Soil properties data from State Plant Protection Service, climate data from Latvian Environment, Geology and Meteorology Centre. Soil pH given as pH_{KCl}.
5) 10th and 90th percentile of pH_{H2O} and organic carbon content (OC) derived from a database of 12 598 samples of arable topsoils systematically covering 92.7 % of arable land in Sweden, published in Jordbruksverkets Rapport 2015:19.
6) 10th and 90th spatial percentile of annual average air temperature and annual precipitations for agriculture-related land-use, derived from EFSA/ESDAC raster dataset.
7) Soil pH data from Lithuanian Reseach Centre for Agriculture and Forestry. pH given as pH_{KCL}.
8) Average annual air temperature (°C) and precipitation (mm) 1981-2010. Climate data from Lithuanian Hydrometeorological Service.
9) 10th and 90th percentile of soil pH_{H2O} data from Lucas 2015 and 2018 topsoil data (https://esdac.jrc.ec.europa.eu/content/lucas-2018-topsoil-data#tabs-0-description=1).
10) 1st and 99th percentile of pH_{H2O} derived from a database of >500 000 samples of arable topsoils in Denmark from 2018-2022 - Jensen J.E., Hørfarter R. & Knudsen L.: Statistik om reaktionstal (pH) i dansk landbrugsjord. Analyser udført for Miljøstyrelsen. SEGES Innovation P/S, Planter & Miljø. December 2022.

[24] EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil. EFSA Journal 2014;12(5):3662.

The Nordic PEC_{soil} calculator permits to use SFO or DFOP kinetics for the worst-case DT_{50}. If the worst-case DT_{50} is derived with FOMC or HS-kinetics, a pseudo-SFO degradation rate may be applied (for FOMC-kin. pseudo $DT50_{SFO}=DT90_{FOMC}/3.32$; for HS-kin. pseudo $DT50_{SFO}=ln2/k_{slow\ phase}$).

With the Nordic PEC_{soil} calculator, it is not necessary to correct the applied dose of metabolites for molecular weight and maximum observed % AR, as the Nordic PEC_{soil} calculator internally accounts for this, and these variables are input parameters.

For the active substance(s) and metabolite(s), $PEC_{max\ (1st\ season)}$, PEC_{acc}[25] should be reported and used in risk assessments in line with Section 22.9.2 "exposure assessment" (earthworms and other soil organisms). Time weighted average (TWA) values with a maximum duration of 21 days ($PEC_{acc,21dTWA}$) should be reported and used in risk assessment. The duration of the TWA interval should be in accordance with the EFSA Guidance on Birds and Mammals (Cf. Section 22.9.2 "exposure assessment").

PEC_{acc} can be calculated for applications every year, every 2nd or every 3rd year. Calculations for biennial and triennial applications may be provided for any crop to demonstrate acceptable use for all MS except Denmark (valid for EE, LV, LT, FI, SE, NO). Please note that DK only accepts calculations for applications every 2 or 3 years if it is in accordance with the normal crop rotation period of the specific crop i.e. if the crop is grown with such interval in practice, in accordance with Table 21.4.

$PEC_{max\ (1st\ season)}$ and PEC_{acc}, and $PEC_{acc,21\text{-}dTWA}$ values towards a soil depth of 5 cm shall always be presented. A soil depth of 20 cm can be considered as a refinement for the years before the last application if tilling is a normal agricultural practice[26]. The calculator permits for adjustment of the mixing depth (5-20 cm) according to tilling practice for the crop. The last year mixing depth must however always be set to 5 cm. Examples of situations where this refinement cannot be used are uses on perennial crops, orchards and golf courses. For the product, the PEC_{max} of the first year should be reported and referred to as $PEC_{product}$.

21.1.1 National cut-off criteria

DK: For authorisation, DT_{50} for both the active substance and some metabolites must be <180 days. Please consult the latest version of Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off:

[25] PEC_{acc}: the highest concentration during a period of 20 years including all applications from the last year
[26] A substantial amount of the agricultural fields in Finland are managed by conservation tillage or no-tillage. Therefore, in Finland, a tilling depth of 20 cm has only been accepted for crops such as potato and sugar beet for which light tilling practices are not relevant.

https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework

NO: For authorisation of non-professional use: When evaluating such products persistence is especially important. Products that have a geometric mean DT_{50}lab (normalised) in soil of more than 100 days will not be authorised for outdoor use.

21.2 Ground water

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted. Only substance specific parameters can be changed. The latest FOCUS models available at the time of submission must be used in PEC calculations. In addition to the summary in the dRR, the modelling report with example input and output files representative for worst-case PEC_{gw} should always be provided. Other output files shall be made available when requested from the regulatory authority.

21.2.1 Surrogate crops

When a crop is not parameterised in the relevant scenario(s), the user should select a crop that most resembles the intended crop, based on expert judgement and provide a factual justification for this choice.

21.2.2 Substance input data

If K_{oc} and/or DT_{50} are pH dependent, the data representative for the pH range of soils in the cMS (see Table 21.1) should be used for selection of appropriate input values for the groundwater simulations[27] (acidic or alkaline endpoint(s) from the EFSA List of Endpoints). In cases where both acidic and alkaline conditions are relevant for a MS, please consider that worst case-conditions for metabolites can be different from worst case conditions for parent compounds or precursors.

Modelling endpoints in accordance with the FOCUS degradation kinetics report should be used. All input values used for the simulations must be reported. Field DT_{50} values[28] used as model input need to follow EFSA GD on $DegT_{50}$ (2014).

21.2.3 Plant uptake factor

For transpiration stream concentration factor (TSCF), sometimes referred to as plant uptake factor (PUF), a value of 0 should be used unless Briggs' equation is applicable, in accordance with current FOCUS guidance on GW assessments[29]. The

[27] Latvian requirement: the PECgw modelling for both acidic and alkaline conditions should be presented initially (Tier I). If PECs for alkaline conditions are worst-case compared to acidic conditions (parent and/or metabolites), the PECgw modelling for whole data set (acidic and alkaline endpoints merged) can be performed as Tier II.

[28] Latvia generally accept the field studies from central zone. This applies to the selection of endpoints for GW and SW modelling. If the modelling endpoint become more conservative after exclusion of southern zone field studies the southern zone field data will not be accepted by LV.

[29] Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version: 2.3, Date: June 2021; Implemented from 1 January 2022.

applicant must include a justification as to why Briggs' equation is considered applicable (i.e. relating to the substance being non-ionic and the reliability of the log Pow value at neutral pH). The maximum calculated value for TSCF from Briggs' equation is 0.8. The TSCF presented in the EFSA conclusion on the active substance is only acceptable if the current guidance on plant uptake was considered in the active substance assessment.

Experimentally determined plant uptake factors (e.g. plant uptake in hydroponic test systems) are currently not accepted, as there is no standardised EU-agreed guideline on how these studies should be performed or how the results should be assessed.

21.2.4 Application dates

The program AppDate 3.06 should be used when selecting the application dates for all FOCUS PELMO and PEARL scenarios.

21.2.5 National requirements for PEC_{gw} simulations

When triggered, as specified in Table 21.2, the core assessment should contain modelling with all national scenarios for the MSs for which an authorisation is applied for.

The Swedish scenarios: The Swedish national groundwater scenarios are not designed to represent geographical areas in Sweden, although they were developed and named after specific locations. Rather they represent the most vulnerable hydrogeological and agroclimatic conditions within Sweden. A risk assessment covering all of Sweden must be provided and therefore, all three scenarios (Krusenberg, Näsbygård and Önnestad) must always be simulated. If a crop is not parameterized in a scenario, please choose a surrogate crop for that scenario according to the section **Surrogate crops** above. Furthermore, if an unacceptable risk is identified in the scenarios Näsbygård or Önnestad, PLAP-data may, if certain criteria are fulfilled, be used to support an acceptable use. Please refer to "PLAP" in Appendix V.

Swedish weather data (files not changed): The weather data files needed by MACRO In FOCUS for the 3 Swedish scenario (Näsbygård, Önnestad, Krusenberg) are not delivered with the MACRO In FOCUS installation file. As the data is the property of the Swedish Meteorological and Hydrological Institute (SMHI), the weather data files need to be ordered from SMHI, and the Swedish Chemicals Agency is not allowed to distribute these files on our website or by mail. SMHI's contact person for this issue is Magnus Asp (magnus.asp@smhi.se); Tel no. switchboard: +46 (0)11 495 80 00). SMHI currently takes a fee of 4750 SEK + VAT for delivering the files.

Once you have the files they should be saved in "C:\SWASH\macro\bin" (in the "bin" folder of MACRO installation directory). In total there should be 8 files

(*.bin). Please notice that the two scenarios Näsbygård and Önnestad in fact share the same weather data files.

Please notice that three scenarios are included in MACRO In FOCUS installation package. It is only the weather data files which are not included. Also, for Swedish modelling, make sure to always use the MACRO In FOCUS package that was downloaded from FOCUS DG SANTE so that all currently relevant (and requested) scenarios are included.

Table 21.2. National requirements for PEC_{gw} simulations. The newest model version should always be used, unless otherwise specified.

MS	Tier I - PELMO	Tier II – simulations with MACRO[30]			
		Triggered when one of the following applies	**The following scenarios shall be used**	**Comment to MACRO assessment**	**Evaluation of MACRO results**
SE and NO	FOCUS PELMO: Hamburg	Risk of leaching to GW is listed as an area of concern in the EU review report a.s./relevant metabolites/non-assessed metabolites[31] ≥ **0.001 µg/L** Non-relevant metabolites evaluated up to step 5 in EU assessment ≥ **0.1 µg/L** Non-relevant metabolites evaluated up to step 4 in EU assessment ≥ **0.0075 µg/L**	**Krusenberg** **Önnestad** **Näsbygård[32]** **Rustad[33]**	If MACRO-simulations are triggered for the parent substance, all (relevant and non-relevant) metabolites have to be simulated with MACRO. Non-relevant metabolites cannot be excluded.	a.s./relevant metabolites ≤ **0.10 µg/L** → ok. Non-relevant metabolites evaluated up to step 5 in EU assessment ≤ **10 µg/L** → ok. Non-relevant metabolites evaluated up to step 4 in EU assessment ≤ **0.75 µg/L** → ok. Non-relevant metabolites evaluated up to step 4 in EU assessment > 0.75 µg/L and ≤ **10 µg/L** → Step 5 of relevance assessment needed.
MS	**Tier I - PELMO**	**Tier II - simulations with MACRO (Karup and Langvad) or PELMO (Hamburg) with specified input/output**			
		Triggered when	**MS specific comment**		**Evaluation of MACRO/PELMO results**
DK	FOCUS PELMO: Hamburg	a.s./any metabolite > **0.001 µg/L**	As input the following shall be used: 80th percentile for DT50 (not geomean), 20th percentile for K_{foc} (not geomean) and 80th percentile for 1/n (not arithmetic mean).		a.s./all metabolites ≤ **0.10 µg/L** →ok. Only 1 year out of 20 may exceed 0.1 µg/L.

[30] Information about the different versions of the MACRO model and their bugs is available at: http://esdac.jrc.ec.europa.eu/projects/macro.

[31] Metabolites which have not been assessed as being relevant or non-relevant at EU-level since the PECgw of the metabolites was < 0.1 µg/L in the EU-assessment.

[32] For Näsbygård, several simulations with different application dates are required if the Koc < 500 L/kg and the $DT50_{soil}$ < 50 days (modelling endpoint). The simulations shall cover the earliest and latest possible treatment period applied for in relation to the GAP BBCH window. The treatment period is defined by the maximum number of applications (≥ 1) and the minimum number of days between each application. If the time between the first and the last treatment period is more than 40 days, at least one additional treatment period "in between" shall be simulated. The time between the starting dates of the treatment periods in each simulation must not exceed 30 days. In those cases only a single simulation is required, the starting date of the simulated treatment period has to be chosen to represent a worst case situation regarding contamination of groundwater.

[33] Rustad is only required for Norway (Norway requires Krusenberg, Önnestad, Näsbygård and Rustad). Sweden's requirements in 21.2.5 regarding the Swedish scenarios and surrogate crops are also valid for Norway. However, the Rustad scenario is not requested if the selected crop or the surrogate crop selected for the Swedish scenarios is not parameterized there (i.e. spring and winter cereals). Relevant files and background information for the Rustad scenario is available at www.mattilsynet.no or on request.

			As output, the number of years that exceed 0.1 µg/L out of 20 years as output (not 80th percentile). All metabolites need to be covered by the assessment. Further guidance available in the Danish national guidance: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework Please note that for crop interception, the values reported in annex 11 in the Danish national guidance must be used. Values for crops that are not covered by the tables must be taken from EFSA (2014).	In some cases, and after evaluation by DEPA (see the Danish national guidance) some metabolites may be accepted at concentrations up to 0.75 µg/L.
MS	**Tier I – PEARL and PELMO**	**Tier II – simulations with PEARL and PELMO (Hamburg)**		
		Triggered when	**MS specific comment**	**Evaluation of PEARL/PELMO results**
LT	FOCUS PEARL and PELMO: Hamburg	Risk of leaching to groundwater is listed as an area of concern in the EU review report	As input the following shall be used: 80th percentile for the degradation (not geomean DT_{50}), 20th percentile for K_{foc} (not mean) and 80th percentile of output. If a product is applied in DK with the same GAP, modelling as required by DK is sufficient for LT as well.	a.s./relevant metabolites **≤ 0.10 µg/L** → ok Non-relevant metabolites evaluated up to step 5 in EU assessment **≤ 10 µg/L** → ok Non-relevant metabolites evaluated up to step 4 in EU assessment **≤ 0.75 µg/L** →ok Non-relevant metabolites evaluated up to step 4 in EU assessment **> 0.75 µg/L and ≤ 10 µg/L** → Step 5 of relevance assessment needed.
MS	**Tier I – PEARL and PELMO**			**Evaluation of PEARL/PELMO results**

LV EE	Hamburg and Jokioinen	a.s./relevant metabolites ≤ **0.10 µg/L** → ok Non-relevant metabolites evaluated up to step 5 in EU assessment ≤ **10 µg/L** → ok Non-relevant metabolites evaluated up to step 4 in EU assessment ≤ **0.75 µg/L** →ok Non-relevant metabolites evaluated up to step 4 in EU assessment > **0.75 µg/L and ≤ 10 µg/L** → Step 5 of relevance assessment needed.
MS	**Tier I – PEARL and PELMO**	**Evaluation of PEARL/PELMO results**
FI	Hamburg and Jokioinen	• a.s./relevant metabolite ≤ **0.10 µg/L** (total sum ≤ 0.50 µg/L) → ok. • non-relevant metabolite (Step 4) ≤ **0.75 µg/L** → ok[34] • non-relevant metabolite (Step 5) > **0.75 µg/L and ≤ 10 µg/L**: assessment needed for toxicological relevance (data on sub-chronic toxicity (90-day study) + data/information on carcinogenicity, reproductive and developmental toxicity, at a minimum. Please, see SANCO/221/2000 – rev.11 21 October 2021.) → ok[34] • non-relevant metabolites total sum ≤ **10 µg/L** → ok[35] (National legislation)[35]

[34] With groundwater risk mitigation. See the criteria for the restriction on the use of the product on the classified ground water areas in Appendix VI.

[35] Finland does not approve products for which the total sum of non-relevant metabolites exceeds 10 µg/L. This applies for products containing either one active substance or more than one active substance. See Decree of the Ministry of Social Affairs and Health amending the Decree of the Ministry of Social Affairs and Health on quality requirements and monitoring of drinking water (Sosiaali- ja terveysministeriön asetus talousveden laatuvaatimuksista ja valvontatutkimuksista annetun sosiaali- ja terveysministeriön asetuksen muuttamisesta (2/23) (link).

21.2.6 General guidance on simulating PEC_{gw} for metabolites in MACRO:

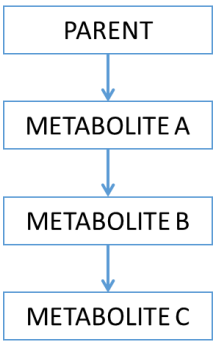
The purpose of the following text is to give practical advice on how to simulate PEC_{gw} for metabolites in MACRO. MACRO can only handle one parent compound and one metabolite in a single simulation. Hence, additional simulations are required if several metabolites are formed. Depending on the quality and availability of input data for the compounds, two main different approaches may be followed.

If true degradation ($DegT_{50}$) and formation fraction (ff) data are available for both the parent and metabolites:

Simulating the formation of a metabolite from the parent is straightforward and only requires the additional compound properties and conversion factor for the metabolite (example A, Table 21.3). However, if the degradation pathway includes a chain of degradation where a metabolite is formed from another metabolite, the PEC_{gw} for the metabolite of concern is simulated by using its precursor metabolite as "parent". In such cases, the applied dose in MACRO needs to be adjusted to represent the occurrence of the precursor metabolite in soil (examples B and C, Table 21.3). Note that the results obtained for the precursor metabolite designated as "parent" in each separate run should not be used. Additional metabolites may be added in the chain as required.

Table 21.3. Metabolite degradation pathway in MACRO.

A. PARENT → METABOLITE A	
Applied dose	Dose parent x (1-i)
Conversion factor	$ff_{met\ A}$ x ($Mw_{met\ A}$ / Mw_{par})
Use results from	Parent and metabolite A
B. METABOLITE A → METABOLITE B	
Applied dose	Dose parent x (1-i) x $ff_{met\ A}$ x ($Mw_{met\ A}$ / Mw_{par})
Conversion factor	$ff_{met\ B}$ x ($Mw_{met\ B}$ / $Mw_{met\ A}$)
Use results from	Only metabolite B
C. METABOLITE B → METABOLITE C	
Applied dose	Dose parent x (1-i) x $ff_{met\ A}$ x $ff_{met\ B}$ ($Mw_{met\ B}$/Mw_{par})
Conversion factor	$ff_{met\ C}$ x ($Mw_{met\ C}$ / $Mw_{met\ B}$)
Use results from	Only metabolite C
ff = formation fraction Mw = molecular weight, met = metabolite par = parent i = plant interception	



If no reliable degradation and formation fraction data are available, a metabolite can be simulated separately as if it was a parent compound in MACRO. The simulation is then performed using $DisT_{50}$ (decline from peak) or a default DT_{50} of 1000 days instead of true degradation $DegT_{50}$. In such cases the applied dose in MACRO is adjusted to match the maximum observed occurrence (%) of the metabolite from degradation studies:

$$Applied\ dose = Dose\ parent * (1 - Interception) * Max\ observed * \frac{Mw_{Met}}{Mw_{Parent}}$$

21.2.7 Presentation of results from PEC_{gw} model simulations:

The documentation must be well structured and transparent in order to demonstrate which models and scenarios have been used for each country.

If one or both of the limit values (0.1 µg/L for each individual substance[36] and 0.5 µg/L for the sum of substances[37]) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. field studies, and/or monitoring data[38]) convincingly demonstrate that unacceptable leaching will not occur in a NZ context. When evaluating such studies, consideration must be given to whether soil properties, climate conditions and application (crops, vegetation cover, application method, formulation of the product, dose and time of application) correspond to NZ conditions and the applied GAP.

Metabolites for which the PEC_{gw} exceeds 10 µg/L are considered to pose a non-acceptable risk, except for cases where the metabolite clearly is harmless to human health and the environment ("degradation product of no concern")[39]. This is the official policy in the following NZ MS; EE, FI, LT, LV, NO, SE. For more information, see Assessment of the relevance of metabolites in groundwater 21.5.

21.2.8 Simulations with applications every second or third year

Simulations with annual application shall always be reported. Modelling for biennial and triennial applications may be provided for any crop to demonstrate acceptable use for all MS except Denmark (valid for EE, LV, LT, FI, SE, NO).

[36] Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.

[37] Sum of substances in a sample refer to all active substances + metabolites stated as relevant. For DK please refer to the latest national guidance: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework

[38] Note that monitoring data for higher tier groundwater assessments is only accepted by Denmark and in specific cases by Sweden (In both cases using The Danish Pesticide Leaching Assessment Programme, PLAP). For Sweden, see specific policy in Appendix V.

[39] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. SANCO/221/2000 rev. 10-final, 25 February 2003; hereafter: guidance document on the relevance assessment of metabolites. Note that DK does not follow this guidance document (ref. to footnote 9).

Please note that every fourth- (or fifth-) year simulations are not accepted by Sweden, Norway[40], Finland[41], Latvia or Estonia.

Please note that DK only accepts modelling for applications every 2, 3, 4 and 5 years if it is in accordance with the normal crop rotation period of the specific crop i.e. if the crop is grown with such interval in practice, in accordance with Table 21.4.

Table 21.4. Crop rotation period in years in Denmark - The numbers in the table indicate 1: every year. 2: every second year. 3: every third year etc.

Crop	Crop rotation period in years
Potatoes	3/4*
Sugar beets	3
Cereals (winter, spring), maize	1
Beans, peas	5
Carrots	5
Cabbage, Oil seed rape (winter, spring)	4
Onions	5

* crop rotation every fourth year is for certified seed potatoes only

21.3 Surface water

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted. The latest FOCUS models available at the time of submission have to be used in PEC calculations. For calculations at Step 1 and 2 the latest version (version 3.2) should be used. Table 21.5 lists when Step 3 is not required:

Table 21.5. Coupling between the PEC_{SW} obtained at FOCUS Step 1 and 2 and the ecotoxicology assessment.

FOCUS step 1-2	**Parent-substance**	**Metabolite**
Version 3.2	Step 3 not required if RAC ≥ $PECsw_{step1-2}$*10	Step 3 not required if RAC ≥ $PECsw_{step1-2}$

Step 3 and 4 is to be calculated with the FOCUS scenarios in accordance with the country specific requirements (Table 21.6).

In addition to the summary in the dRR, the modelling report with example input and output files representative for some of the worst-case $PEC_{SW/SED}$ values should always be provided. Other input and output files shall be made available when requested from the regulatory authority.

[40] Every fourth-year simulations are not accepted by the Swedish Chemicals Agency Agency and the Norwegian Food Safety Authority because 4th year PECgw simulations are not supported by the FOCUS-MACRO model (in the user interface). The official FOCUS-MACRO (controlled by FOCUS DG SANTE) model can only handle yearly, biennial and triennial application scenarios.

[41] Finland does not accept conditions of use restricting the product application to one application every four years (or more), as it may not be possible to follow or control such a use condition in practice.

21.3.1 Input parameters

For DT_{50} in soil, sediment and water, modelling endpoints in accordance with the recent version of FOCUS degradation kinetics report should be used. If K_{oc} and/or DT_{50} are pH dependent, data representative for the cMS should be applied in the simulations[42] (see Table 21.1 and text in Section 21.2.2 – Substance input data). FOCUS default values should be applied where appropriate. For the plant uptake factor the requirements are the same as for groundwater, i.e., a default value of 0 should be used unless Briggs's equation is applicable (see further information under Section 21.2 - Groundwater). All input values used for the simulations have to be reported, including the application window chosen for the step 3 & 4 simulations.

21.3.2 Application dates

Applicants need to ensure that the choice of the application window results in an application date that is relevant and representative enough of the worst-case use (i.e. the application date should be representative of the growth stages with the lowest interception). The program AppDate 3.06 should be used when selecting the application dates for all FOCUS Step 3 scenarios. There is a problem in AppDate (3.0.6) for the FOCUS MACRO D1 scenario for the early spring application timing in winter cereals (e.g., BBCH 20 and BBCH 30). At BBCH 20 in winter cereals, AppDate suggests an application window starting with the 10th of Oct, which is not correct. For BBCH 30, the suggested application window starting the 25th of March is considered early. For BBCH 20 and above, it is possible to use a more realistic application window in winter cereals, however, a justification always needs to be provided if the chosen application window deviates from the application window suggested by AppDate. Please note that the application date chosen by PAT in Focus Step 3 should represent a 'realistic worst-case' with respect to precipitation and crop interception for the intended uses. The application date selected by PAT and the date for the max PEC_{sw} must be reported in the dRR in the surface water modelling results.

21.3.3 Surrogate crops

All scenarios in which a crop is parameterised should be simulated. When a crop is not parameterised in the relevant scenario(s), the user should select a crop that resembles most the intended crop, based on expert judgement and provide a factual justification for this choice. In case a crop is parameterised only for run-off or drainage scenario, a similar crop (surrogate) must be selected based on expert judgement to obtain results for at least one drainage and one run-off scenario (run-

[42] Latvian requirement: the PECsw modelling for both acidic and alkaline conditions should be presented initially (Tier I). If PECs for alkaline conditions are worst-case compared to acidic conditions (parent and/or metabolites), the PECsw modelling for whole data set (acidic and alkaline endpoints merged) can be performed as Tier II.

off scenarios not relevant for DK and SE; see MS specific scenarios in Table 21.6 below).

21.3.4 Surface water scenarios and mitigation measures

The core assessment should contain all national scenarios for the MSs where authorisation is applied for.

Table 21.6. Member State specific requirements for FOCUS scenarios considered in the assessment of surface water and sediment exposure.

Scenarios						
Country	**D1**	**D3**	**D4**	**R1**	**R2**	**R4**
Denmark[1]		X	X			
Estonia[2]	X	X	X	X		
Sweden[3]	X		X			
Norway[4]	X	X	X	X	X	X
Lithuania[2]	X	X	X	X		
Latvia[2]	X	X	X	X		
Finland[4]	X		X	X		

1. D3 and D4 scenario should always be simulated for use on field crops. When a crop is not parametrised for these scenarios, use a surrogate crop.
2. D1 and R1 should always be simulated for use on field crops. When a crop is not parametrised for these scenarios, use a surrogate crop.
3. For Sweden, if a crop is parametrised in both D1 and D4, both scenarios shall be presented. If a crop is only parametrised in D4, no simulations with a surrogate crop in D1 are needed. If a crop is not parametrised in D4, both scenario D1 and D4 need to be simulated with a surrogate crop except for trees, bushes, vines and hops where only D4 is required.
4. For Norway and Finland, results need to be obtained for at least one D and one R scenario. If a crop is not parameterised in any of the required scenarios, or it is parameterised for only R or D scenarios, a similar crop (surrogate) must be selected to obtain results for at least one D and one R scenario. Only the scenarios where the surrogate crop is parameterised need to be simulated, i.e., it is not necessary to select several surrogate crops to obtain results for all scenarios required.

Table 21.7. Possible surface water mitigation measures in the Member States of the NZ

Width of non-spray buffer zones to mitigate drift (m)							
Drift mitigation(m)	**Denmark**	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden**
2	FVOB	-	-	-	-	-	-
3	-	-	FVOB	-	FVOB	-	-
5	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB
10	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB
15	-	FVOB	FVOB	FVOB	FVOB	-	FVOB
20	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB	O
25	-	FVOB	-	FVOB	OB	-	-
30	VOB	FVOB	OB	FVOB	OB	FVOB	-
35	-	OB	-	-	OB	-	-
40	O	OB	O	OB	OB	-	-
45	-	-	-	-	-	-	-
50	O	-	O	O	-	-	-
Runoff vegetative buffer zone (m)[1]							
	Denmark	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden**
Buffer zone (m)	-	10	10	10	10	10	-
Drift reducing nozzles (%) [2]							
nozzles (%)	**Denmark**	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden**
25	-	-	-	-	-	-	O
50	-	FVOB	FVOB	FVOB	FVOB	FVOB	FVOB
75	-	FVOB	FVOB	FVOB	FVOB	FV	FVOB
90	-	FVOB	FVOB	FVOB	FVOB	FV	FVOB
99	-	-	-	-	-	-	O

F = Field crops, V = Vegetables, O = Orchards, B = Bush berries & nurseries

1. Calculation shall be performed with the SWAN tool, applying the reduction factors for a 10-12 m buffer strip, as outlined in table 7 p. 33 in FOCUS Landscape and mitigation[43]. The use of the VFSmod tool is not accepted.

2. for the combination of drift reducing equipment with non-spray buffer zones and vegetated filter strips, please see text below for national approaches and further information in Appendix VI

The documentation must be well structured and transparent in order to demonstrate which scenarios and mitigation measures are relevant for each country. It should be clear which PEC_{sw} are to be used in the aquatic risk assessment.

In addition to the above Table 21.7, MSs have specific risk management approaches regarding how the different risk mitigation options (non spray buffer zones, vegetated filter strip and drift reducing nozzles) can be combined, as listed below:

- **Estonia:** Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk. If risk is not acceptable using at most the maximum allowed buffer zone for Estonia together with 50% drift reducing nozzles, the product cannot be authorized

[43] C. Brown et al. 2007, Landscape and Mitigation factors in aquatic ecological risk assessment. Volume 1, Extended Summary and Recommendations (SANCO/10422/2005, version 2.0, September 2007)

- **Finland:** Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk.

- **Latvia:** Non-spray buffer zones and vegetated filter strips alone is to be used as first option for off-field mitigation. If necessary, non-spray buffer zones and vegetated filter strips can be combined with drift reducing nozzles to further reduce the exposure.

- **Lithuania:** Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk.

- **Norway:** The plant protection product must pass the risk assessment for aquatic organisms with a non-spray buffer zone of maximum 30 meters without spray drift reduction techniques (e.g. drift reducing nozzles). The non-spray buffer zone can then be narrowed using drift reduction techniques. The results from different non-spray buffer zones in combination with drift reduction techniques should be presented in the risk assessment. Vegetated filter strips (VFS) of 10 meters may also be required to reduce the risk from runoff. We would like to point out that certain conditions (e.g. the slope of the field being less than 2 %) may lead to an exemption from the VFS requirement in Norway[44]. Thus, when a non-spray buffer zone is required in combination with a VFS, non-spray buffer zones narrower than the VFS of 10 meters and in combination with drift reduction techniques should also be presented in the risk assessment.

- **Sweden:** Spray-free buffer zone ("Hjälpredan"/"the Helper") is to be used as first option for off-field risk mitigation. If the maximum distance of the buffer zone for respective crop is not enough to achieve acceptable risk, drift reducing nozzles can be added. See further information in Appendix VI.

21.3.5 Spray-drift values (Rautmann)

For spray-drift values relevant for NTA, NTTP or handheld sprayer, please consult https://wissen.julius-kuehn.de/mediaPublic/AT-Dokumente/03-Abdrift/Table-drift-reduction/Drift_values_for_single_application_in_field.xlsx from where the latest version of Rautmann values in English (excel sheet) can be downloaded.

21.4 Monitoring data

Available monitoring data from the zone (see Table 21.8) concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction

[44] The conditions leading to an exemption are described in the Norwegian Food Safety Authority's guidance on vegetated filter strips (https://www.mattilsynet.no/planter-og-dyrking/plantevernmidler/veileder-om-vegeterte-buffersoner-mot-plantevernmidler-i-overflatevann)

products should be reported. The data might, in some MSs, be used in support of the groundwater and surface water modelling. Note that monitoring data is not accepted as a higher tier by MS other than by Denmark and in specific cases by Sweden (see specific policy in Appendix V). Please read the Danish Framework for the Assessment of Plant Protection Products for more details. Monitoring data indicating higher environmental exposure than the predicted modelled values could for some MSs lead to restrictions in the use of plant protection products at national level.

Table 21.8. Monitoring programmes in the NZ.

Member state	Monitoring programme
Denmark	The Danish Pesticide Leaching Assessment Programme PLAP
Estonia	National groundwater and surface water monitoring results can be found from KESE
Sweden	"Nationell miljöövervakning av bekämpningsmedel (växtskyddsmedel) i miljön", Swedish University of Agricultural Sciences (SLU), on behalf of the Swedish Environmental Protection Agency (Naturvårdsverket). www.slu.se > Forskning > Institutioner och fakulteter > Institutionen för vatten och miljö > Miljöanalys > Bekämpningsmedel.
Norway	The Norwegian Agricultural Environmental Monitoring Programme (JOVA), Norwegian Institute of Bioeconomy Research (NIBIO)
Lithuania	-
Latvia	-
Finland	Public Monitoring Data in Groundwaters 2004 - 2020

SE: See specific policy in Appendix V

21.5 Assessment of the relevance of metabolites in groundwater

A metabolite is considered to be of concern when the concentration is above 0.1 µg/L. In some cases, the NZ FOCUS scenarios may predict higher concentrations of groundwater metabolites than the EU FOCUS scenarios. An assessment of the relevance of metabolites of concern in groundwater should be included in the core assessment if the metabolite has not been assessed during the EU evaluation. Note, that unless the metabolite can be considered a "degradation product of no concern"[45], the upper limit value is 10 µg/L.

The assessment of the relevance should cover all the requirements in the GD (SANCO221/2000 – rev.11, 21 October 2021) on the relevance of metabolites in groundwater. The full relevance assessment is to be presented in the core dRR, Part B section 10. Denmark generally considers all metabolites as relevant, but in some

[45] SANCO/221/2000 – rev.11, 21 October 2021. Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC. Note that DK does not follow this guidance document (ref. to footnote 36).

cases, and after evaluation by DEPA (see the Danish national guidance), some metabolites may be accepted at concentrations up to 0.75 µg/L.

22. Ecotoxicology

This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. Specific national requirements are presented in Appendix V: Summary of national requirements. This guidance highlights parts which MS in NZ have different approaches to current EU and EFSA Guidance Documents. Please note, other parts of EU and EFSA Guidance Documents not mentioned here may still be considered unacceptable in the NZ.

Ecotoxicological data used for risk assessment in the NZ:

- List of endpoints data including data from the representative product if that product is applied for in the NZ and endpoints from confirmatory data. Endpoint for similar (or more adverse) formulation may also be used as surrogate for product applied for if valid bridging studies can support this. A qualified bridging statement should address all components in the formulation in Part C. An argumentation on why the formulations can be considered similar or more adverse, and hence eligible for bridging should also be included.
- Endpoint according to product data requirements (284/2013), if not covered by LoEP.
- Please consult the spreadsheet with NZ harmonised endpoints, assessment factors, RAC and/or PEC values that must be used for ecotoxicology risk assessment by https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/cooperation-in-the-northern-zone.

If applicable the latest version of the following guidance documents shall be used for the core assessment (abbreviation for guidance document):

- Guidance on the risk assessment for Birds and Mammals. EFSA Journal 2023;21(2):7790. (EFSA B&M (2023))
- Pesticide Risk Assessment for Birds and Mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the NZ in accordance with Regulation EC 1107/2009.
- Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters. EFSA Journal 2013; 11(7): 3290 (EFSA AGD (2013))
- Guidance Document on Terrestrial Ecotoxicology. Under Council Directive 91/414/EEC. (SANCO/10329/2002)
- EPPO 2010, OEPP/EPPO Bulletin 40, 313–319: Side effects for honeybees; For chronic risk assessment for bees from exposure from seed treatment, and

ECPA 2017: POS/17/LO/28028; modified EPPO for chronic RA for adult honeybees from spray applications. ((EPPO (2010), (ECPA (2017))

- Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods, ESCORT 2, Candolfi et al. 2001. (ESCORT 2)
- EFSA (European Food Safety Authority), 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019. EN-1673. (EFSA (2019))
- EFSA (European Food Safety Authority), 2015. Technical report on the outcome of the pesticides peer review meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2015:EN-924. 62 pp. (EFSA (2015))
- OECD, 2023. (Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure − Activity Relationship models, predictions, and results based on multiple predictions (OECD QAF, 2023), OECD, Series on Testing and Assessment, No. 386, 2023, https://www.oecd.org/chemicalsafety/risk-assessment/qsar-assessment-framework.pdf.

In principle, the guidance given in PPR opinions may be used for the risk assessment, but each country can on a case-by-case basis decide to deviate from this. Therefore, both the use and possible deviation from PPR opinions should be clearly documented in the dRR.

Use of ecological modelling is not accepted. This will be reconsidered when models and guidance documents with criteria for assessing the output are adopted at the European level. Effect modelling such as TKTD have been reviewed by EFSA, and there is some guidance available. These models are however based on detailed exposure patterns, a refinement option which is currently not accepted in the NZ (see Section 22.6.2.1). In addition, the NZ does not accept modelling data based on unofficial FOCUS-model versions (see Section 0).

22.1 Mixture toxicity

Mixture toxicity should be considered for acute and long-term risk assessment for non-target organisms, as specified in the respective sections for the different non-target organism.

For areas where there is no EFSA guidance available for assessing cumulative risk, this risk should be calculated based on the model of concentration addition using the following equation[46]:

[46] Exception being bumble bees, see Section 22.7.7.1 for details.

$$\frac{Trigger_A - value}{TER_A} + \frac{Trigger_B - value}{TER_B} + \cdots = SUM$$

if $SUM < 1$ *the risk is acceptable*

22.2 Non-professional use/Home gardens

No harmonised approach for risk assessments of non-professional/home garden products have yet been agreed within the NZ. If an assessment for agricultural use is presented, the assessment should include a bridging statement clarifying how the agricultural use can be considered to cover the use in home gardens. It should be considered if the risk mitigation measures for agricultural use are applicable and/or necessary for the home garden use. If home garden use is not covered by the agricultural use, the risk assessment should be presented in the core assessment and the risk mitigation measures at national addendum.

See Appendix V: Summary of national requirements for national criteria for non-professional use.

22.3 Risk assessment for uses in protected structures

The Interzonal Steering Committee has developed an interim approach for uses in protected crops (protected structures)[47]. This interim approach should be applied for uses in professional greenhouses (low-and high technology). For more information on requirements for the interzonal core risk assessment for non-target organisms please refer to the interim approach.

Please note that the core assessment may be considered as worst-case scenario that could be further refined at national level[48]. It is therefore important that information on cultivation system is clear as well as other presumptions regarding the standard on the professional greenhouse.

The risk assessment for uses in other protected structures than low-and high technology professional greenhouses are evaluated as field uses at zonal level.

22.4 Vertebrate testing

Generating new studies on vertebrate animals should be avoided whenever possible[49], and duplication of vertebrate tests is not accepted[50]. In cases where generating new vertebrate studies is considered an option by the applicant, they

[47] PPP Zonal – Bibliotek (europa.eu)
[48] Denmark has national guidance for the assessment of use in ”open” greenhouses that must be applied for national assessments, see Appendix V.
[49] According to the data requirements (Commission Regulation (EC) 283/2013 and 284/2013, Annex Introduction, Point 5) tests on vertebrate animals shall be undertaken only where no other validated methods are available.
[50] Regulation (EC) No1107/2009, Chapter V, Article 62.

should always engage a dialog with the zRMS prior to initiating the studies to discuss other possible options for refining the risk assessment.

22.5 Birds and mammals

The risk assessments for birds and mammals (including the mixture toxicity assessment) should be presented in the core assessment using the guidance document EFSA B&M (2023) (EFSA Journal 2023;21(2):7790). Please note, that BMD_{10} values shall be used when they are available in LoEPs. If not available, existing NOAEL values shall be used.

The max. $PEC_{soil, TWA}$ (after 20 years) calculated in the Nordic PEC_{soil} calculator should be used in the risk assessment for secondary poisoning of earthworm-eating birds and mammals. The use and duration of TWA of PECsoil values shall follow the recommendation in EFSA B&M (2023).

22.5.1 Geometric mean

EFSA B&M (2023) states that for the acute risk assessment, a geometric mean of the acute toxicity data can be used in a refined risk assessment. In the NZ, a geometric mean can only be used if endpoints from at least three species are available. In the case the most critical single endpoint is lower than a GM/10 value then a WoE approach should be used. The most critical single endpoint should then be used with a reduced assessment factor on ad-hoc basis. The reduced assessment factor should be >3, supported with an argumentation for the size of the reduction. A geometric mean with only two species is not considered sufficiently protective[51]. If endpoints from two species are available, the lowest endpoint should be used in the risk assessment.

22.5.2 Tier 1 refinement options

No refinements of the EFSA (2023) tier 1 assessment scenarios are accepted, except that MAF and the fTWA factor may be refined if permitted according to the EFSA 2023 GD, and if adequate substance specific data on DT50 in plants are available.

For NZ requirements concerning refinement of DT50, please refer to the NZ Bird and mammals higher tier guidance document, section 4.4 (available at the Danish EPA webpage regarding Pesticides:

https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/cooperation-in-the-northern-zone

[51] Historically, before the new data requirements and EFSA (2009), most often endpoint from two species were present and the lower was used in a risk assessment. I.e. the use of a GM with only two species available, is considered as lowering the protection level.

22.5.3 Higher tier risk assessment

When further refinements of the risk assessment are necessary, the NZ higher tier guidance document should be used together with the associated spreadsheet (both available at the Danish EPA webpage, see link above). When a higher tier assessment is triggered, by any generic focal species at Tier 1 in a crop/growth stage scenario, the risk should be assessed for all NZ higher tier focal species relevant for that crop/growth stage scenario. All focal species required for the crop and growth stage in question according to the NZ higher tier guidance document are relevant, even if the focal species were already assessed as generic focal species at tier 1. The main reason for this is that the tier 1 scenarios are not necessarily worst case with respect to diet in the NZ, where some of the generic focal species are rare or missing and the niches of the remaining focal species may thus be broader. Higher tier TER calculations are however not required for generic focal species which passed the trigger by a factor of 2 or more at tier 1.

22.6 Aquatic ecosystems

In the core assessment, a first-tier risk assessment in accordance with Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters, EFSA Journal 2013; 11(7): 3290 (abbreviated as EFSA AGD) should be presented. The terminology used in the EFSA AGD (2013) is accepted in aquatic ecotox section of this NZ GD, e.g., regulatory acceptable concentration (RAC). A table containing all relevant FOCUS PEC SW and PEC SED (see Section 0) divided by RACs should be included[52]. The risk assessment tables shall contain all country specific scenarios and relevant mitigation measures for the countries in which authorization is applied for. It is important to present all calculations made in the risk assessment in a transparent way.

For formulations containing one active substance, the risk assessment should be performed with the lower of the endpoints of active substance or formulation (calculated as active substance content) following the recommendation in 7.5.3.1 of EFSA AGD (2013).

No risk assessment is needed with formulation endpoint and PEC_{sw} based on spray drift of formulation.

Please observe that the risk assessment should be based on additional FOCUS Step 3 values when required as described in Section 0, Table 21.5.

[52] See Section 0 regarding the use of an extra safety factor of 10.

22.6.1 Mixture toxicity assessment

For formulations containing more than one active substance, the aquatic mixture toxicity risk assessment shall follow the recommendations in 10.3 of EFSA AGD (2013).

An excel based Aquatic MixTox calculation tool has been developed in order to ensure correct calculations and can be accessed at:
https://zenodo.org/record/7788826

When reporting the results in the dRR the "template for AGD Aqua mix" should be used (can be found at zenodo). The excel-file should also be provided as a separate file together with the application.

If the mix-tox calculation is based on active substance endpoints i.e. ETRmix-ca, and it shows unacceptable mix-tox risk, this risk cannot be refined using PEC_{sw} based on spray drift of formulation and formulation endpoint. Formulation toxicity is already considered in Aquatic MixTox tool. Although not recommended, it is accepted for pragmatic reasons to use ETO-RAC from micro/mesocosms in the mixture-toxicity assessment. The chronic mixture toxicity risk assessment for fish and aquatic invertebrates are not covered by the spreadsheet but should be calculated using the formula for RQmix[53]:

$$RQ_{mix} = \sum_{i=1}^{n} \frac{PEC_i}{RAC_i} < 1, \text{ the risk is considered acceptable}$$

$$n = number\ of\ mixture\ components$$
$$i = index\ from\ 1 \ldots n\ mixtures\ components$$
$$PEC_i = PEC\ of\ component\ i$$
$$RAC_i = RAC\ of\ component\ i$$

The mixture toxicity risk assessment for algae and macrophytes is based on standard endpoint that are considered to cover both acute and chronic conditions.

22.6.2 Higher tier risk assessment

If refinements are needed in the aquatic risk assessment, the below considerations must be followed.

22.6.2.1 Refinement of the exposure by different risk mitigation options

For the core assessment, risk mitigation by spray drift buffer zones are accepted (see MS specific buffer zones in Section 0). Other nationally specific mitigation options

[53] For the chronic mixture toxicity risk assessment for fish and aquatic invertebrates, the Step 8b (RQmix) of the spreadsheet can also be used. Instead of the LC50, add the chronic endpoints for fish and invertebrates in the "Input Tox"-sheet and change the AF from 100 to 10. Go directly to Step 8b (RQmix)

(run-off reduction and spray drift reducing nozzles) are accepted in some MSs. PEC/RAC-calculations based on these mitigation options should also be presented in the core assessment. The documentation must be well structured and transparent in order to demonstrate which scenarios and mitigation measures that are relevant for each MS.

Refinement by using PEC_{TWA}

It is not accepted to use PEC_{TWA} in acute risk assessments for aquatic organisms. For the long-term risk assessment, it is acceptable to follow the EFSA AGD (2013)[54] regarding use of $PEC_{sw,twa}$. In addition to fulfilling the conditions of the decision scheme regarding use of $PEC_{sw;twa}$ in the EFSA AGD (2013), it has to be clearly demonstrated, that the boundary conditions of reciprocity and latency of effects are fulfilled for the relevant twa period.

Refinement by using detailed analysis of exposure profiles

Chapter 9.1 of the EFSA AGD (2013) describes how time-variable exposures (e.g. pulse durations and/or intervals between pulses) derived from the FOCUS modelling could be used to refine the aquatic risk assessment. The refinement described in Chapter 9.1 in EFSA AGD (2013) is, however, not accepted for refined risk assessments in the NZ. Based on the many site- and time-variable parameters affecting the shapes of the FOCUS peaks, it is not considered scientifically justified to mimic the exposure profiles from FOCUS modelling in higher tier studies at the resolution described in chapter 9.1 of EFSA AGD (2013). Some of these variable parameters affecting the exposure profiles are described in the EFSA AGD (2013), e.g.; physical–chemical properties of the PPP, the application regime in the crop, the relative importance of different entry routes (e.g. drift, surface run-off, drainage) and properties of the receiving water bodies (e.g. water flow, water depth, pH, light penetration, biomass of plants). Additionally, exposure profiles from FOCUS modelling are event driven and dependent on weather conditions from only one year. This indicates that the uncertainty, when it comes to high resolution analyses, of the FOCUS peaks will be high.

Additionally, refined exposure tests with single or few species (chapter 9.2 of the EFSA AGD (2013)) cannot be consider covering all sensitive life stages or all species in the field, since the effect of e.g. a pulsed exposure is highly species specific and dependent on sensitive life stages and/or different life strategies. Consequently, in the NZ, time-variable exposures derived from the FOCUS modelling cannot be used to refine the aquatic risk assessment as described in chapter 9.1 and parts of chapter 9.2 of the EFSA AGD (2013).

Likewise, chapter 10.3.10 in EFSA AGD (2013) utilizes detailed analysis of exposure profiles to refine the worst case PEC_{mix} in risk assessments of

[54] PECtwa can be used in risk assessments of algae and macrophytes if the criteria for TWA are fulfilled.

combinations of active substances in formulations. Based on the high uncertainty considering detailed analysis of FOCUS peaks (see above), chapter 10.3.10 in EFSA AGD (2013) is not accepted to be used in refined risk assessments within the NZ.

Refinement when more species than required at tier 1 have been tested

Valid toxicity data from additional species, exceeding data requirements (Regulation (EU) No 283/2013) can be used to refine the aquatic risk assessment. There are two possible options to refine the toxicity endpoint used in the risk assessment, which depends on the amount of additional data. 1.) the use of geometric mean (GM) and 2.) the use of Median Hazardous Concentration 5 % (Median HC5) from a species sensitivity distribution (SSD). When the two different methods are considered acceptable, the risk assessment follows the EFSA AGD (2013) recommendations, for algae, aquatic plants and invertebrates. For fish, however, exceptions are given in Table 22.1 below.

Table 22.1. Method accepted (marked with X) in the NZ for refinement of fish toxicity data when more data than required is available.

Aquatic organism	Acute/Long-term	Geometric mean	N_{GM}*	Median HC5	N_{HC5}
Fish	Acute	X	3-4	X	5+
Fish	Long-term**				

* N_{GM} = number of species required for geometric mean.

** Not accepted, for more details please see below.

The use of geometric mean RAC values refers to section 8.3 in the EFSA AGD (2013). However, use of geometric mean for long-term invertebrate risk assessment requires both that the EFSA AGD (2013) is respected[55] and that only EC10 appearing in the List of Endpoints (LoEP) are used in the geometric mean calculation. The same type of endpoints from comparable long-term studies has to be used, the duration of the studies should be in similar range and water studies should not be combined with water/sediment studies. The use of geometric mean or median HC5 for long-term fish endpoint is not accepted as there remain concerns around application of protective assessment factor (AF).

Geometric mean

A geometric mean (GM) approach shall always be assisted by a deterministic approach (DA) and the lower value of the two shall always be used in a risk assessment. Guidance on how a deterministic approach is performed is given below for the acute endpoints for fish and invertebrates, as well as for algae and aquatic plants. Many of the concerns identified in relation to derivation of acute RAC based on GM or DA is also relevant for the long-term situation and need to be addressed

[55] I.e. disregard the conclusions the EFSA expert meetings in 2015 and 2019 regarding reccuring issues.

by the applicant. However, until enough experience is gained in deriving long-term RAC based on geometric mean or DA, such long-term RACs will be assessed on a case-by-case basis, applying expert judgement, except for algae and aquatic plants (see below).

The theory behind the DA approach is that the lower the endpoint of the most sensitive test species, the more of the species variability is considered to have been addressed and therefore the AF can be reduced. The overall AF ($AF_{overall}$) applied to acute and long-term endpoints can be related to variation in species sensitivity (AF_{spec}) and other uncertainties (AF_{other}). The latter includes e.g. inter-laboratory variation and lab to field extrapolation for both acute and chronic situations. For acute AF it seems reasonable to maintain as a default approach the assumption from the former aquatic GD (EC, 2002) that the AF_{spec} and AF_{other} have an equal weight, i.e. AF_{spec} = 10 and AF_{other}= 10 for acute toxicity AF: $AF_{overall} = AF_{spec} \times AF_{other}$. However, for chronic tests, it can be assumed that the AF_{spec} has a larger weight than AF_{other} since the uncertainties remaining in AF_{other} are reduced. Indeed, AF_{other} does not to the same extend need to account anymore for the extrapolations from acute to chronic effects.

For the acute assessment for fish and invertebrates:

i. When the endpoint of the most sensitive species tested is lower than the derived RACGM (RACGM = geometric meanacute / 100), RACDA should be used in the risk assessment. Here, the RACDA is the endpoint of the most sensitive species divided by a default AF of 20 for invertebrates and 30 for fish[56].
ii. When the endpoint of the most sensitive species tested is lower than the derived geometric mean value by a factor between 10 and 100, RACDA should be used in the risk assessment. Here, the RACDA is the endpoint of most sensitive species divided by a default AF of 60[57].
iii. When the endpoint of the most sensitive species tested is lower than the derived geometric mean value by a factor between 1 and 10, the RACGM should be used in the RA (RACGM = geometric meanacute / 100).

For the long-term assessment for algae and aquatic plant assessment:

Algae and aquatic plants should be treated as different taxonomic groups (see EFSA AGD (2013)) and should not be merged in the assessment.

[56] Following recommendation by EFSA (EFSA, 2019. Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology. EFSA supporting publication 2019:EN-1673. 117 pp. doi:10.2903/sp.efsa.2019.EN-1673). $AF_{overall}$ = 10 (AF_{other}) x AF_{spec}. As a default value for the AF_{spec}, a value of 2 and 3 as minimum is proposed for invertebrates and fish, respectively, giving an $AF_{overall}$ of 20 for invertebrates and 30 for fish.

[57] $AF_{overall}$ = 10 (AF_{other}) x AF_{spec}. As a default value for the AF_{spec} a value of 6 at minimum is proposed, leading to a **default $AF_{overall}$ of 60**.

i. When the endpoint of the most sensitive species tested is lower than the derived RACGM (RACGM = geometric meanLT / 10), the RACDA should be used. Here, the RACDA is the is the endpoint of most sensitive species divided by a default AF of 6[58].

ii. When the endpoint of the most sensitive species tested is equal to, or higher than, the RACGM (RACGM = geometric meanLT / 10), compare RACGM to the RACDA and use the lowest RAC for the risk assessment. Here, the RACDA is the is the endpoint of most sensitive species divided by a default AF of 8[59]

The use of species sensitivity distribution approach (except chronic SSD for fish) refers to section 8.4 (including subsections) in EFSA AGD (2013).

Refinement with mesocosms

Mesocosm studies (including "old" mesocosms for which a LoEP value is available and used in the risk assessment) should always be reported and evaluated according to the EFSA AGD (2013) and presented in the core dossier. Minimal detectable differences (MDD) should be reported together with the NOEC table for each investigated endpoint in time and used as recommended in the EFSA AGD (2013). Only the RAC derived on basis of the Ecological Threshold Option (ETO) from mesocosms can be used in the core risk assessment, with an AF as proposed in the EFSA AGD (2013). The RAC based on Ecological Recovery Option (ERO) is only accepted by Denmark, but only in certain cases with specific considerations regarding recovery period and AF (see Danish national guidance via link in Appendix V for further details). Especially if the dissipation rate of the tested substance is e.g. pH dependent it should be explicitly described whether the exposure profile in the mesocosm is considered to cover the exposure in surface water in the NZ MSs[60].

22.7 Bees

Please note that this is an interim approach awaiting the EFSA guidance documents on bees. Therefore, this interim approach will be replaced by EFSA Bee GD (2023) and follow the implementation date.

An acceptable acute and chronic risk and risk to colony survival and development must be demonstrated. According to Regulation (EU) No. 284/2013, chronic

[58] The values of 6 and 8 attributed to the $AF_{overall}$ in the deterministic approach could be revised on the basis of more experience.
The introduction of a RAC_{DA} is considered as a "safety net" to the RAC_{GM} and is especially relevant when the lowest available endpoint of the dataset is in a range close to the trigger of 10 below the geomean. In such case, the use of the RAC_{DA} instead of RAC_{GM} helps maintain an adequate protection level.
[59] The values of 6 and 8 attributed to the $AF_{overall}$ in the deterministic approach could be revised on the basis of more experience.
The introduction of a RAC_{DA} is considered as a "safety net" to the RAC_{GM} and is especially relevant when the lowest available endpoint of the dataset is in a range close to the trigger of 10 below the geomean. In such case, the use of the RAC_{DA} instead of RAC_{GM} helps maintain an adequate protection level.
[60] In particular Sweden, Finland and Norway tend to have slightly acidic surface water.

toxicity studies for adult bees and honey-bee larvae should be submitted as part of the application dossier, in addition to acute toxicity studies. Furthermore, where Regulation (EU) No. 284/2013 refers to bees without specifying "honeybees", the interpretation in the NZ is that studies with other bee species (bumble bees and solitary bees) are also relevant. However, the risk assessment scheme described in the currently agreed guidance document for the risk assessment of bees (SANCO/10329/2002)[61] only takes into account acute toxicity data on honeybees.

To manage the discrepancy between the data requirements of Commission Regulation (EU) No 284/2013 and the guidance in SANCO (2002), the following interim approach for the risk assessment of bees is required for applications in the NZ until the reviewed EFSA bee guidance has entered into force.

22.7.1 First-tier risk assessment

22.7.1.1 Acute risk assessment

Acute oral and contact toxicity studies with honeybees should always be submitted, and a tier 1 risk assessment using HQ acute oral and HQ acute contact should be presented, in accordance with SANCO/10329/2002.

The OECD test guideline for acute oral and contact toxicity to bumble bees are available. Therefore, acute studies with bumble bees should always be submitted. If acute studies on the active substance(s) and bumble bees are available, acute studies with bumble bees and the formulation can be waived according to Table 22.3. For the time being, a tier 1 risk assessment using HQ acute oral and HQ acute contact should be presented for bumblebees[62] as described for honey bees in SANCO/10329/2002.

There are currently no agreed test guidelines for the acute toxicity to solitary bees. Consequently, such studies are not required for the time being, and no acute risk assessment for solitary bees will be requested.

22.7.1.2 Chronic risk assessment

Chronic toxicity studies with adult honeybees and honeybee larvae should always be submitted. The chronic risk assessment for adult honeybees and honeybee larvae should be performed for exposure via pollen and nectar. Assessments for exposure to contaminated water and accumulative toxicity are not necessary for the time being. The following alternative approaches can be used:

The chronic risk assessment of solid applications (granules and seed treatment) may be conducted according to the EPPO (2010)[63] risk assessment scheme. This scheme

[61] SANCO, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (Working Document, SANCO/10329/2002 rev 2 final, 17 October 2002).
[62] The HQ for bumble bees is reasonable pragmatic interim solution.
[63] 2010 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 40, 323–331

is cited in the Regulation (EC) 1107/2009 as a current risk assessment scheme. For spray applications we accept the use of EPPO modified by ECPA (2017)[64] approach. The ECPA (2017) risk assessment scheme may also be accepted for seed treatment products.

The chronic risk assessment for adult bees and larvae from solid and spray applications may also be conducted according to the EFSA bee guidance (2013)[65]. If the EFSA bee guidance (2013) is followed, it is recommended to use the EFSA calculator tool (Bee-Tool v.3), which can be downloaded at:

https://zenodo.org/records/56669

For chronic risk assessments using the EPPO (2010) and EPPO as modified by ECPA (2017) schemes, it is recommended to use The Nordic calculator tool for chronic bee risk assessment, which can be downloaded at "DKs website Cooperation in the NZ (mst.dk)" https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/cooperation-in-the-northern-zone.

Chronic risk assessment of spray formulations honeybee adult and larvae

In view that there are no agreed risk assessment schemes for the chronic risk assessment of spray formulations, the NZ has agreed that the adult and larvae risk assessment may be conducted according to the modified EPPO 2010 approach as suggested by ECPA (2017) in option 1 on page 5 and 6, respectively.

Please note that in the document by ECPA (2017), the equations for the risk assessment have been corrected with respect to the units (g to microgram). The corrected calculations are used in the Nordic calculator tool for chronic bee risk assessment.

Chronic risk assessment for solid applications (granules and seed treatments) honeybee adult and larvae

Following the EPPO (2010) risk assessment scheme, the NOED[66] is compared to the daily dose based on daily sugar demand and residue levels in plant matrix and it is based on a TER approach.

The NOEDD values must always be expressed in terms of active substance, irrespective if it is from an active substance study or a formulation study.

[64] 2017 ECPA, Proposal for a protective and workable regulatory European bee risk assessment scheme based on the EFSA bee guidance and other new data and available approaches (POS/17/LO/28028 09 June 2017)
[65] EFSA Journal 2013;11(7):3295
[66] In EPPO NOEDD is expressed as NOEL, here for consistency the term NOEDD is used.

The daily dose is a generic worst-case exposure of 0.128 µg a.s./bee/day for adult bees and 0.015 µg a.s./larva/day[67]. These values are based on a worst-case residue value of 1 mg a.s./kg plant matrix and the worst-case sugar intakes of bee foragers and drone larvae of 128 mg sugar/bee/day and 15.1 mg sugar/larva/day, respectively (Rortais et al., 2005). The sugar content of nectar and product specific application rate is thus not included in the risk assessment.

Alternatively, the chronic risk assessment for seed treatment formulations can also be conducted according to ECPA (2017). This approach considers sugar demand of a bee, sugar content of nectar, application rate and uses the EFSA Bee GD (2013) default residue values and compares NOED values to exposure.

22.7.2 Refinement of the exposure using residue data for nectar and pollen

Pending EFSA Bee guidance document, there is currently no agreed guidance on how to refine the risk assessment for bees. It is however in theory possible to use a refined RUD for nectar or pollen in the EPPO as modified by ECPA (2017) scheme. Please refer to the NZ B&M GD version 2.1, 2020[68], chapter 4.4 *Recommendation for residue decline refinements (DT50). The same criteria are required* for refinement of the exposure from nectar and pollen (RUD), as are required for the refinement of DT50 values.

22.7.3 Test methods/guidelines

For an overview of test methods/guidelines that are considered suitable, see Table 22.2 below.

Table 22.2. List of available test guidelines for bees

Datapoint[69]	Test methods
10.3.1.1.1 Acute oral toxicity	*Honeybees:* • OECD Test Guideline 213: Honeybees, acute oral toxicity test • EPPO Standard PP1/170[70] (2010). Test methods for evaluating the side-effects of plant protection products on honeybees. *Bumble bees:* • OECD Test Guideline 247. Bumblebee, acute oral toxicity test

[67] In Table 1 in Rortais et al. (2005) sugar intake is presented as mg/larva over N days. Worst-case is 98.2 for drones. In table text it is stated that N=6.5 for drones. Thus, 98.2 divided by 6.5 is 15.1 mg sugar/larva/day.
[68] NZ 2020. Pesticide risk assessment for birds and mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the NZ in accordance with Regulation EC 1107/2009.

[69] Reference to Part A of the Annex to regulation (EU) No. 284/2013.
[70] 2010 OEPP/EPPO,OEPP/EPPO Bulletin 40, 313–319.

10.3.1.1.2 Acute contact toxicity	*Honeybees:* • OECD Test Guideline 214: Honeybees, acute contact toxicity test • EPPO Standard PP1/170 (2010). Test methods for evaluating the side-effects of plant protection products on honeybees. *Bumblebees:* • OECD Test Guideline 246: Bumble bee, acute contact toxicity test
10.3.1.2 Chronic toxicity to bees	*Honeybees:* • OECD Test Guideline 245: Honeybee chronic toxicity test (10-day feeding) • Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honeybee brood. Redia XC: 87-90 • Oomen, P.A., de Ruijter, A., van der Steen, J. (1992). Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.
10.3.1.3 Effects on honeybee development and other honeybee life stages	*Honeybees:* • OECD Guidance Document 239 on HoneyBee Larval Toxicity Test following Repeated Exposure • OECD Guidance Document 75 on the honeybee (*Apis mellifera* L.) brood test under semi-field conditions • Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honeybee brood. Redia XC: 87-90 • Oomen, P.A., de Ruijter, A., van der Steen, J. (1992). Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.
10.3.1.4 Sub-lethal effects[71]	*Honeybees:* • Oomen, P.A., de Ruijter, A., van der Steen, J. (1992). Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616. • OECD Guidance Document 75 on the honeybee (*Apis mellifera* L.) brood test under semi-field conditions
10.3.1.5 Cage and tunnel tests	*Honeybees:* • EPPO Standard PP1/170. Test methods for evaluating the side-effects of plant protection products on honeybees
10.3.1.6 Field tests with honeybees	*Honeybees:* • EPPO Standard PP1/170. Test methods for evaluating the side-effects of plant protection products on honeybees

There is currently no validated methodology for the assessment of sublethal effects in the first-tier risk assessment. This is also the case for the chronic toxicity to bumble bees and solitary bees. Consequently, such studies are not required for the

[71] Data requirement according to Regulation (EU) No. 284/2013, but it is currently not considered mandatory to address this specific point for plant protection products.

time being, and no chronic risk assessment for bumble bees and solitary bees is needed.

22.7.4 Higher tier risk assessment

If the first-tier risk assessment for honeybees fails, a higher tier risk assessment should be presented, including the evaluation of higher tier studies, e.g. semi-field or field studies. Higher tier risk assessments should be in agreement with SANCO/10329/2002. An evaluation of the acceptability/representativeness of the field study for the intended use and NZ conditions should be presented, and relevant risk mitigation options considered.

It should be noted that exposure is relevant for field uses for crops which are attractive to bees for either nectar and/or for pollen collection. For applications in crops that are not attractive to bees or where application is after flowering, no exposure from the treated crop itself is expected, however, bees may be present in the field to forage on flowering weeds and bees foraging in the off-field area may be exposed via spray drift.

For **bumblebees**, there are currently no agreed higher tier test guidelines. Although there are differences between bumble bees and honeybees, in the interim period, if the risk assessment demonstrates acceptable use with regard to the risk to honeybees (either at the first tier or at higher tier), then it may be assumed to cover the risk to bumbles bees as well. Please note that, as stated above, in the interim period only acute risk to bumbles bees is included in the risk assessment[72]. In case there is still a concern, risk mitigation measures should be considered.

22.7.5 Risk mitigation options

A common mitigation option for all MSs is either a restriction in timing of application or restriction of use in flowering crop[73], these mitigation measures can therefore be used in the core assessment. However, MSs may differ in their view on whether flowering weeds should be considered when restrictions on use are considered. See Appendix VI for mitigation options.

22.7.6 Waiving of formulation toxicity studies

In accordance with Regulation (EU) 284/2013 the risk to bees shall be investigated except where the plant protection product is for exclusive use in situations where bees are unlikely to be exposed. In such situations, an argumentation should be submitted clearly demonstrating that no exposure is expected.

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[72] This does not mean that a risk assessment for bumble bees is not necessary if an acceptable risk to honeybees is demonstrated. The acute bumblebee studies need to be submitted, and a tier 1 risk assessment is to be performed.

[73] No treatment of flowering growth stages of the crop (BBCH 60-69) or when flowering weeds are present. For systemic active substances it may be that treatment is only demonstrated acceptable after flowering (≥ BBCH 70) or if the crop is harvested before flowering.

Testing with the formulation is required if the plant protection product contains more than one active substance, or the toxicity of a plant protection product cannot be reliably predicted to be either the same or lower than the active substance tested (e.g., a water solution).

An overview of the acceptable waiving of formulation studies in the NZ is given in Table 22.3.

Table 22.3. Acceptable waiving of formulation toxicity studies on bees in the NZ

Acceptable waiving		
Formulation data	**Formulations containing one active substance**	**Formulations containing two or more active substances**
Acute oral and contact toxicity for honeybees	If the toxicity of the formulation can be reliably predicted to be the same or lower than the active substance**	-
Acute oral and contact toxicity for bumble bees	If the toxicity of the formulation can be reliably predicted to be the same or lower than the active substance**	If acute oral and contact LD_{50} of the formulation (expressed in terms of active substances) for honey bees is less than 3 times lower than the surrogate mixture acute oral LD_{50} of the active substances.***
Chronic toxicity for adult honeybees and honeybee larvae	If the toxicity of the formulation can be reliably predicted to be the same or lower than the active substance.** If acute oral LD_{50} of the formulation (expressed in terms of active substance) less than 3 times lower than the acute oral LD_{50} of the active substance.**	No exposure of bees expected* If acute oral LD_{50} of the formulation (expressed in terms of active substances) less than 3 times lower than the surrogate mixture acute oral LD_{50} of the active substances.***
*No risk assessment for bees required. **Conduct risk assessment based on active substance data. ****Conduct mixture toxicity risk assessment based on active substance data according to paragraph for mixture toxicity further down.*		

22.7.6.1 Plant protection products containing only one active substance

It is not necessary to perform chronic toxicity studies on honeybees with the formulation when the acute oral toxicity of the formulation is comparable to that of the active substance. Chronic studies with the active substance are sufficient in this case. To compare the acute oral toxicity of the active substance and the formulation, a factor of 3[74] is proposed: if the acute oral endpoint (expressed in terms of active substance) for the formulation is at least a factor 3 below the endpoint of the active substance, then the toxicity of the formulation is considered higher. In that case, chronic formulation studies should be submitted.

[74] This factor was agreed by the majority of the experts, to be applied consistently to Tier 1 studies for all groups of non-target organisms in the Technical report "Outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology", 2019: "In relation to when a formulation should be considered more toxic than the active substance, the proposal was to account for a difference of a factor of three, as recommended in the guidance from the Directorate-General for Health and Food Safety (SANCO/10597/2003 rev. 10.1) (European Commission, 2012) on the equivalence of batches and in the aquatic guidance (EFSA PPR Panel, 2013). This means that when the endpoint of the PPP (expressed in terms of the active substance) is at least three times lower than the equivalent endpoint for the active substance, it should be considered to be more toxic."

22.7.6.2 Plant protection products containing more than one active substance

To decide if the formulation increases the toxicity compared to the toxicity of the active substances alone, the acute surrogate endpoint for the mixture toxicity of active substances can be calculated[75] and compared with the acute formulation endpoint[76] (both expressed in terms of µg sum a.s./bee). It is recommended to use the "waiving calculation" sheet in the "Chronic bee calculation tool", which can be downloaded at the https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/cooperation-in-the-northern-zone.

If the acute formulation endpoint for honeybees is at least a factor 3 below the calculated acute endpoint for the mixture (both expressed in terms of active substances), it can be considered that the formulation is more toxic than predicted from the toxicity of the individual components. In that case, acute bumblebee and chronic honeybee formulation studies should be submitted. If this is not the case, the toxicity of the formulation can be reliably predicted from the toxicity of the active substances it contains. The acute bumble bee and chronic honeybee risk assessment should then be performed based on the calculated mixture toxicity, based on the endpoints from toxicity studies with the active substances. See instructions for mixture toxicity calculations below.

22.7.7 Mixture toxicity calculations

22.7.7.1 Acute toxicity

Acute formulation toxicity studies for honeybees should be available for formulations containing more than one active substance; therefore, no mixture toxicity calculations are needed. If a formulation study is waived for bumblebees (see Table 22.3 above), mixture toxicity risk should be calculated using the equation below:

$$\frac{HQ_A - value}{50} + \frac{HQ_B - value}{50} + \cdots = SUM$$

$$if\ SUM < 1\ the\ risk\ is\ acceptable$$

Where $HQ_{A,B}$ = Exposure Toxicity Ratio

$$\text{Exposure ToxicityRatio} = \frac{Expected\ environmental\ exposure}{Substance\ specific\ effect\ concentration(LD_{50})}$$

$$Expected\ Environmental\ Exposure = Application\ rate\ i\ g\ a.s./ha$$

[75] Equation 13, p.148, EFSA AGD.

[76] Please, consider the density of the formulation and the weight fractions of the a.s. in the calculation of the acute formulation endpoint (µg sum a.s./bee). Calculation sheet included in the Nordic calculator tool for bees.

22.7.7.2 Chronic toxicity

If chronic formulation studies for adult honeybees and honeybee larvae are available, mixture toxicity risk is covered by these studies; if not, chronic mixture toxicity should be calculated using the equation given in Section 22.1 for mixture toxicity using the TER values for the individual active substances obtained with the Chronic Bee Calculation tool.

22.8 Non-target arthropods

In the core assessment, first tier in-field and off-field risk assessments using HQ (ESCORT 2; standard lab glass plate studies) should be presented. If necessary, higher tier laboratory studies should be presented and evaluated against the 50 % trigger value for negative effects. Several reviews indicate that the Vegetation Distribution factor (VDF) of 10 is not appropriate (EFSA, 2015 and EFSA 2019). Experts at EFSA (2019) agreed on VDF of 5 instead. The VDF is therefore set to 5 in the NZ as an interim approach.

If aged residue studies are submitted to demonstrate the potential for recolonisation of NTAs in In-field areas, a justification must be provided regarding why the study shows that recovery is possible under NZ conditions and the proposed GAP.

The evaluation of field studies and the higher tier risk assessment should also be presented in the core assessment according to the guidance document of the Dutch Platform for the Assessment of Higher Tier Studies (de Jong, Bakker, Brown, Jilesen, Posthuma-Doodeman, Smit, van der Steen, van Eekelen):

http://www.rivm.nl/bibliotheek/rapporten/601712006.pdf

The interpretation of acceptability/representativeness of the field study for specific agricultural landscape(s) and protection goals should be done for each MS.

In the off-field risk assessment, in-field non-spray buffer zones should be used if required. For spray-drift values relevant for NTA, NTTP or handheld sprayer, please consult:

https://wissen.julius-kuehn.de/mediaPublic/AT-Dokumente/03-Abdrift/Table-drift-reduction/Drift_values_for_single_application_in_field.xlsx

from where the latest version of Rautmann values in English (excel sheet) can be downloaded. Please notice that also 3 m buffer zone is relevant for arable crops and should be reported (drift values for arable crops at 3 m can be calculated by replacing 1 with 3 in cell A4 in the excel sheet). See Appendix VI: List of mitigation options available in the MSs in the zone, for relevant buffer zones in each MS and for the possibility to use drift reducing nozzles for further risk mitigation. A table containing all country specific buffer zones (including drift reducing nozzles,

if accepted) should be provided for the countries in which authorization is applied for.

22.9 Earthworms and other soil organisms

In the core assessment, a first-tier risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002 rev 2 final) should be presented[77]. Pending an updated EFSA guidance, the NZ interpretation of the data requirements in Regulation 284/2013 is that the risk assessment should be based on sublethal effects for earthworms together with studies on *Folsomia candida* and *Hypoaspis aculeifer* where relevant.

For PPPs applied as soil treatment

According to Regulation 284/2013 studies on *Folsomia candida* and *Hypoaspis aculeifer* are always required.

For PPPs applied as foliar treatment

According to Regulation 284/2013: *For plant protection products applied as a foliar spray, data on the relevant two non-target arthropod species **might** be taken into account for a preliminary risk assessment. If effects do occur on either species, testing on Folsomia candida and Hypoaspis aculeifer shall be required (see point 10.4.2.1).*

If data on Aphidius rhopalosiphi and Typhlodromus pyri are not available, then the data outlined in point 10.4.2.1 shall be required.

- In the NZ, "if effects do occur" is interpreted as:
    1) if the HQ is above the trigger of 2 in the first-tier risk assessment for foliar treatments on non-target arthropods other than bees, or
    2) the risk assessment starts at tier 2 with extended laboratory data.

  Then testing on *Folsomia candida* and *Hypoaspis aculeifer* shall be required.

- In the data requirements it is stated that data on non-target arthropod species **might** be taken into account. Even if there is no risk identified in the NTA risk assessment (i.e. HQ < 2), product studies on *Folsomia candida* and *Hypoaspis aculeifer* can be required by competent authorities in some cases such as:
- If available active substance or metabolite data on *Folsomia candida* and/or *Hypoaspis aculeifer* raise concern. This will especially be relevant for products with more than one active substance.
- If active substance data on *Folsomia candida* and/or *Hypoaspis aculeifer* is not available and the interception is 0 for some of the uses applied for since the exposure can be considered as equal to soil treatment.

[77] For seed treatments, granules, pellets and substances with limited solubility, studies on *Hypoaspis aculeifer* or *Folsomia candida* is recommended.

22.9.1 Endpoint correction factor

The endpoints (NOEC/EC_{10}) used in the risk assessment of earthworms (and other soil organisms) should be divided by a factor of 2 when the log Kow is greater than 2, even if the toxicity tests are performed with soil containing less organic matter than 10%. The correction factor 2 can be omitted only if it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of organic matter content in soil. The toxicity data required is described below for studies in artificial soil. If the independency of toxicity of organic matter content in soil has not been demonstrated, the correction factor 2 cannot be omitted even in case toxicity studies have been performed in natural soil.

22.9.1.1 Based on sorption data

If the sorption of a substance is shown to be independent of soil organic carbon content in the Environmental Fate -assessment, the assessment factor of 2 can be omitted.

22.9.1.2 Based on toxicity data

To demonstrate that the toxicity of a substance is independent of soil organic matter content, at least four toxicity studies following OECD TGs of 222, 226 or 232 with the concerned species are required in artificial soil covering at least the range of 2 to 10 % *Sphagnum* peat (as given in OECD TGs). By using artificial soil, the only parameter changing in the tests is the organic matter content making the interpretation of the results more reliable. If the toxicity is independent of organic matter content in soil a geomean from the available toxicity studies can be used in the risk assessment without a factor 2. The correction factor may then also be omitted in the risk assessment for other soil organisms.

22.9.2 Exposure assessment

The risk assessment for soil organisms shall be based on PEC_{acc} values from the Nordic PEC_{soil} Calculator (see Section 21.1).

22.9.3 Formulation and mixture toxicity assessment

The risk assessment for the formulation should always be based on the formulation endpoint expressed on active substance basis and the PEC_{acc} of the active substance. If a formulation contains more than one active substance, then the endpoint also must be expressed as the sum of the active substances (mg Σ a.s./kg dw soil) and be divided with the sum of the PEC_{acc} of the active substances ($PEC_{acc\ mix}$). The expression of the formulation endpoint on active substance basis is based on the density of the formulation and the weight fraction(s) of the active substance(s). For these calculations, it is recommended to use the Northern Zone Mixture Risk Calculator for Soil Macro-organisms, which can be downloaded at https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/cooperation-in-the-northern-zone.

For formulations containing more than one active substance and/or where metabolites are equally or more toxic than the active substance, mixture toxicity for soil organisms should also be calculated using the equation in Section 22.1.

22.9.4 Higher tier risk assessment

22.9.4.1 Field studies

If required, a higher tier risk assessment based on higher tier field studies should be presented and evaluated in the core assessment. The field studies should be evaluated following the guidance given in part 2 of the document by de Jong et al. (A guidance document for summarizing earthworm field studies, RIVM 2006. See reference in Section 22.8) and Appendix I of the Technical report on the outcome of the Pesticides Peer Review Meeting on general recurring issues in ecotoxicology (EFSA, 2019). Old field studies should always be re-evaluated according to this guidance. The interpretation of the acceptability/representativeness of the field study for the specific agricultural landscape and protection goals should be done for each MS. Field studies from the Southern zone are not accepted. If field studies from the Central zone are used, it must be shown that the exposure profile is representative for the uses applied for and NZ conditions (see Table 21.1), taking into account the chemical properties of the active substance(s). If a new field study is performed, the concentration of the active substance in the soil must be measured and presented. The measured concentration of the active substance should be compared to the calculated PEC_{acc} used in the tier 1 risk assessment. If the measured concentrations do not cover the calculated PEC_{acc}, it must be demonstrated by scientific reasoning why the exposure in the field study could still be considered relevant. The evaluation should also include recovery times for the organisms and information on how many % of the organisms that are affected. For the core assessment initial effect less than 50 % (according to RIVM 2006) and recovery within a growing season for representative field studies are required.

22.9.4.2 Litter bag test

Litter bag test as the only mean to address the risk to soil organisms is not acceptable. Litter bag studies may be used as supportive evidence.

22.9.5 Risk mitigation options

For risk mitigation options, see Appendix VI: List of mitigation options available in the MSs in the zone.

22.10 Non-target terrestrial plants

In the core assessment, a risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002) should be presented. If a probabilistic risk assessment is used, endpoints from at least 8 species are required. It is not recommended to include unbounded values in SSD, except in cases explained in

AGD EFSA (2013), pp. 92-93. Unacceptable effects must be excluded for all species tested. Hence, the HC_5 must not exceed the EC_{50} of the most sensitive species in the SSD. If so, a deterministic risk assessment should be used instead. Additionally, the use of assessment factor 1 presented for the probabilistic risk assessment in SANCO/10329/2002 is not accepted in the NZ as it means that no remaining uncertainty exists. Since HC_5 is based on a limited number of single species tested in the laboratory an assessment factor of 3 is required to cover uncertainties related to ecological representativeness of the tested species, extrapolation from laboratory to field and from vegetative phase to reproductive phase (seed production) etc. If a plant species has been tested more than once, a geometric mean of the endpoints should be used in the SSD assessment.

The PER calculations shall be based on the correct number of applications according to the GAP (please refer to the formula below).

$$PER\ off-field = application\ rate \times MAF \times basic\ drift\ value$$

The MAF value must be according to Appendix V in "Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods" (ESCORT 2). A default MAF based on degradation in leaf substrates (i.e. T½ : spray interval is 2.3 : 1) is acceptable for exposure calculations in the risk assessment for non-target plants.

The NZ does not accept the use of interception as refinement for lowering the exposure concentration in the risk assessment of non-target plants. Instead, non-spray in field buffer zones could be used as risk mitigation measure. For spray-drift values relevant for NTA, NTTP or handheld sprayer, please consult:

https://wissen.julius-kuehn.de/mediaPublic/AT-Dokumente/03-Abdrift/Table-drift-reduction/Drift_values_for_single_application_in_field.xlsx

from where the latest version of Rautmann values in English (excel sheet) can be downloaded. Please note that also 3 m buffer zone is relevant for arable crops and should be reported (drift values for arable crops at 3 m can be calculated by replacing 1 with 3 in cell A4 in the excel sheet). See Appendix VI: List of mitigation options available in the MSs in the zone, for relevant buffer zones in each MS and for the possibility to use drift reducing nozzles for further risk mitigation. A table containing all country specific buffer zones (including drift reducing nozzles, if accepted) should be provided for the countries in which authorization is applied for.

22.11 Risk assessment of metabolites

If toxicity data for metabolites is not available in the LoEP, the evaluation can be carried out based on the assumption that the metabolite is 10 times more toxic than the parent on a molar basis as a tier 1 approach:

$$EP_{\mathrm{xx},met} = \frac{1}{10}\frac{M_{met}}{M_{as}} EP_{xx,as}$$

If there is evidence that the metabolite is less toxic than parent (e.g. toxophore is missing) or more toxic (e.g. from read-across), another factor than 10x may be applied on a case by case basis. This procedure is considered acceptable for all groups of organisms. If higher tier risk assessment is needed further data is required (e.g. QSAR approaches, see Section 22.12 below).

For some organisms, neither data on the metabolite nor on the parent may be available in the LoEP (e.g., for soil organisms). In such cases, the endpoint from the representative formulation (expressed as a.s. content), rather than from the product under evaluation, should be used as the basis for setting the metabolite surrogate endpoint. This ensures that the same endpoint is applied to the same metabolite across different products. If the representative formulation contains more than one a.s., an alternative approach may be more appropriate and should be determined on a case-by-case basis.

New toxicity data is only considered in case there is a data gap identified by EFSA that is specifically left out to MS-level to resolve (please refer to Section 8 "Data gaps identified in active substance evaluation") or if available information indicates an unacceptable risk.

Metabolites in mixture toxicity calculations: In case a metabolite is equally or more toxic than the active substance the toxicity of the metabolite needs to be taken into account in mixture toxicity calculations. Further advice for aquatic organisms is given in FAQ to Aquatic Mixtox tool:

https://zenodo.org/record/4593676

22.12 Use of non-testing methods (e.g. QSAR) as higher tier refinement for metabolites

When the use of a QSAR derived endpoint[78] for a metabolite has been accepted at EU level, such metabolite endpoints can be used in NZ aquatic risk assessment as a

[78] Endpoints covers both toxicity and bioconcentration factors (BCF)

higher tier refinement approach. QSAR derived BCF-endpoints for metabolites can also be used in the secondary poisoning risk assessment for birds and mammals.

If no EU agreed QSAR metabolite endpoints exist, it needs to be assessed if QSAR can be derived, based on the EFSA AGD (2013) recommendations. If this is acceptable according to EFSA AGD (2013), the derivation of QSAR endpoints for use in NZ aquatic risk assessment following the most recent version of OECD reporting formats (Q)SAR Model Reporting Format (QMRF) and (Q)SAR Prediction Reporting Format (QPRF) shall be submitted. See the *(Q)SAR Assessment Framework: Guidance for the regulatory assessment of (Quantitative) Structure - Activity Relationship models, predictions, and results based on multiple predictions, OECD Series on Testing and Assessment, No. 386*.

Appendix I. Form to notify zones

Please use the pre-notification form in the latest version of the guidance document **Template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009** (SANCO/12544/2014, rev 2) to notify the zones of upcoming zonal applications.

Template to notify intended zonal applications under Article 33 of Regulation (EC) No 1107/2009.

This template may also be used for notifications of mutual recognitions, amendments (article 45) and article 43-applications.

Appendix II. Reporting table

Active substance:

Trade name:

Formulation type:

Rapporteur:

General				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 0 – Product Background, Regulatory Context and GAP information				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 1 – Identity				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**

Section 2 – Physical and chemical properties				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 3 – Efficacy data and information				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 4 – Further information				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 5 – Analytical methods				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**

Section 6 – Toxicology				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 7 – Metabolism and Residues				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 8 – Environmental fate				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**
Section 9 – Ecotoxicology				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**

Section 10 – Relevance of metabolites				
Annex III point	**Country/ Applicant**	**Comment**	**Reply rapporteur**	**Accepted Yes/No**

Confidential reporting table

Active substance:
Trade name/Formulation type:
Rapporteur:
Applicant:

dRR - overall GENERAL COMMENTS				
Annex III point	**Country/ Applicant**	**Comment**	**Reply zRMS**	**Outcome**
dRR – Part C Confidential information				
Annex III point	**Country/ Applicant**	**Comment**	**Reply zRMS**	**Outcome**

Appendix III. Application contact points

Pre-notifications and applications should be submitted to:

Member State	E-mail	Postal Address
Denmark[79]	pesticider@mst.dk	Pesticider Miljøstyrelsen Lerchesgade 35 5000 Odense C
Estonia	Rauno.Aljas@pta.agri.ee with copy to Triinu.Ehala@pta.agri.ee	Estonian Agriculture and Food Board Plant Protection and Fertilizer Department Teaduse 2 Saku 75501, Estonia
Finland	ppp@tukes.fi	Finnish Safety and Chemicals Agency P.O.Box 66 (Opastinsilta 12 B) FI-00521 Helsinki, Finland
Iceland	ust@ust.is kristin.s.gudlaugsdottir@uos.is	Icelandic Environment and Energy Agency Sudurlandsbraut 24 108 Reykjavík, Iceland
Latvia	zonal@vaad.gov.lv	State Plant Protection Service Plant Protection Department Lielvardes iela 36, Riga, LV-1006
Lithuania	info@vatzum.lt VATIS (vatzum.lt)	State Plant Service under Ministry of Agriculture Ozo str.4A LT-08200 Vilnius, Lithuania
Norway [80]	postmottak@mattilsynet.no with copy to pesticider@mattilsynet.no	Norwegian Food Safety Authority, National Registration Department, Felles postmottak, P.O.Box 383, N-2381 Brumunddal, Norway
Sweden[81]	kemi@kemi.se	Kemikalieinspektionen P.O Box 2 SE-172 13 Sundbyberg, Sweden

[79] For large or many files send a request for a Filkassen-link to pesticider@mst.dk. (Please avoid using long file names or deep file structures, if possible, due to Microsoft's limit of path names to 255 characters.)

[80] Address for transfer of documentation: Norwegian Food Safety Authority, National Registration Department, Glynitveien 30, NO-1400 Ski, Norway. To share/send large or many files: https://mattilsynet.filemail.com/

[81] For large or many files use an open file share service can be used or send a request for a transfer link to kemi@kemi.se. (Please avoid using long file names or deep file structures, if possible, due to Microsoft's limit of path names to 255 characters.)

Appendix IV. Contact points of for Steering Committee in the NZ

Member State	CONTACT POINT
Denmark	**Title:** Coordinator for National Approvals **Name:** Lars Voss Jepsen **Authority:** Danish EPA **Address:** Lerchesgade 35, 5000 Odense C **Tel:** + 45 20484564 **E-mail:** larvj@mst.dk
Estonia	**Title:** Advisor **Name:** Rauno Aljas **Authority:** Agriculture and Food Board **Address:** Teaduse 2, Saku 75501 Estonia **Tel:** +372 5324 6604 **E-mail:** Rauno.Aljas@pta.agri.ee
Finland	**Title:** Senior Officer **Name:** Emilia Laitala and Sanni Toratti **Authority:** Finnish Safety and Chemicals Agency (Tukes) **Address:** P.O. Box 66, FI-00521 Helsinki, Finland **E-mail:** ppp@tukes.fi
Iceland	**Title:** Advisor **Name:** Kristín Silja Guðlaugsdóttir **Authority:** Environment Agency of Iceland **Address:** Sudurlandsbraut 24, 108 Reykjavik **Tel (direct):** 00354 591 2000 **E-mail:** kristin.s.gudlaugsdottir@umhverfisstofnun.is
Latvia	**Title:** Director of Plant Protection Department **Name:** Vents Ezers **Authority:** State Plant Protection Service **Address:** Lielvardes iela 36/38, Riga, LV-1006 **Tel:** +371 67550929 **E-mail:** vents.ezers@vaad.gov.lv
Lithuania	**Title:** Head of Plant Protection products authorisation division **Name:** Kristina Valioniene **Authority:** State Plant Service under Ministry of Agriculture **Address:** Ozo Str. 4A LT-08200 Vilnius, Lithuania **Tel:** +370 5 26 24 940 **E-mail:** kristina.valioniene@vatzum.lt
Norway	**Title:** Head of Department **Name:** Abdelkarim Abdellaue **Authority:** Norwegian Food Safety Authority **Address:** Glynitveien 30, NO-1400 Ski, Norway **Tel:** +47 22 77 91 33

	E-mail: Abdelkarim.Abdellaue@mattilsynet.no
Sweden	**Title:** Regulatory Coordinator **Name:** Camilla Thorin **Authority:** Swedish Chemicals Agency **Address:** P.O. Box 2, SE-172 13 Sundbyberg, Sweden **Tel:** +46 8 519 41 256 **E-mail:** camilla.thorin@kemi.se

Appendix V. Summary of national requirements

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Phys. Chem. properties and anal. method	Yes	In accordance with KCP 2.11 of Commission Regulation (EU) No 284/2013, all classification categories must be addressed including whether the PPP is corrosive to metals. A study for corrosiveness to metals compliant with Regulation (EC) No 1272/2008 (CLP Regulation) shall be submitted unless a reasoned case can be made as to why a study is not needed and a classification is not warranted. Guidance on the Application of the CLP Criteria, Part 2 lists criteria for considering a substance or mixture for classification where no test data is available. If any of these criteria are fulfilled, a test should be performed in order to conclude on the classification of the PPP.	CLP Regulation: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02008R1272-20221217 Guidance on the Application of the CLP Criteria Part 2: Physical Hazards: https://echa.europa.eu/documents/10162/2324906/clp_part2_en.pdf/e86ac2ec-269f-94aa-48ff-f2dd1205bdd2?t=1730718819524 UN Manual of Tests and Criteria: https://digitallibrary.un.org/record/3846833/files/Manual_Rev7_E.pdf
Phys. Chem. properties and anal. method	Yes	For packaging extrapolation, upward extrapolation up to 50 L can be accepted without data in bulk containers. For acceptance of larger sizes, additional data is required. For downwards extrapolation, half the tested size is accepted. Therefore, if the storage stability test is performed in e.g. a 1 L container and	

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		sufficient stability is demonstrated, the acceptable packaging sizes is 0.5 L – 50 L without further data.	
Toxicology	Yes – for non-professional uses and for metabolites that potentially leach to groundwater.	DK does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix IX. DK does not accept EUROPOEM II or German Guidance (Martin et al) as second tier for bystander and resident risk assessment. DK requires risk assessment for toddlers/small children for uses on recreational lawns in public areas but not for golf courses. In DK, recreational resident exposure assessment also applies to products intended for use on private lawns. DK does not accept the use of re-entry times as a refinement for risk assessment of recreational residence. DK does not accept the EU definition of non-relevance of metabolites. Denmark generally considers all metabolites as relevant, but in some cases, and after evaluation by DEPA (see the Danish national guidance), some metabolites may be accepted at concentrations up to 0.75 µg/L.	Danish: https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		Pesticides that are classified acute toxic in categories 1, 2, or 3 or with specific target organ toxicity SE in category 1 according to CLP, may not be used in private gardens, public areas and similar areas which are accessible to the public, areas around residential buildings, childcare institutions and similar, or to treat vegetation on borders with public roads or private gardens. In addition, these products cannot be sold to or be used by non-professional users. A minimum buffer strip of 2 meter to bystander and resident should be stated on the label when used by professionals. Buffer strips of 1, 2, 5 or 10 meter due to risk assessment for the bystander and resident may be necessary on the label (see the Danish national guidance). PPP's intended to be sold to and used by non-professional users have to fulfil the criteria outlined in Annex 14 of the Framework for Risk Assessment of Plant Protection Products (DEPA). Only concentrated products containing the following active substances can be authorised for non-professional use: insect soaps	

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		fatty acids sulphur or iron microbiological agents pheromones for insect confusion Products for non-professional users: Products which can bepurchased and used by everyone, including garden owners without a spraying certificate or spraying permit. In DK, operator exposure assessment is considered as worst case and therefore covers worker, bystander and resident exposure for non-professional products. Except for resident exposure on private lawns, no worker, bystander or resident exposure assessment is necessary. Non-professional users are assumed to use handheld spray equipment and have no PPE to protect them.	
Residues	Dossier must cover Danish conditions	N.A.	

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Efficacy	Dossier must cover Danish conditions. Bridging studies required for similar products.		
Fate and behaviour	Specific persistency assessment	DT_{50} soil < 180 days for active substance and some metabolites – otherwise no approval. Please consult the Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off	Danish: https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework
Fate and behaviour	Specific groundwater modelling – including all metabolites	The following requirements should be included in the core assessment: PELMO Hamburg or MACRO with Danish scenarios Karup and Langvad + specific input and output values. All metabolites that are not inherently non-relevant needs to be covered by the assessment. For uses in open greenhouses the half-life in soil measured in standard tests (representative for Danish agricultural soil) must be below 60 days (DT_{50} < 60 days) for active substances and their metabolites. Danish Environmental Protection Agency's supplementary framework for the environment for plant protection product uses in open greenhouses.	Danish: https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		Please consult the Danish supplementary framework for Plant Protection Product uses in open greenhouses.	
Ecotoxicology - Birds and Mammals	Higher tier guidance on risk assessment for birds and mammals	Danish refinement options for: FS, PD, PT, RUD, DT_{50} and interception	Find guidance in the latest Danish risk assessment framework at the respective webpages: Danish: https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework
Ecotoxicology - Aquatic organisms	Specific aquatic risk assessment	Specific assessment principles for mesocosm studies	Find guidance in the latest Danish risk assessment framework at the respective webpages: Danish: https://mst.dk/erhverv/sikker-kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation/evaluation-framework
Risk assessment for open greenhouses	Specific assessment for uses in open greenhouses	Please consult the Danish supplementary framework for Plant Protection Product uses in open greenhouses.	See above

Estonia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Phys. Chem. properties and anal. method	No		
Toxicology - Non-professional use	Yes	Authorisation of plant-protection products for non-professional use is done in case-by-case basis. However, products are considered not suitable for non-professional use if they have any of the following characteristics: • Products with several or far-reaching conditions for use. This may, for an example, mean requirements for safety distances, waiting periods or personal protective equipment. Gloves assigned due to product classification do not automatically exclude non-professional use. • Products that are labelled with at least one of the following pictograms: GHS05, GHS06, GHS08 and/or have following classification(s) according to CLP: - Acutely toxic (Acute tox. 1-3) - H300 Fatal if swallowed. - H301 Toxic if swallowed. - H310 Fatal if in contact with skin. - H311 Toxic if in contact with skin. - H330 Fatal if inhaled. - H331 Toxic if inhaled. - Highly corrosive (Skin corr 1a, 1B, 1C) - H314 Causes severe skin burns and eye damage.	

Estonia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- Severely damaging to to eyes (Eye Dam 1) - H318 Causes serious eye damage. - Respiratory sensitisation (Resp sens 1) - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. - Specific organ toxicity (STOT SE 1, 2; STOT RE 1, 2) - H370 Causes damage to organs. - H371 May cause damage to organs. - H372 Cause damage to organs through prolonged or repeated exposure. - H373 May cause damage to organs through prolonged or repeated exposure. - Mutagenic, carcinogenic or toxic to reproduction (Muta 1A, 1B, 2; Carc 1A, 1B, 2; Repr 1A, 1B, 2) - H340 May cause genetic defects. - H341 Suspected of causing genetic defects. - H350 May cause cancer. - H351 Suspected of causing cancer. - H360 May damage fertility or the unborn child. - H361 Suspected of damaging fertility or the unborn child. - Toxic by aspiration (Asp tox 1) unless childproof packaging has been used. - H304 May be fatal if swallowed and enters airways.	

Estonia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		• The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL.	
Toxicology - Acute Inhalation Toxicity	Yes	EE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix IX.	
Toxicology – Bystander and residents		EE does not accept EUROPOEM II as second tier toxicological risk assessment for bystander and resident risk assessment.	
Residues	No		
Efficacy	Dossier must cover Estonian conditions		
Fate and behaviour	No		
Ecotoxicology	No		

Finland			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
General	No	Mandatory appendix to applications from 1 May 2025 is Instructions for Use table, filled in in Finnish and Swedish. It is no longer mandatory to submit draft label texts to Finland.	For more information: Change of the authorization process for plant protection products | Finnish Safety and Chemicals Agency (Tukes)
General	No	Information on national requirements for the selection of precautionary statements for plant protection products in Finland can be found in Tukes website.	Classification and labelling | Finnish Safety and Chemicals Agency (Tukes)
Phys. Chem. properties and anal. method	No		
Toxicology	No	FI does not accept unknown toxicity as a part of CLP calculation method. This is in line with Commission Regulation (EU) No 284/2013 and Section 18.1.1.4 of this guidance.	
Toxicology. – Bridging priciples	No	Bridging to a vertebrate study initiated after June 14 2011, may be accepted under step 2, if the applicant can demonstrate that the vertebrate study was a last resort for the comparable formulation.	
Toxicology - Acute inhalation toxicity requirements	No	FI does not accept the pre-evaluation method described Appendix IX. Until a change in condition i) of the data requirement for inhalation toxicity of Regulation (EU) No 284/2013 has been made, or a harmonised EU interpretation of this condition has been established, an acute inhalation toxicity study **is required** if the applicant cannot justify an alternative approach under CLP. If an alternative approach is used, an acute inhalation toxicity of all components shall be provided or reliably predicted with a validated method, and it is the responsibility of the applicant to ensure that	

Finland			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		all necessary data about the co-formulants is provided by the supplier to the competent authority	
Toxicology- Skin sensitization	No	Finland applies the lower generic concentration limit < 0.1 % for acceptance of unknown skin sensitisation potential.	
Toxicology - Exposure assessment	No	National work rate / day for barley is 40 ha. Margin of safety (MOS) between the carcinogenic/reproductive NOAEL and AOEL shall be approximately 1000. In case where MOS is too small, a comparison between the modelled exposure level (e.g. % of AOEL for exposed group) and the carcinogenic/reproductive NOAEL will be made and should be approximately 1000.	
Toxicology - Non-professional use	No	Authorization of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be authorized for non-professional users if those have any of the following characteristics: • Product is explosive. • Extremely flammable, highly flammable or flammable. • Fatal or toxic if swallowed, in contact with skin or if inhaled. • Skin corrosive • Causes serious eye damage or is irritating to eyes. • Causes respiratory or skin sensitisation. • Carcinogenic, toxic to reproduction, mutagenic or fulfils criteria for specific target organ toxicity.	

Finland			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		• Product is presenting an aspiration hazard. • Waiting period exceeds 7 days. The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL.	
Residues	NO		
Efficacy	Dossier must cover Finnish conditions		
Fate and behaviour	NO	No specific requirements	
Ecotoxicology - Non-professional use	NO	Authorisation of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be authorized for non-professional users if those have any of the following characteristics: • Products containing an active substance listed as candidate for substitution at the EU level • Products with several or far-reaching conditions for use. This may, for example, mean requirements for safety distances, restriction of use in the ground water areas, restriction of use in the consecutive years (if risk for the soil organisms occurs after use in consecutive years) • Products which are particularly harmful to pollinating insects • Products (granules) which are particularly harmful to birds and mammals.	

Latvia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Phys. Chem. properties and anal. method	No		
Toxicology - Non-professional use	Yes	The following products cannot be accepted for non-professional use: • classified with any of the following (Acute Tox. 1, 2) H300; (Acute Tox. 3) H301; (Acute Tox. 1,2) H310; (Acute Tox. 3) H311; (Eye Dam. 1) H318; (Acute Tox. 1, 2) H330; (Acute Tox. 3) H331; (Muta. 1A, 1B) H340; (Muta. 2) H341; (Carc. 1A, 1B) H350; (Carc. 2) H351; (Repr. 1A, 1B) H360D; (Repr. 1A, 1B) H360F; (Repr. 2) H361d; (Repr. 2) H361f; (Lact.) H362 • if operator risk during use of PPP or after it when not using individual personal equipment exceeds allowable value PPP can not be authorised for non-professional use.	National regulation, Latvian 2012.gada 24.jūlija MK noteikumi Nr.509 „Noteikumi par augu aizsardzības līdzekļu laišanu tirgū saskaņā ar Regulu Nr.1107/2009”
Residues	No		
Efficacy	No		
Fate and behaviour	Yes	See footnote 27 in Section 21.2.2. and footnote 42 in Section 0.	
Ecotoxicology	No		

Lithuania			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Phys. Chem. properties and anal. method	No		
Toxicology - Acute inhalation toxicity requirements	No	Until a change in condition i) of the data requirement for inhalation toxicity of Regulation (EU) No 284/2013 has been made, or a harmonised EU interpretation of this condition has been established, an acute inhalation toxicity study should not be required if the applicant can justify an alternative approach under CLP. For this purpose, acute inhalation toxicity of all components shall be provided or reliably predicted with a validated method, and it is the responsibility of the applicant to ensure that all necessary data about the co-formulants is provided by the supplier to the competent authority. LT does not accept the pre-evaluation method described Appendix IX. If the substance(s) with unknown acute inhalation toxicity present(s) in the PPP, the data gap for this endpoint could be identified by LT on the case-by-case basis.	
Toxicology - Non-professional use	Yes	Plant protection products may not be authorised for non-professional use if those are classified for: • acute toxicity categories 1, 2 or 3, • for skin corrosion; for carcinogenicity.	Lithuanian:

Lithuania			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		• germ cell mutagenicity and reproductive toxicity, • for effects on or via lactation, • for respiratory sensitisation, • for specific target organ toxicity (H370, H371, H336, H372 and H373). A re-entry interval after an application of a PPP on turf, lawns, grassland etc. is not acceptable for non-professional use.	https://www.e-tar.lt/portal/lt/legalAct/26596c906f4611eabee4a336e7e6fdab
Toxicology – Re-entry periods		**Waiting period** in the greenhouses/tunnels/warehouses/empty warehouses after indoor application of PPP until re-opening is 24 hours without ventilation.	Lithuanian: https://www.e-tar.lt/portal/lt/legalAct/TAR.19431CB8A7D7/asr
Residues	No		
Efficacy	Dossier must cover Lithuanian conditions.		
Fate and behaviour	Yes	See core text in Section 21.2	
Fate and behaviour - Non-professional use	Yes	Plant protection products may not be authorised if risk mitigation measures are required to protect groundwater from contamination	
Ecotoxicology	No		

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
General	No	All use of PPPs is forbidden on children's play areas.	Document available in Norwegian.
Phys. Chem. properties and anal. method	No	The following plant protection products may not be authorised for use by non-professional users: • Products that are explosive (E) or oxidizing (O).	
Toxicology – Acute inhalatation	No	Acute Inhalation Toxicity: Until a change in condition i) of the data requirement for inhalation toxicity of Regulation (EU) No 284/2013 has been made, or a harmonised EU interpretation of this condition has been established, an acute inhalation toxicity study should be required according to the old data requirement on testing for inhalation toxicity (Regulation (EU) No 545/2011). This does not mean that we always will require an acute inhalation toxicity study. Looking at the listed circumstances in which such a study will be required according the old data requirement, we may for instance first consider submitted information concerning the proportion of small sized particles if the product is formulated as a powder, or whether the product is to be applied in a manner that is expected to generate a significant proportion of small sized particles (<50 µm). In cases where this information is not available, we may consider bridging arguments to another formulation. An evaluation of bridging to another formulation will require a full overview of the physical and chemical composition of the two formulations to be bridged, allowing a proper evaluation of whether the inhalation toxicity of the	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		formulation applied for should be considered as equal or less toxic than the other formulation (which has been tested for inhalation toxicity)	
Toxicology-non-professional use		<u>The directions for authorisation of non-professional use:</u> Important issues are: -use of substitutional principle - evaluation regarding storage of the plant protection product - evaluation regarding personal protection equipment for non-professional users lacking skills in handling plant protection products.	Document available in Norwegian.
Toxicology-non-professional use Not acceptable		<u>The following plant protection products may not be authorised for use by non-professional users:</u> Products that are acutely toxic category 1-2 (deadly) or category 3 (toxic); that are corrosive for the skin and eyes or can cause serious eye damage; that may cause allergy or asthma symptoms or breathing difficulties if inhaled; that may or possibly may give cancer, genotoxic effects or impair fertility or the unborn childs (CMR-substances) or that cause or may cause damage to organs by single or repeated exposure. Thus, plant protection products in Norway for non—professional use labelled with one or more of the following risk phrases according to CLP, will not be authorised: - H300 Fatal if swallowed. - H301 Toxic if swallowed. - H304 May be fatal if swallowed and enters airways	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- H310 Fatal if in contact with skin. - H311 Toxic if in contact with skin. - H314 Causes severe skin burns and eye damage. - H318 Causes serious eye damage. - H330 Fatal if inhaled. - H331 Toxic if inhaled. - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. - H335 May cause respiratory irritation - H336 May cause drowsiness or dizziness - H340 May cause genetic defects. - H341 Suspected of causing genetic defects. - H350 May cause cancer. - H351 Suspected of causing cancer. - H360 May damage fertility or the unborn child. - H361 Suspected of damaging fertility or the unborn child. - H362 May cause harm to breast-fed children - H370 Causes damage to organs. - H371 May cause damage to organs. - H372 Cause damage to organs through prolonged or repeated exposure. - H373 May cause damage to organs through prolonged or repeated exposure.	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		For products containing substances carcinogenic, reprotoxic or toxic by prolonged exposure below the classification limit, estimating exposure without personal equipment will be done. If the exposure is above the AOEL, the product will not be approved for non-professional use.	
Toxicology-non-professional use Acceptable	No	The following PPPs can be accepted for non-professional use: Ready for use: Plant protection products without classification/labelling, or with irritating characteristics (if there are no better alternatives). These products will not be approved if there is extensive need for personal protection equipment. Concentrate: Plant protection products with irritating characteristics may be approved. Products labelled as harmful to health may be approved if there are no better alternatives (health). These products will not be approved if there is extensive need for personal protection equipment. Powder soluble in water: Powder soluble in water is not suitable for non-professional use because of the danger for exposure. But if the products are delivered in small disposable packages as water soluble bags they may be accepted for non-professional use.	
Toxicology-non-professional use Worker assessment		Worker assessment for non-professional users will be considered case by case. As an example, ornamentals indoors and use of plant rodlet (via soil insertion) would not be considered relevant.	
Residues	No		The Norwegian Food Safety Authority is the responsible authority.

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Efficacy	Dossier must cover Norwegian conditions		The Norwegian Institute of Bioeconomy Research is responsible for the efficacy evaluations.
Fate and behaviour	No	Directions for approval of non-professional use: When evaluating such products persistence is especially important. Products that have a mean half-life in soil of more than 100 days will not be authorised for outdoor use.	
Ecotoxicology-bees	No	Directions for labelling of PPPs toxic to bees: A pictogram of a bee may be required on the label*. The bee pictogram shall be applied if an evaluation according to the uniform principles shows for one or more of the labelled uses that risk mitigation measures must be applied to protect bees or other pollinating insects. While waiting for the update of the EFSA Bee guidance document, the bee pictogram shall also be applied if risk mitigation measures need to be applied to protect bees or other pollinating insects according to the interim methodology in the NZ. Furthermore, the plant protection product shall be labelled with the bee pictogram if the acute oral or contact LD50 for the product (given as µg a.s./bee), active substance or relevant metabolites is lower than or equal to 11 µg/bee.	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		The bee pictogram shall always be accompanied by the phrase «SPe 8 Dangerous to bees». The bee pictogram will be attached to the decision letter.	
Ecotoxicology-Permanent-greenhouse		Directions for labelling of PPPs authorised for use in permanent greenhouses: Greenhouse products may, depending on their environmental profile, be identified as a "spesialpreparat for veksthus" *.	
Ecotoxicology-non professional use		Directions for authorisation of non-professional use: As a general rule, products that are in focus because of their ecotoxicological profile, should not be authorised for non-professional use. When evaluating such products, toxicity to bees is especially important. Products that are very toxic too bees/pollinating insects (LD50 <1.0 a.s. µg/bee) will not be authorised for outdoor use.	
Overall	Yes	National requirements for approval of adjuvants (see https://www.mattilsynet.no/language/english/plants/plant_protection_products/Approval_plant_protection_products/adjuvants.22424).	
Comparative assessment (CA)		The Norwegian Food Safety Authority will perform the assessment for the product, containing a candidate for substitution. The steps of the CA will be included it in the final Part A of the Registration Report. The applicant will be given the possibility to comment, if the conclusion of the CA is negative for the applicant.	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		Mandatory Comparative Assessment - Article 50.1 The applicant should submit the information to support the process of comparative assessment, by using the template in the Appendix of SANCO/11507/2013. Optional Comparative Assessment - Article 50.2 The Member State may in exceptional cases also perform an optional CA when evaluating an application for authorisation of a plant protection product not containing a candidate for substitution or a low-risk active substance, if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State. The applicant should address the following question in the application for the plant protection product: Does a non-chemical control or prevention method exist for the same use and is it in general use in the Member State? This information could be included in the Part A of the Registration Report, chapter 4.	

*Criteria for defining a ppp as “spesialpreparat for veksthus” are under development.

Sweden			
Section	**Supplementary data requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Monitoring		Monitoring data is only accepted as an option for higher tier assessments in Sweden if all the following conditions are met: (a) Monitoring data from the Danish PLAP is available for the active substance and any potentially relevant metabolite at the time of application. (b) The proposed conditions of use of the product in Sweden are directly comparable to the experimental condition of application of the product in the Danish PLAP. The applicant needs to provide a factual argumentation regarding this 'comparability', if necessary using a risk-envelope. (c) The results from MACRO In FOCUS simulations with the Swedish scenario Näsbygård and/or Önnestad indicate a non-acceptable leaching risk for the active substance or potentially relevant metabolites, while they indicate an acceptable leaching risk with the Swedish scenario Krusenberg. The Swedish Chemicals Agency considers that environmental conditions of the Danish PLAP fields do not cover the Krusenberg-scenario.	

Sweden			
Section	**Supplementary data requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		In such cases, the results of the Danish PLAP, as published by the Geological Survey of Denmark and Greenland (GEUS), can be used by the applicant as higher tier assessment, as a complement for the simulation results. To be acceptable, results must very convincingly demonstrate that unacceptable leaching will not occur. Only data from PLAP 'groundwater installations' shall be used and not samples from drains or suction cups. The standard tiered modelling procedure for groundwater (described in the table 'National requirements for PEC_{gw} simulations') must be followed, and simulation results presented, even when PLAP-results are used. PLAP-results are thus seen as a 3rd tier in the groundwater exposure assessment. Historical monitoring data does not override any unacceptable risks identified from modelling results. In all cases, conditions including future monitoring programs does not justify disregarding any unacceptable risks identified from modelling results.	
Products which may be used by non-professional users		Only products containing approved low risk substances or active substances listed in appendix 1 of the Agency regulation KIFS 2022:3 can be authorised for use by non-professional users.	

Sweden			
Section	**Supplementary data requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		The Swedish Chemicals Agency generally recommends that products intended for non-professional use are sold as ready-to-use formulations, in package size not exceeding 10 kg or 10 L.	
Phys. Chem. properties and anal. method	Yes	In addition to the requirements specified in Section 17.2 on adjuvants, the following information must be provided by the applicant to KemI for all recommended and mandatory adjuvants Chemical name or trade name Full composition of the adjuvant Compatibility with the plant protection product	
Toxicology		SE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix IX. SE refers to the CLP regulation (Annex I, section 3.1.3.6.2.2) in terms of accepting unknown toxicity in the interest of animal welfare. Regarding acute inhalation toxicity SE will not draw conclusions via pre-evaluation method as a stand-alone tool.	
Residues	No		
Efficacy	No		
Fate and behaviour	No		
Ecotoxicology	No		

Appendix VI. List of mitigation options available in the MSs in the NZ

Denmark		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology: Operator exposure	- limits on spraying methods authorised - requirements on special permits for spraying personnel - requirements on special packaging (dimensions, design, possibly water-soluble packaging) - specific requirements concerning use of protective equipment - Rain wear triggered by exposure calculation in EFSA OPEX online calculator is accepted as PPE, when applied as a two piece protective suite that is chemically resistant and waterproof. See also Table 18.4 on the use of risk mitigation measures in the EFSA OPEX online calculator. See the 'Danish Framework for Assessment of Plant Protection Products' for specific requirements	50% drift reduction equipment is accepted for operator, bystander, and resident exposure assessment in the EFSA GD exposure calculator
Toxicology: Worker exposure	- waiting periods before entry into treated areas - re-entry periods before working in/with treated crops - specific requirements concerning use of protective equipment See also Table 18.4 in the use of risk mitigation measures in the EFSA OPEX online calculator. See the 'Danish Framework for Assessment of Plant Protection Products' for specific requirements	50% drift reduction equipment is accepted for operator, bystander, and resident exposure assessment in the EFSA GD exposure calculator
Toxicology: Bystander and resident exposure	- buffer zone for spraying See also Table 18.4 on the use of risk mitigation measures in the EFSA OPEX online calculator. See the 'Danish Framework for Assessment of Plant Protection Products' for specific requirements	50% drift reduction equipment is accepted for operator, bystander, and resident exposure assessment in the EFSA GD exposure calculator
Residues	- PHI	
Fate	Groundwater: Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications	
Ecotoxicology: Birds and mammals	The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; Spe 7) is not accepted.	

Denmark		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology: Aquatic organisms Surface water	Buffer zones, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards. Further details regarding non-spray buffer zones can be found in the latest version of Danish Framework for Assessment of Plant Protection Products.	Not accepted*
Ecotoxicology: Bees	Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise.	
Ecotoxicology: Non-target arthropods	Buffer zones to protected areas, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards. Further details regarding non-spray buffer zones can be found in the latest version of Danish Framework for Assessment of Plant Protection Products.	Not accepted*
Ecotoxicology: Soil organisms	Restrictions of use, dose and frequency	
Ecotoxicology: Non-target plants	Buffer zones to protected areas, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards. Further details regarding non-spray buffer zones can be found in the latest version of Danish Framework for Assessment of Plant Protection Products.	Not accepted*

* Drift reducing equipment are not applied in the risk assessment for approval, but are accepted to be used by famers in order to reduce buffer zones.

Estonia		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
General	- It is prohibited to spray a plant protection product if wind speed exceeds 4 m/s unless it is permitted to use the plant protection product at a higher wind speed in the technical data provided in the user manual of the plant protection equipment. - It is prohibited to spray when the air temperature exceeds 25 ºC. - Professional users of plant protection products must have undergone plant protection training and they must hold a plant protection certificate certifying it.	
Toxicology		
Operator exposure	- specific requirements on the use of protective equipment See also Table 18.4 on the use of risk mitigation measures in the EFSA OPEX online calculator	50% drift reduction equipment is accepted for operator, bystander and resident exposure assessment in the EFSA GD exposure calculator
Worker exposure	- waiting periods for re-entry into treated areas (indoor and field) Default waiting period in greenhouses/tunnels (greenhouse/tunnel is closed-off/locked) after application is 18 hours. - specific requirements on the use of protective equipment See also Table 18.4on the use of risk mitigation measures in the EFSA OPEX online calculator	
Bystander and resident exposure	- buffer zone for spraying up to 10 m See also Table 18.4 on the use of risk mitigation measures in the EFSA OPEX online calculator	50% drift reduction equipment is accepted for operator, bystander and resident exposure assessment in the EFSA GD exposure calculator
Residues	- PHI	
Fate	- the same plant protection product on the same field in consecutive years - it is prohibited to spray a plant protection product in a water protection zone closer than 20 meters from the water boundary of the Baltic Sea, Lake Võrtsjärv, Lake Lämmijärv, Lake Peipus and Lake Pskov, 10 meters from the water boundary of other lakes, reservoirs, rivers, brooks, springs, main ditches and channels, and artificial recipients of land	

Estonia		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
	improvement systems, 1 meter from the water boundary of artificial recipients of land improvement systems with a catchment area of less than 10 km2 unless a wider buffer zone is noted on the labelling of the packaging of the plant protection product.	
Ecotoxicology- Birds and mammals	The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; Spe 7) is not accepted.	
Ecotoxicology - Bees	It is prohibited to spray crop plants and weeds when in flower. - Restrictions of use during flowering and foraging activity, including restrictions in time: plants may be sprayed after the flying time of bees between 22:00 and 05:00.	-
Ecotoxicology - Aquatic organisms	Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk (Table 21.7). If risk is not acceptable using at most the maximum allowed buffer zone for Estonia together with 50% drift reducing nozzles, the product cannot be authorized.	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology- Non-target plants	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. If risk is not acceptable using at most the maximum allowed buffer zone for Estonia together with 50% drift reducing nozzles, the product cannot be authorized.	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology - Non-target arthropods	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. If risk is not acceptable using at most the maximum allowed buffer zone for Estonia together with 50% drift reducing nozzles, the product cannot be authorized.	Nozzles with 50, 75 and 90 % reduction

Finland		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology	FI accepts using the EFSA OPEX Online Calculator (described in 18.2.1.3) for determining the worker **re-entry period** (Option1) and for time restriction on the use of gloves (PPE)/work wear (Option 2 and 3) in case-by-case basis. Operator exosure: Rain wear triggered by exposure calculation in EFSA OPEX online calculator is not automatically accepted as PPE, this will be assessed case by case. See also Table 18.4 on the use of risk mitigation measures in the EFSA OPEX online calculator.	50% drift reduction equipment is accepted for operator, bystander and resident exposure assessment in the EFSA GD exposure calculator.
Fate and behaviour Ground water	If a non-relevant metabolite(s) is mobile in the soil (i.e. PEARL/PELMO result > 0.10 µg/l) the product may not be used in the classified groundwater areas used or suitable for water supply (groundwater area classes 1 and 2). The product is not allowed to be used nearer than 30-100 metres to the wells and springs used for drinking water. The use of the product should be avoided in fine sand soils or soils coarser than fine sand. A restriction on the use in the consecutive years can be set for the plant protection products, if risk occurs after use in consecutive years.	
Ecotoxicology -Birds and mammals	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011. The risk mitigation option “Do not apply during the bird breeding period” ((EU) No 547/2011; Spe 7) is not accepted.	
Ecotoxicology- Aquatic organisms	Buffer zones, max width 20 m for field crops, 30 m for bush berries, nurseries and 50 m for orchards or vegetated filter strips (max 10 m). Drift reducing nozzles can be used to further reduce the risk from spray drift (Table 21.7).	Nozzles with 50, 75 and 90 % reduction

Finland		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology- Bees	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. Restrictions of use during flowering and foraging activity including restrictions in time: plants may be sprayed after the flying time of bees between 22 and 5 o'clock.	Nozzles with 50, 75 or 90% reduction Only inspected spraying equipment can be used. See: https://tukes.fi/en/inspection-of-plant-protection-application-equipment
Ecotoxicology- Non-target arthropods	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk.	Nozzles with 50, 75 or 90% reduction Only inspected spraying equipment can be used. See: https://tukes.fi/en/inspection-of-plant-protection-application-equipment
Ecotoxicology- Soil organisms	A restriction on the use in the consecutive years can be set for the plant protection products, if risk occurs after use in consecutive years (calculated according to the Nordic PEC_{soil} calculator).	-

Finland		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology- Non-target plants	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk.	Nozzles with 50, 75 and 90 % reduction Only inspected spraying equipment can be used. See: https://tukes.fi/en/inspection-of-plant-protection-application-equipment

Latvia		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology	Latvia accepts mitigation options as shown in Table 18.4 **NZ approach of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator.** Latvia accepts using the EFSA OPEX online calculator for determining the number of days after application when worker re-entry is acceptable.	50% drift reduction equipment in the EFSA GD exposure calculator is accepted
Ecotoxicology - Birds and mammals	The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; Spe 7) is not accepted. For seed treatments: Risk mitigation phrase SPe 5 and SPe 6 in Appendix III of "Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products" should be used.	
Ecotoxicology - Aquatic organisms and surface water	Protection Zone Law sets minimum widths of surface water body protection zones. Therefore a 10 m buffer zone is a requirement for all PPPs. If risk assessment result is that buffer zone of 1-10 meters is necessary, it is not on the label. If >10 m zone is necessary, it is indicated on the label. Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk (Table 21.7). Buffer zones calculating on every 5 meters which are based on toxicity to water organisms: min – 5 m, max – 30 m for field crops and vegetables, 40 m for bush berries & nurseries, 50 m for orchards. Mitigation of run-off: 10 m vegetative buffer zone is acceptable.	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology - Bees	Risk mitigation options in SPe 8 in Appendix III of "Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products" could be used. And those are usually restrictions of use during flowering and foraging activity. Including restrictions in time: use only from 22.00-05.00. Restrictions in use on flowering weeds are also used.	

Latvia		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology - Non-target arthropods	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. Buffer zone is set as minimum - 3 m (following of 5 m and calculated on every 5 meters). There is no limit for the maximum buffer zone width set in the national legislation. For glasshouse uses option not to introduce pollinators or beneficial arthropods for certain period of time after application is used.	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology - Soil organisms	If product is toxic to earthworms, soil macro- or micro- organisms, or if there is a possibility that product will ac-cumulate in soil use restrictions of application timing (growth stage – BBCH), dose or/and frequency.	
Ecotoxicology - Non-target plants	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. Buffer zone is set as minimum - 3 m (following of 5 m and calculated on every 5 meters). There is no limit for the maximum buffer zone width set in the national legislation.	Nozzles with 50, 75 and 90 % reduction

Lithuania		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology	Lithuania accepts risk mitigation measures as shown in Table 18.4 *NZ approach of choosing PPE and other risk mitigation measures.* **Rain suit,** determined by the EFSA OPEX online calculator for greenhouse only (dense crop), is acceptable as one of risk mitigating measures for operator. Rain suit at national LT level currently requires a statement on the label: "*The operator should wear a waterproof and chemical-resistant one-piece coverall or two-piece suit that provides no less protection than Type 3 protective clothing (certified to LST EN 14605).*" **An Acceptable re-entry interval**, determined by the EFSA OPEX online calculator, as one of risk mitigating measures for worker is acceptable on case-by-case basis. Considering the different PPE cases, only realistic time point post application could be acceptable. **Waiting period** in the greenhouses/tunnels/warehouses/empty warehouses after indoor application of PPP until re-opening is 24 hours without ventilation.	50% drift reduction equipment is accepted for operator, bystander and resident exposure assessment in the EFSA GD exposure calculator
Residues	- PHI - in some cases, restrictions for straw or haulm from treated crops as animal feed or bedding at all or for some period after last application - in some cases, all livestock keeping out of treated areas for some period after treatment	
Fate - Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications.	
Ecotoxicology - Birds and mammals	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011. The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; Spe 7) is not accepted.	
Ecotoxicology - Aquatic	Non-spray buffer zones and vegetated filter strips alone or in combination with drift reducing nozzles can be used to reduce the risk.	Nozzles with 50, 75 and 90 % reduction

Lithuania		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
organisms and surface water	Min – 3m, max – 20 m for field crops and vegetable and 40 m for orchards. Mitigation of run-off: 10 m of vegetative buffer zone is acceptable.	
Ecotoxicology - Bees	Restrictions of use during flowering and foraging activity including restrictions in time: plants should be sprayed after the flying time of bees between 21 and 4 o'clock. Regulation of use PPP: to inform beekeepers those have bees in radius of 2.5km not later than 48 hours before application.	
Ecotoxicology - Non-target arthropods	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. Min – 3m, max – 15m for field crops and vegetable and 30 m for orchards.	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology - Soil organisms	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
Ecotoxicology - Non-target plants	In-field non-spray buffer zones alone or in combination with drift reducing nozzles can be used to reduce the risk. Buffer zones: min – 3m.	Nozzles with 50, 75 and 90 % reduction

Norway		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology	NO accepts mitigation options as shown in Table 18.4**: NZ approach of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator.** When rain suit is applicable as RMM "waterproof protective coverall" will be stated on the label. As a general rule, after indoor application of PPP thorough ventilation is required, and re-entry within 48 h after application should only be done wearing PPE as specified on the label.	50% drift reduction equipment in the EFSA GD exposure calculator is accepted
Ecotoxicology - Birds and mammals	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011. The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; Spe 7) is not accepted.	
Ecotoxicology - Aquatic organisms	The accepted mitigation measures include no-spray buffer zones, drift-reducing nozzles and vegetated filter strips, and the accepted distances to surface water are listed in Table 21.7. If FOCUS step 3 PEC-values are required to demonstrate no unacceptable risk for aquatic organisms, the need for a 5 m no spray buffer zone will be determined on a case-by-case basis.	Yes (see Table 21.7)
Ecotoxicology - Bees	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
Ecotoxicology - Non-target arthropods	To protect non-target arthropods, in-field buffer zones and/or drift-reducing nozzles to non-agricultural land may be used. The acceptable widths of the in-field buffer zones are currently not defined but will be given in the decision letter.	Yes (see Table 21.7)
Ecotoxicology - Soil organisms	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
Ecotoxicology - Non-target plants	To protect non-target plants, in-field buffer zones and/or drift-reducing nozzles to non-agricultural land may be used. The acceptable widths of the in-field buffer zones are currently not defined but will be given in the decision letter.	Yes (see Table 21.7)

Ecotoxicology - Greenhouse products	Greenhouse products may be identified as a “spesialpreparat for veksthus”. For these products, a mitigation option is to handle greenhouse waste in accordance with the requireme set down in § 25 in the Norwegian national regulation (Forskrift om plantevernmidler). PPPs will be labelled to indicate their status as a “spesialpreparat for veksthus”. For greenhouse products identified as “spesialpreparat for veksthus” the following text shall be included on the label: “Dette er et spesialpreparat for veksthus. Vegetativt avfall, jordblandinger, vekstmedium og lignende som fjernes fra veksthuset skal lagres i minst ett år på tett underlag og være skjermet fra nedbør på en slik måte at det ikke gir avrenning til omgivelsene.»	

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
General spray drift reduction	For application with boom sprayer and air blast sprayer fixed buffer zones are not applied in Sweden, instead we use the tool "Hjälpredan" Please refer to the website Hjälpredan – a tool for determining safety distances for more information.	
Chemistry	Sweden may set the shelf-life of the PPP based on acceptable interim data from ambient shelf-life study.	
Toxicology	Sweden accepts mitigation options as shown in Table 18.4**: NZ approach of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator.** Waiting period before re-entry (indoor uses) is decided on a case-by-case basis and is either 24 h or 48 h with/without ventilation.	50% drift reduction equipment in the EFSA GD exposure calculator is accepted
Fate - groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications. Modelling for biennial and triennial applications may be provided for any crop to demonstrate acceptable use. Please note that every fourth- (or fifth-) year simulations are not accepted by Sweden. **Permanent structures for protected uses (not walk in tunnels)** Possible risk mitigation options are restrictions based on eliminating exposure routes via drainage, in case risk is identified or if risk has not been addressed.	
Ecotoxicology - Birds and mammals	The risk mitigation option "Do not apply during the bird breeding period" ((EU) No 547/2011; SPe 7) is not accepted. **Permanent structures for protected uses (not walk-in tunnels)** Possible risk mitigation options are restrictions based on eliminating exposure routes, e.g via drainage and or treated plants transferred to field, in case risk is identified or if risk has not been addressed.	

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology - Aquatic organisms and surface water	**Boom sprayer and air blast sprayer** Buffer zones, max width 15 m for field crops, bush berries, nurseries and 20 m for orchards. Drift reducing nozzles can be used to further reduce the risk from spray drift (please refer to Table 21.7. Possible surface water mitigation measures in the Member States of the NZ . "Possible surface water mitigation measures in the Member States of the Northern zone"). **Handheld sprayer, professional use** Drift reducing equipment, e.g shield or nozzles. **Handheld sprayer, non-professional use** Buffer zones, max width 10 m. **Permanent structures for protected uses (not walk in tunnels)** Possible risk mitigation options are restrictions based on eliminating exposure routes, e.g via drainage, condensation water, filter rinsing water and air/ventilation, in case risk is identified or if risk has not been addressed.	Boom sprayer and handheld sprayer: 50, 75 or 90% Air blast sprayer: 25, 50, 75, 90 or 99%
Ecotoxicology - Bees	Mitigation options in Spe8 in Commission Regulation (EU) No 547/2011 are accepted. In addition, in-field buffer zones are accepted to avoid exposure of beehives outside the field. **Boom sprayer and air blast sprayer** Buffer zones, max width 15 m for field crops, bush berries, nurseries and 20 m for orchards Drift reducing nozzles can be used to further reduce the risk from spray drift. **Handheld sprayer, professional use**	Boom sprayer and handheld sprayer: 50, 75 or 90% Air blast sprayer: 25, 50, 75, 90 or 99%

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
	Drift reducing equipment, e.g. shield or nozzles. **Handheld sprayer, non-professional use** Buffer zones, max width 10 m. **Permanent structures for protected uses (not walk-in tunnels)** Possible risk mitigation options are restrictions based on eliminating exposure routes, e.g via air/ventilation and or treated plants transferred to field, in case risk is identified or if risk has not been addressed.	
Ecotoxicology - Non-target arthropods	**Boom sprayer and air blast sprayer** Buffer zones, max width 15 m for field crops, bush berries, nurseries and 20 m for orchards. Drift reducing nozzles can be used to further reduce the risk from spray drift. **Handheld sprayer, professional use** Drift reducing equipment, e.g shield or nozzles. **Handheld sprayer, non-professional use** Buffer zones, max width 10 m. **Permanent structures for protected uses (not walk-in tunnels)** Risk mitigation options are restrictions that are based on eliminating possible exposure routes, e.g via air/ventilation, in case risk is identified or if risk has not been addressed.	Boom sprayer and handheld sprayer: 50, 75 or 90% Air blast sprayer: 25, 50, 75, 90 or 99%
Ecotoxicology - Soil organisms	Modelling of PEC_{soil} with biennial and triennial applications may be provided for any crop to demonstrate acceptable use. Please note that every fourth- (or fifth-) year simulations are not accepted by Sweden. **Permanent structures for protected uses (not walk-in tunnels)**	

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
	Risk mitigation options are restrictions that are based on eliminating possible exposure routes, e.g via distribution of contaminated substrate, in case risk is identified or if risk has not been addressed.	
Ecotoxicology - Non-target plants	**Boom sprayer and air blast sprayer** Buffer zones, max width 15 m for field crops, bush berries, nurseries and 20 m for orchards. Drift reducing nozzles can be used to further reduce the risk from spray drift. **Handheld sprayer, professional use** Drift reducing equipment, e.g shield or nozzles. **Handheld sprayer, non-professional use** Buffer zones, max width 10 m. **Permanent structures for protected uses (not walk-in tunnels)** Risk mitigation options are restrictions that are based on eliminating possible exposure routes, e.g via air/ventilation, in case risk is identified or if risk has not been addressed.	Boom sprayer and handheld sprayer: 50, 75 or 90% Air blast sprayer: 25, 50, 75, 90 or 99%

Appendix VII. Recommended structure for the documentation

Folder structure (dRR format version 2015):

- Admin (Cover letter, application form)
- dRR
  1) Part A
  2) Part B
     a) dRR section 0 (Product Background, Regulatory Context and GAP information)
     b) dRR section 1, 2, 4 (Identity, physical and chemical properties and further information)
     c) dRR section 3 (Efficacy data and information)
     d) dRR section 5 (Analytical methods)
     e) dRR section 6 (Mammalian toxicology)
     f) dRR section 7 (Metabolism and Residues)
     g) dRR section 8 (Environmental fate)
     h) dRR section 9 (Ecotoxicology)
     i) dRR section 10 (Assessment of the relevant metabolites in groundwater)
  3) Part C
     a) dRR Part C
     b) Other confidential documents (e.g. SDS)
  4) Part K (KIIIA test and study reports)
     a) Section 0 (Product Background, Regulatory Context and GAP information)
     b) Section 1 (Identity)
     c) Section 2 (Physical and chemical properties)
     d) Section 3 (Efficacy data and information)
     e) Section 4 (Further information)
     f) Section 5 (Analytical methods)
     g) Section 6 (Mammalian toxicology)
     h) Section 7 (Metabolism and Residues)
     i) Section 8 (Environmental fate)
     j) Section 9 (Ecotoxicology)
     k) Section 10 (Assessment of the relevant metabolites in groundwater)
- GAP (Master GAP, GAP for each country)
- Label (Master label, country specific labels)
- Letter of Access (if relevant)
- Additional documents

Appendix VIII. Acute inhalation toxicity – for spray application

Until a change in the Data Requirements Regulation (EU) No 284/2013 section 7.1.3, condition i) or a harmonised EU interpretation is established, information on acute inhalation toxicity should always be submitted when a Ready-to-Use PPP is to be applied by spraying. All other PPPs that are to be applied by spraying should undergo the pre-evaluation[82] as described below before gathering further information on acute inhalation toxicity. See Figure 3.

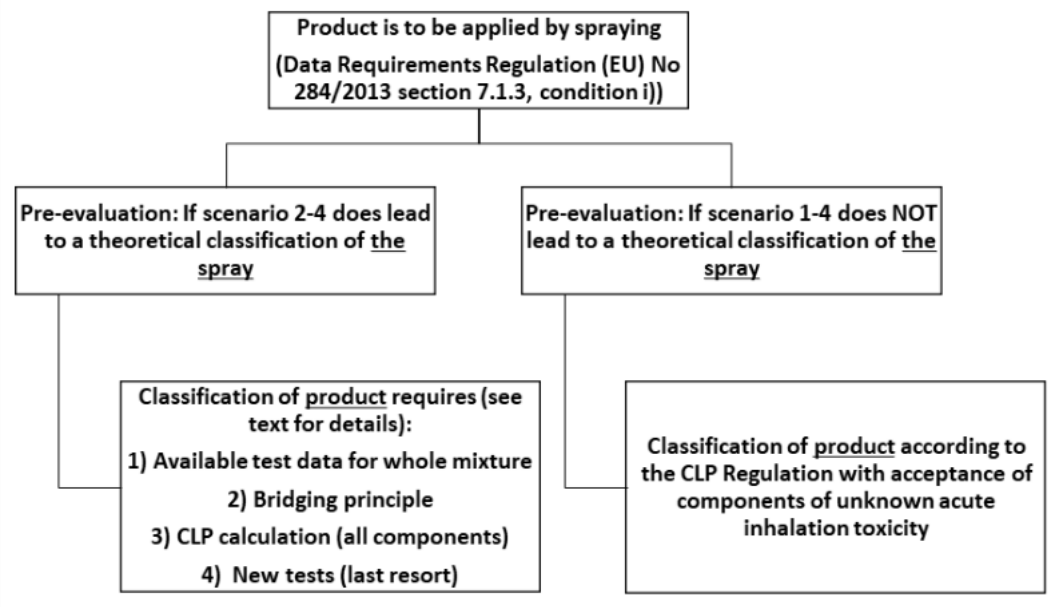

Figure 3 Overview of pre-evaluation and classification of product applied by spraying

The aim of the pre-evaluation is to establish if the *spray dilution* should theoretically[83] be classified, according to CLP, under worst-case assumptions. The pre-evaluation is based on the dilution rate in the GAP and assumes worst case acute inhalation toxicity (cat. 1 classification) of the product and its components[84] with unknown acute inhalation toxicity. The outcome of the pre-evaluation is either A) the spray is theoretically classifiable or B) the spray is not theoretically classifiable.

It can be calculated, if the spray dilution should, theoretically, be classified under the following scenarios:

1) The product is diluted more than 1000 times (assume ATE 0.005 mg/L): The spray dilution is not theoretically classifiable

[82] This approach is not accepted by NO, FI and LT. SE will not draw conclusions via pre-evaluation method as a stand-alone tool. Please refer to Appendix V for national requirements.
[83] Only products on the market are classified, not the spray dilution. Calculating a theoretical classification of the spray dilution is only to aid the decision making as to whether acute inhalation toxicity of the product is relevant for situations in which the product is to be applied by spraying.
[84] The word 'component' originates from the Data Requirements Regulation (EU) No 284/2013. No definition is provided but in the above context it includes co-formulants, synergists, safeners, and impurities as a minimum.

2) The product is diluted less than 1000 times and the component(s) of unknown inhalation toxicity are considered orally acute toxic (LD50< 2000 mg/kg bw):
The acceptable amount of components with a theoretical classification of acute inhalation tox cat. 1 and unknown acute inhalation toxicity can be calculated with the following equation assuming an ATE of 0.005 mg/L (acute inhalation cat. 1). The 5 mg/l reflects the upper limit of cat. 4 classification and hence if above, the spray dilution is theoretically not classifiable:

Acceptable amounts [Aa_2][85] of components with unknown and cat 1 classification:

$$Aa_2\ \% < \frac{dilution\ x\ 0.005\ mg/l}{5\ mg/l} x100\%$$

Simplified:

$$Aa_2\ \% < dilution\ x\ 0.1\%$$

For instance, if the product is diluted by more than 100 times, then an acceptable amount (Aa) of the components of unknown acute inhalation toxicity or with a classification of acute tox cat. 1 is 10% or less.

3) The product is diluted less than 1000 times and the component(s) of unknown inhalation toxicity are not considered orally acute toxic (LD50> 2000 mg/kg bw):

It is possible to refine the assumptions of worst case by assuming an ATE of 0.05 mg/L, when the component(s) are not considered orally acute toxic. Then the acceptable amount of components with a classification of acute inhalation tox cat. 2 and unknown acute inhalation toxicity can be calculated using the following equation:
Acceptable amounts [Aa_3][86]of components with unknown and cat. 2 classification:

$$Aa_3\ \% < \frac{dilution\ x\ 0.05\ mg/l}{5\ mg/l} x\ 100\%$$

Simplified:

[85] Components present ≥ 0.1 % are relevant to include
[86] Components present ≥ 1 % are relevant to include

$$Aa_3\,\% < \ dilution\ x\ 1\%$$

For instance, if the product is diluted 100 times, then an acceptable amount (Aa) of the components of unknown acute inhalation toxicity or with a classification of acute tox cat. 2 is 100% or less.

4) If the product is diluted less than 1000 times and contains several components with unknown acute inhalation toxicity, where some ingredients fulfil the criteria for scenario 3 while others fulfil criteria for scenario 2, a calculation combining these two options (scenario 2 and 3) can be used:

$$If \sum_{i=1}^{n} \frac{C_{2i}}{Aa_2} + \sum_{j=1}^{m} \frac{C_{3j}}{Aa_3} \leq 1, the\ combined\ amount\ of\ components\ is\ acceptable$$

$n\ =\ the\ number\ of\ components\ fulfilling\ scenario\ 2$

$m\ =\ the\ number\ of\ components\ fulfilling\ scenario\ 3$

$C_{2i} =\ concentration\ (\%) of\ component\ i\ with\ oral\ LD50\ <\ 2000\ mg/kg\ bw$

$C_{3j} =\ concentration\ (\%)\ of\ component\ j\ with\ oral\ LD50\ >\ 2000\ mg/kg\ bw$

$Aa_2 = dilution\ \times 0.1\%$

$Aa_3 = dilution\ \times 1\%$

Once it has been determined if the *spray dilution* is theoretically classifiable or not, one should proceed to option A) or B) below to address acute inhalation classification of the *product*.

A) <u>The spray dilution is theoretically classifiable</u>
If the <u>spray</u> is theoretically classifiable based on the worst case assumption (see scenarios 1-3 above for the assessment), further information on acute inhalation toxicity will be required, according to the data requirements, to address the classification of the <u>product</u>.
The information should be given according to the tiered approach in the CLP Regulation: 1) available test data for the whole mixture, 2) bridging principle, 3) calculation of classification (however for PPPs information is required for all components in contrast to the CLP regulation), and 4) new tests (which is a last resort).
If the information leads to classification of the <u>product</u>, MS will decide whether the product can be authorised for professionals and specific conditions for use will be set.

B) <u>The spray dilution is not theoretically classifiable</u>

If the spray is not theoretically classifiable based on the worst-case assumption, further information on acute inhalation toxicity will not be required (see scenarios 1-4 above for the assessment).
The classification of the product should then be based on information fulfilling the CLP Regulation without the addition of PPP data requirements. Hence, this is the only case where the sentence from CLP ‘x percent of the mixture consists of ingredient(s) of unknown toxicity’ is usable for PPPs.

Appendix IX. Calculation of classification – co-formulants

All information about the toxicity of a co-formulant, including skin and eye irritation and skin sensitisation, must be supported by a thorough and transparent justification, so that MS can evaluate the information. There may be information available from several sources (see example list below) and by applying the weight of evidence approach the combined information can be used for the toxicological assessment of a co-formulant.

If the co-formulant is a mixture, information on all components in the mixture must be provided - unless the mixture has been tested.

All information must be provided by the applicant or supplier. The justification must contain an indication of sources and why they are considered reliable. A justification is always required.

The provided and justified information will be assessed case-by-case in relation to whether it is sufficient for assessing the toxicity of the co-formulant. The following is a non-prioritised and non-exhaustive example list and is only for the purpose of gathering information from a wide range of sources. Since the process of classification of plant protection products differ between zonal member states, the outcome of classification may be different from country to country. However, it is encouraged that MSs should seek harmonisation during the commenting process.

- MSDS/SDS (material safety data sheet) e.g, data available in the Section 11 Toxicological information.
    - When data in SDS is based on read-across data/similar/analogue – the mixture/substance should be identified. If it is not identified in SDS, applicant should ask supplier for this information.
    - Information concerning the studies conducted shall be provided (e.g. OECD TG and study result (i.e. LC50/LD50) or conclusion by route-to-route extrapolation/ QSAR/Read-across/analogy).
    - If an exposure route is waived (e.g. acute inhalation toxicity) for co-formulants, this must be justified.
    - "No data available" (or similar) stated in the SDS should not be considered as no toxicity
- Literature search (e.g. a guideline study reported in a scientific paper, review papers, several reports with similar outcome). From valid source (e.g. Whitelist identifies sites which are confirmed to be trustworthy: Directory of Open Access Journals – DOAJ, OASPA | Open Access Scholarly Publishers Association).

- Database search (e.g. Cesio, European new chemicals database (NCD), Draize eye test reference database (DRD), ChemID), OECD (https://hpvchemicals.oecd.org/UI/Search.aspx), cosmetics (https://single-market-economy.ec.europa.eu/sectors/cosmetics/cosmetic-ingredient-database_en)
- REACH/ECHA database search (https://echa.europa.eu). Information stated in RAC opinions[87], studies incorporated in the REACH registration dossier or REACH Chemical Safety Report. The available classification from the disseminated dossier from the ECHA website or from the list of ECHA notifications.
- The co-formulant is "well known" and used under other legislations (for instance cosmetics, food additive etc.)
- In silico analysis (QSARs/read-across) – with report. An investigation of the toxicity potential of the co-formulants based on the QSAR analyses and read-across (analogue) approach. Adequate and comprehensive documentation should be provided, especially if it is not listed in the REACH registration dossier.
- The source of information should be clearly stated (e.g. link or other) when presenting the co-formulant information (see table below in this appendix as example).

Example of addressing all steps in step-wise approach in Part B6:
Step 1) No existing/accepted test data are available for acute oral toxicity.
Step 2) No similar or useful products known, bridging not possible.
Step 3) No validated and reliable in vitro test methods available for this endpoint.
Step 4) Calculation method used to assess toxicity of the PPP. Please see Part C.

Table 22.4Example of presentation of data for calculation of acute oral toxicity in Part C:

Name of co-formulant	Conc. in PPP w/w %	Meets criteria for classification in CLP	Included in ATE calculation	Rationale	Source
A	5	Yes (LD_{50} is 510 mg/kg)	Yes	LD_{50} = 510 mg/kg	REACH dossier, link xxxx
B	0.5	No data available	No	≤1% in formulation (i.e., not relevant ingredient)	-
C	0.5	Yes (LD_{50} is 700 mg/kg)	No	LD_{50}= 700 mg/kg (Below the generic cut-off value for category 4, <1% in formulation)	MSDS/SDS, e.g. OECD TG xxx, analogue.
D	41	No	No	LD_{50} > 2000 mg/kg	Harmonised classification - Annex VI of CLP"

[87] Some MS do not accept to consider the RAC Opinions for the classification until implementation in the national legislation.

E (mixture of E1 + E2)	10	No data available	No	E1 and E2	E1 and E2

Appendix X. Precision of criteria for field studies on dislodgeable foliar residue

Extrapolation between formulations and crops – DT50, DFR, TTR and human exposure

Experimentally determined DFR, TTR, DT50 or human exposure based on other formulations may be accepted on a case-by-case basis, if the two formulations are sufficiently similar in terms of formulation category, composition and physical/chemical properties (pH, viscosity, density, surface tension and dustiness for solid etc.) or if it can be argued that the plant protection product used in the field study covers a worst case scenario in terms of adhesion and/or slower decay.

For DFR and DT50, some extrapolation between crops may be accepted in the NZ (i.e., same crop group) on a case-by-case basis if extrapolation can be justified taking parameters such as crop type/architecture and leaf texture (waxy, smooth, hairy) and the amount of foliage (leaf area index) into account. According to EFSA OPEX GD 2022, there are currently no data available to identify critical parameters for extrapolation between crops.

For determination of human exposure (residents and bystanders), the growth stage should be similar to growth stage(s) for the relevant uses in the NZ GAP. In general, data in lower growth stages cover later growth stages, as the growth and the changing density of the foliage can directly influence the spray drift.

Climatic conditions - DT50, DFR, TTR and human exposure: Experimental determination of DT50, DFR, TTR or human exposure for refinement of exposure scenarios of outdoor uses, should be based on data from field studies performed under test conditions representative for climatic conditions in the NZ. The countries in the NZ belong to two EPPO zones (Maritime and North-East). Another option is to apply Köppen–Geiger criteria to demonstrate representativeness in relation to climatic conditions in the NZ e.g., in case of studies performed outside the EU. For DT50, geographic locations where the slowest dissipation is expected i.e., due to low temperatures, may cover all NZ countries by representing ‘worst-case’ conditions. The relevance of climatic conditions is based on whether reported weather conditions are typical for the crop’s growing season and should be well justified. There should be no rainfall for 24 h before and after applying the product. Relevance is evaluated on a case-by-case basis. Meteorological conditions must be fully reported.

Fitting of data – DT50: The fitting of DT50 data and the statistical validation of the fit should be performed in accordance with FOCUS 2014 (FOCUS Work Group on Degradation Kinetics, Version 1.1., 18 December 2014) and EFSA 2019 (EFSA supporting publication 2019; EN-1673, 117 pp). Briefly, the following information should be given:

- Kinetic model (SFO, FOMC, DFOP, HS, etc.) together with the relevant parameter estimates (and related 95 % uncertainty limits. In general, a single first order fitting is applied first. Fitting of SFO, FOMC and DFOP may be compared to find the best fit.
- Software package used for the fitting.
- For values below the LOQ/LOD or outliers, the procedure in section 4, EFSA 2019, should be followed.
- Goodness of fit, evaluated according to all the parameters listed in Appendix F, section 4, EFSA 2019:
- Visual fit (plot of time vs concentration)
- Residual plot (Plot of time vs residuals against the y = 0 line)
- Chi-square ($\chi 2$) %[88]
- A t-test and/or confidence interval for the rate constant (k)[89]

[88] If the visual fit is satisfactory, $\chi 2 > 15$ % may be accepted, especially for field studies where variation generally is higher.

[89] If the t-test results in p-values > 0.05 (or confidence intervals including zero), it is indicative of large uncertainty in the estimation of model parameters and should not be accepted. In some cases, if the determined DT50 is close to zero, as can be judged from confidence interval, a p-value < 0.1 may be acceptable.