NZSC
Northern Zone Steering Committee

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

Version 11.1. This guidance document replaces the version of June 2021 and can be voluntarily applied from July 2023. 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. Changes made for version 11.1 are highlighted in turquoise.

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January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products	DK + expert groups	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.	Steering and expert groups	1 November 2018

Date	Revision	Issues	Responsible	Implementation date
		Changes in the following sections: All sections		
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: All sections	Steering and expert groups	1 November 2019
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

The correct reference for the NZ work sharing GD: Northern Zone, 2023. Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products. Version 11, July 2023.

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/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 Member States.

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 and thereof an inclusion in Regulation (EU) No 540/2011.

The Northern Zone 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) and Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 (SANCO/13170/2010). The intension 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 Northern zone. 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) 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 Member States 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 Member States, 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 Member States 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 Member State 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 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 Northern Zone representative at workshops, conferences etc.

Table 1 Incoming chairs year 2023 – 2029

Year	Country*
2023	Norway
2024	Denmark
2025	Finland
2026	Latvia
2027	Lithuania
2028	Estonia
2029	Sweden

*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 Member States 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 Northern zone 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 concerned MS, 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).

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 Member State (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 when the decision of the re-approval of the active substance applies. An application shall be sent to all concerned Member States 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 Northern zone 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 Member States within the zone where they wish to gain authorisation. Together with the application a zonal rapporteur (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 Northern zone guidance document.

6.3 Submission of label extension

The applicant should submit an application to all Member States within the zone where they wish to gain a label extension. Together with the application a zonal rapporteur (zRMS) has to be proposed.

6.4 Format and requirements for an application

Guidance documents accepted on EU-level are applicable in the Northern zone from the implementation date of each guidance, whether the guidance is mentioned in this document or not. If the Northern zone 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 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/Northern Zone should be presented.
   - If applicable national addenda as indicated in **Appendix V**. Addenda addressing national requirements for concerned member states should also be submitted to the zRMS. zRMS should also receive all national part A. The template for the draft registration report is to be found on the Commissions webpage: http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_reg-report-draft.zip (this template is not required for AIR II substances).
   - 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 VIII 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 Northern Zone for zonal applications and the EU-countries for inter-zonal 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
    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

[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.

amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010).

6.5 Inter-zonal 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.

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 annex II data post-annex I inclusion of an active substance** (SANCO/10328/2004)

8. Data gaps identified in active substance evaluation

The IZSC has agreed on the way applicants and Member States 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 can be found at CIRCABC PPP zonal portal[2]. 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.

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

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.
- 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 Northern zone 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 Member States (MS) 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 Northern Zone requires that the assessment submitted for Article 43 renewals is in accordance with technical guidance in force at the time of application submission.

The Northern Zone 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 16.1.

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 Member States 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 concerned member states 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 Northern zone 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).
4. Part A of the reference Member State.
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 Northern zone 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 registration report 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**. The table below shows which sections of the dRR need to be revised. All changes in the revised sections of the latest registration report, 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 2 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. See section 17.1.2 for additional information that should be submitted. The composition of the co-formulants needs to be submitted to all cMS to make commenting possible.

Type of amendment	Sections and information that should be revised and submitted (section numbers are according to the new dRR-format)
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 17.1.2 for additional information that should be submitted. The 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 Northern zone is initiated during the re-evaluation process (AIR-programs) of the active substances. The work is coordinated by one of the Northern zones 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 9.2 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.

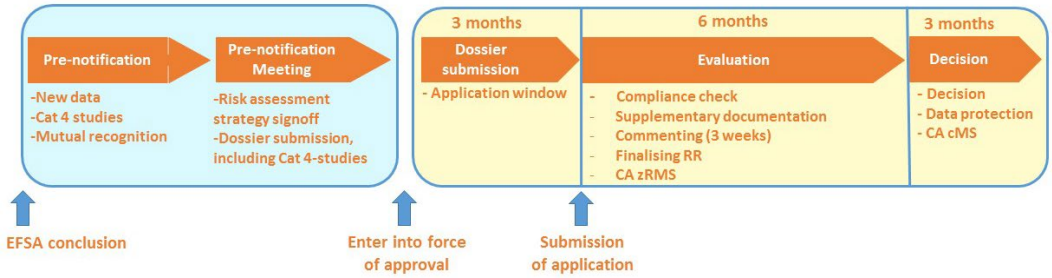


Figure 1 Scheme of the process for re-authorisations

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 member state. 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 draft registration report (dRR) is finalised (revision 0) it will be uploaded on CIRCABC and sent to the other Member States 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 Registration Report (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 concerned Member States should take a decision within 120 days (excluding clock-stop time, if any left) of receipt of the registration report and the copy of the certificate of registration in the zRMS. A scheme of the process for new product is given Figure 2 below.

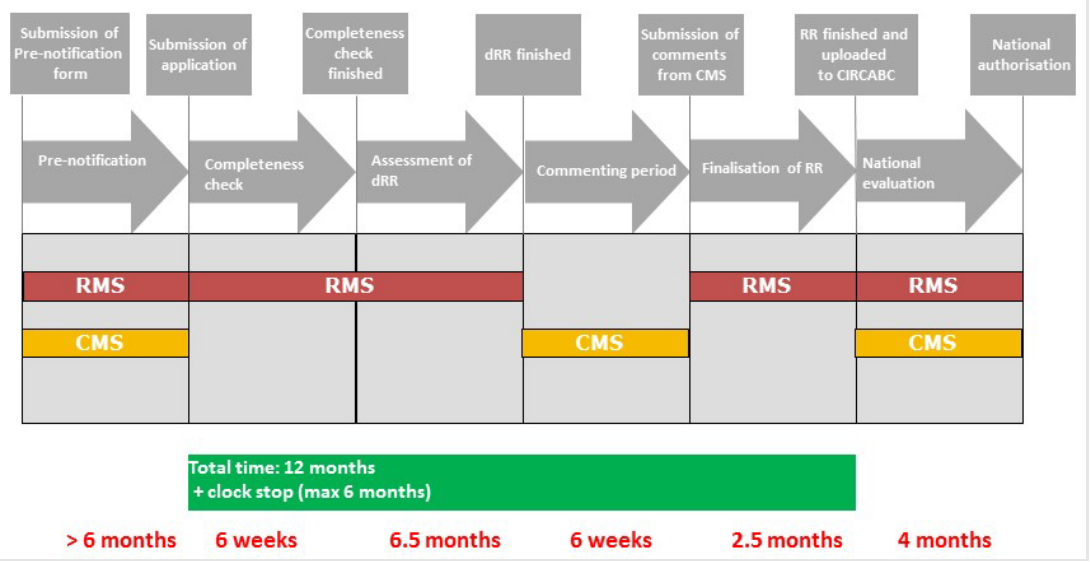


Figure 2 Scheme of the process for assessment of applications for new product authorisations

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. Concerned member states shall at the latest within 120 days of the receipt of the assessment report and the copy of the authorisation of the Member State 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 Northern zone Member States 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 Member States 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

Concerned Member States 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 registration reports (RR) prepared by zRMS should be used by the concerned member states in order to prepare the national regulatory decision. However, the outcome of the decision in each member state may vary due to national requirements, differences in climatic and agriculturally conditions (use of different scenarios) and different options for risk mitigation measures. This means that an authorisation granted in one member state not necessarily mean that an authorisation also will be granted in another. For further details on risk mitigation options in the Northern zone, 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://www.fao.org/3/cb8401en/cb8401en.pdf
- 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/fileadmin/DAM/trans/danger/publi/manual/Rev7/Manual_Rev7_E.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/3030/1999.
- 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:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_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 at a concentration below 0.1 % w/w or less than a relevant specific concentration limit.

17.1.1 Composition statement and SDS of co-formulants

The detailed complete composition shall be provided for all co-formulants. A composition statement must account for 100 % of the chemical components in the co-formulant. The concentration, chemical name, and CAS no. for each component and, if possible, the function of the component (*e.g.*, impurity, biocide), should be stated. Further information, depending on the type of component, may be required, *e.g.* degree of ethoxylation. Information on unacceptable co-formulants (Annex III to Regulation (EC) No 1107/2009) must also be provided, *e.g.* residue levels of ethylene oxide for ethoxylated alcohols. 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. The competent authorities will treat this information as strictly confidential.

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.

17.1.2 Amendment of the composition for a plant protection product

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 member states, the evaluation is made available for commenting to all relevant Northern Zone MSs. To harmonize the assessment within the Northern zone, evaluation of non-significant formulation changes might also be sent to all relevant Northern Zone 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.

17.1.2.1 Procedure for evaluating formulation changes in the Northern zone

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.
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 Member States, 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 Northern zone . 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 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.

If a relevant impurity could, theoretically, be formed during manufacture or storage of the plant protection product, then its content should be determined before and after storage (accelerated and shelf-life studies). If it cannot be formed during storage, then determination of its content is only necessary before storage. If the relevant impurity cannot be formed during manufacture or storage, a justification for not submitting data on the content of the relevant impurity in the formulated product shall be provided. However, a validated analytical method for the determination of the relevant impurity in the formulation is always required.

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 3) under KCP 5.1.2 (dRR template Part B5 Section 5.2.2 Table 5.2.3).

Table 3 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 Council Directive 91/414/EEC. 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[3]. 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.

Specific national requirements are listed for each country within the Northern zone in Appendix V: Summary of national requirements and Appendix VI: List of mitigation options available in the Member States 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[4] classification based on the toxicological profile of the individual ingredients in the product. Likewise, if the study was evaluated according to previous data requirements that do not apply anymore.

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

[3] See section 17.
[4] 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

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, animal testing should be minimised and tests on vertebrates should be undertaken as a last resort (step 5 below). Thus, to make use of all existing information for the toxicity assessment of 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 by considering each of the steps of the step-wise approach below. All data submitted will then be used, in a weight of evidence (WoE) approach, for the evaluation of PPP (e*xpert judgement may differ between the MSs*).

For transparency, the applicant must address all the steps given below in the step-wise approach, and report this in the dRR Part B6 or Part C.

The information, predictions and calculations should be made systematically and transparent (Please see Appendix X). 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 e.g., existing study from previous EU authorization from *year*, or a regulatory requirement from regulations outside EU.

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.

Moreover, a detailed comparison of the compositions should be stated in the dRR Part C and the percent variations in concentrations must be indicated.

18.1.1.3 Step 3 - In vitro tests

This is 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. Examples of relevant documents to consult are the latest versions of the OECD Integrated Approaches to Testing and Assessment (IATA) No. 203 and 263 for skin and eye irritation, and the OECD Guideline No. 497 on Defined Approaches on skin sensitisation.

18.1.1.4 Step 4 - Calculation of classification

If there is sufficient information available on the toxicity of the PPP from steps 1-3, in step 4, the applicant should collect information on the toxicity of the individual ingredients in the PPP from REACH/ECHA (harmonized classifications or RAC opinions [5]) and up-to-date safety data sheets (SDSs). This information must be used in the WoE assessment of the toxicity of the PPP.

If there is not sufficient information available on the toxicity of the PPP from steps 1-3, in step 4 toxicity information is required for all relevant components 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 should be obtained from REACH/ECHA (harmonized classifications or RAC opinions) and up-to-date SDSs. If this is not available, please see appendix X 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:

- **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).
- **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 might therefore be relevant at lower concentrations.
- **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

[5] Note that some MSs do not accept RAC Opinions as a source for classification.

on the Application of the CLP Criteria[6] might have skin sensitising properties. In certain cases[7], additivity may be scientifically justified and may be applied to skin sensitisers with the same mode of action (expert judgement needed).

In contrast to the CLP regulation unknowns[8] 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 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.

Alternatively, it might be possible to predict the toxicity of a co-formulant (or ingredient in a co-formulant) by route-to-route extrapolation (particularly from oral to dermal). For this approach, see the *OECD Guidance No. 237 on Considerations for Waiving or Bridging*. Please note that a comprehensive justification is required. It might 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 tests data according to validated and internationally accepted test methods for the whole mixture (made for the current EU PPP application)

New vertebrate studies should be considered as a last resort. Therefore, 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. For acute inhalation toxicity, please note that some MSs

[6] Table 3.9 in Guidance on the Application of the CLP Criteria, version 5.0- July 2017

[7] 1.6.3.3.3 in Guidance on the Application of the CLP Criteria, version 5.0- July 2017

[8] CLP, Annex I, section 3.1.3.6.2.2

accept the pre-evaluation method described in the Appendix IX – Acute inhalation toxicity – Pre-evaluation of products (Spraying only). See Appendix V for national approaches on how to deal with this data requirement.

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.

18.2 Exposure Assessment

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

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, and adjuvants[9] shall be included in the risk assessment. Until detailed rules and the date of application are established, a hazard assessment using the Safety Data Sheets (SDS) should be performed.

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

Relevant approaches developed by EFSA should be applied when available.

[9] See Appendix V for national requirements for Norway on adjuvants.

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., the input parameters have changed (see Table 4) and 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), 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 4. 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 concentration of active substance	Indoor/Outdoor scenario	N.A.
Use of water-soluble bags	AOEL/AAOEL	Work task	N.A.
Product category	Vapour pressure (if other than default 0.001 Pa)	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	Both Min and Max water volume per hectare	N.A.

	the concentration used in the original dermal absorption study (the absorption is *pro rata* corrected automatically when necessary)		
N.A.	Oral absorption	Buffer strip (2-3 m, 5 m or 10 m)	N.A.
N.A.	Inhalation	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 report with all uses and a summary of critical GAP when submitting the applications for authorisation of plant protection products.

One can also create a report under the menu "Summary" where a summary of the results is presented. Please include screen shots (from EFSA OPEX online calculator) of the representative risk assessments, 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 7for an overview of the tiered approach, use of PPE and other risk mitigation measures applicable in the Northern Zone member states.

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.

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.

- 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 i.e., high crops (high crop is default, low crop use **only** 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 for active substances with a vapour pressure $\geq 10^{-2}$ Pa.

18.2.1.3 Worker Exposure - re-entry interval

The EFSA OPEX online calculator allows calculations regarding re-entry, both for outdoor and indoor scenarios, only after the application solution has dried. An re-entry interval is defined as the specific time-point post application (in hours or days), after which the worker exposure levels are lower than the AOEL, considering different clothing and PPE cases. If worker exposure during the re-entry activities (e.g., inspection, harvesting, reaching, picking, cutting, sorting etc.) exceeds AOEL, even when wearing protective gloves and workwear, an re-entry interval can be used as a risk mitigation measure. The acceptability of the calculated re-entry interval for worker should be examined on a case-by-case basis. Acceptability of an 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 7 and Appendix VI).

A noteworthy fact is that irrespective of calculating 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 length with possible additional requirement of ventilation (for details see Appendix VI).

18.2.1.4 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 of buffer zones and the use of drift-reducing nozzles could be considered. These risk mitigation measures may be accepted by some MS (see Table 7).
- 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.

18.2.1.5 Recreational exposure

A risk assessment for recreational exposure is necessary for an application of a PPP on 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[10,11]. Additionally, for an application of a PPP on golf course, turf, lawns, grassland etc an assessment of acceptable re-entry interval (see section 18.2.1.3) 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,

[10] See Appendix V for restrictions in Norway for the use of PPPs on areas accessible for the public.

[11] In the EFSA OPEX GD Online Calculator choose golf course, turf and other sports lawns to assess the risk of recreational exposure.

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 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).
- UK POEM
- German model (75th percentile). Available on: https://www.bfr.bund.de/de/suche.html?search%5Bquery%5D=operator
- Dutch model (greenhouses). Available on: https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2016/10/27/calculation-model-operator-nl-greenhouse
- PHED
- Puffer pack model. Available on: https://www.hse.gov.uk/pesticides/pesticides-registration/data-requirements-handbook/operator-exposure.htm
- UK Trigger Spray model. Available on: https://www.hse.gov.uk/pesticides/pesticides-registration/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. A product applied both upward and downward 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 both the German and 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 5 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 might affect the user conditions stipulated in the national product authorization.

Table 5 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 maybe 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 like 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 6.

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.

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 criteria listed in appendix J (EFSA OPEX GD 2022).

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 (EFSA OPEX GD 2022).

Table 6. 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 value[2] ≥ 10 sites: geometric mean[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 ≥ 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].	DFR TTR DT50
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	DFR TTR DT50

	- Similar application and growth conditions - Similar irrigation pattern and application technique relevant to NZ GAP	
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 Northern Zone (EPPO zones: Maritime and North-East). Another option is to apply Köppen–Geiger criteria to demonstrate representativeness in relation to NZ climatic conditions. Relevance will be assessed case-by-case.	DFR TTR DT50 Human exposure
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.

18.2.4.4 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.

18.2.5 Risk mitigation measures

Table 7 NZ approach of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator Table 7 gives an overview of the acceptable risk mitigation measures in each of the Member States in the Northern Zone. 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 strip and drift reducing equipment are the risk mitigation measures for the health risk assessment. Hence, not all Member States in the Northern Zone are ready to accept these risk mitigation measures. However, it may be 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 7 NZ approach[12] of choosing PPE and other risk mitigating measures in the EFSA OPEX online calculator.

Operator	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmo -nized**
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	N	Y	N	Y	Y	Y	N
Drift reducing equipment	Y	N*	Y	Y	Y	Y**	Y	N
Rain suit (dense crop) for greenhouse only	CbC	CbC*	CbC	CbC	CbC	CbC		N
Protective clothing (Certified protective coverall)	Y	Y	Y		CbC	Y	Y	N
Residents/ bystanders	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmo -nized**
Buffer strip	Y	N*	Y	N	Y	Y	Y	N
Drift reducing equipment	Y	N*	Y	Y	Y	Y	Y	N
Both buffer strip + drift red.	Y	N*	Y	N	Y	Y**	Y	N
Workers/ Greenhouse	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmo -nized**
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		CbC#	CbC		N
Field use	**DK**	**NO**	**SE**	**FI**	**LT**	**LV**	**EE**	**Harmo -nized**
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		CbC#	CbC		N
CbC: Case-by-Case; *Under evaluation **Experience is needed before changing legislation. #Case-by-Case, please see in Appendix VI.								

[12] See Appendix V for National Requirements and Appendix VI for mitigation options available in the member states in the northern zone.

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 another 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.

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[13] 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.

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

- 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 Northern Zone 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 draft registration report (dRR) for the northern zone only instead of a core dRR for whole EU. The GAP and the residue data should reflect the intended use in the northern zone.

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 northern zone 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:

- 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. 23 November 2020. (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3.)
- Calculation of maximum residue levels and safety intervals. Appendix I, SANCO/7039/VI/95 EN. 22 July 1997.
- MRL Calculator EU. OECD (2015)
- Nature of pesticide residues in fish. Appendix J, SANCO/11187/2013 rev. 3. 31 January 2013.
- 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 Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes. SANTE/2020/12830 Rev. 1, 24 February 2021. (Supersedes SANCO/3029/99 EU, rev. 4 and SANCO/825/00 EU, rev. 8.1.)
- 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)
- 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, 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 at last treatment or date
- Portion analysed
- Residues (mg/kg)
- 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, 23 November 2020). 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 “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 is 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) 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.

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.

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, feed and drinking water.

The assessment of residues on and in food or feed should include estimate acute and chronic exposure levels 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, or on groundwater.

There are no guidelines in EU that describe how consumer safety should be assessed, other than that the evidence should be scientific. Currently most widely used method is PRIMo, in which each MS can use dietary intakes based on their national diets. Deterministic methods have been proven useful to demonstrate the consumer safety for a use or uses of any given plant protection product and are currently the method of choice.

The acute and chronic intake data for various commodities are based on national dietary surveys provided by each MS.

A chronic dietary exposure should be evaluated by calculation of the theoretical maximum daily intake (TMDI) using the relevant version of the EFSA PRIMo tool 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.

A short-term intake calculation should also be performed using the relevant version of the EFSA PRIMo, 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. When estimating the short-term dietary exposure STMR values should not be used, unless the commodity being assessed is usually bulked or blended before consumption (i.e., IESTI case 3 commodities, such as cereals, pulses and milk).

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 resi-dues 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, 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 non-residue situation (guidance document SANTE/2019/12752).

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 Northern zone 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 Northern zone 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 Northern Zone 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 member states 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 **Summary of national** requirements .
- 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[14]. SANCO/221/2000.
- 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). *Please note that no member states in the Northern Zone accept non-equilibrium sorption in the modelling approach.*
- 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.[15] EFSA Journal 2014; 12(5):3662.

[14] 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.
[15] Please note the interception values, which should be used for all submissions.

- 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 Northern Zone would accept aged sorption endpoints if they are agreed at EU level, however the Northern zone can assess, on a case-by-case basis, whether or not to use aged sorption refinements for groundwater modelling.*

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

- For **non-professional use** (home gardens), substantial differences exist between the Member States (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[16]. 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 PECsoil, while PECgw and PECsw modelling is more complex. The risk envelope approach may only be used for calculation of PECgw and PECsw 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.

21.1 Soil

The Nordic PECsoil 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 Northern Zone. 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

[16] 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.

Finnish temperature scenario, which is pre-implemented into the PEC_{soil} calculator, are accepted.

A worst case DT_{50}field (normalized) or a worst case DT_{50}lab (normalized) should be used. If field studies are used for PECsoil calculations, it must be scientifically justified that these are representative with regards to soil conditions (among others, with regard to soil type, pH, orgC) and climate (see Table 8). EFSA Guidance Document for evaluating laboratory and field dissipation studies (2014)[17] should be used to select the proper DT_{50} value.

Table 8. Key properties for climate and agricultural soils in the Northern zone member states

Member state	Soil properties		Climate	
	pH	Org. C %	Annual average air temperature (ºC)	Annual precipitation (mm)
Denmark[3]	5.0 -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]	5 - 7	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	4-8.2(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.
5) 10th and 90th percentile of pHH2O 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 Geological Survey. pH given as pHH2O.
8) Average annual air temperature (°C) and precipitation (mm) 1981-2010. Climate data from Lithuanian Hydrometeorological Service.
9) Soil pH data based on Lucas 2015 topsoil data (link). pH given as pH_{H2O}.
10) 1st and 99th percentile of pHCaCl2 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.

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-kinetics, a pseudo-SFO degradation rate may be applied (pseudo $DT50_{SFO}$=$DT90_{FMOC}$/3.32).

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

[17] 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.

For the active substance(s) and metabolite(s), $PEC_{max\ (1st\ season)}$, $PEC_{21\ dayTWA}$ and PEC_{acc}[18] should be reported and used in risk assessments. In some MS of the Northern Zone, other PEC_{TWA} might exceptionally be considered acceptable for the ecotoxicological risk assessment. In this case, these should additionally be reported. PEC_{acc} can be calculated for applications every year, every 2nd or every 3rd year. Please see Table 12 for possible crop rotations periods in years for each member state.

For $PEC_{max\ (1st\ season)}$ and PEC_{TWA} a soil depth of 5 cm shall be used. For PEC_{acc} calculations 5 cm PEC values should always be reported. 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. 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 crops where this refinement cannot be used are no-tillage farming systems, orchards and golf courses.

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: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/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 PECgw should always be provided. Other output files shall be made available when requested from the regulatory authority. Simulations with annual application should always be reported.

When triggered, as specified in Table 20.2-1, the core assessment should contain modelling with all national scenarios for the Member States for which an authorisation is applied for.

[18] PEC_{acc}: the highest concentration during a period of 20 years including all applications from the last year

21.2.1 Surrogate crops

When a crop is not parameterised in any of 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 concerned member states (see Table 9) should be used for selection of appropriate input values for the groundwater simulations[19] (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[20] 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[21]. The 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.

[19] Latvian requirement: the PEC gw for both acidic and alkaline conditions should be presented initially; if acidic soils do not represent worst case leaching conditions (parent and/or metabolites), the whole data set (acidic and alkaline merged) can be used.

[20] 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.

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

21.2.5 National requirements for PECgw simulations

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 9. 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[22]			
		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[23] ≥ **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**[24] **Rustad**[25]	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** à Step 5 of relevance assessment needed.
MS	**Tier I - PELMO**	**Tier II - simulations with MACRO 4.4.2 or 5.5.3 (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). As output, the number of years that exceed 0.1 µg/L out of 20 years as output (not 80th percentile).		a.s./all metabolites ≤ **0.10 µg/L** →ok. Only 1 year out of 20 may exceed 0.1 µg/L. 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.

[22] Information about the different versions of the MACRO model and their bugs is available at: http://esdac.jrc.ec.europa.eu/projects/macro.
[23] 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.
[24] 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.
[25] Rustad is only required for Norway. Relevant files and background information is available at www.mattilsynet.no or on request.

			All metabolites need to be covered by the assessment. Further guidance available in the Danish national guidance: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/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).	
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** à 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** à Step 5 of relevance assessment needed.

MS	Tier I – PEARL and PELMO	Evaluation of PEARL/PELMO results
FI	Hamburg and Jokioinen	a.s./relevant metabolites/non-relevant metabolites **≤ 0.10 µg/L** → ok. non-relevant metabolites evaluated up to Step 5 < 10 µg/L, with groundwater risk mitigation[26] → ok.

[26] See the criteria for the restriction on the use of the product on the classified ground water areas in Appendix V.

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

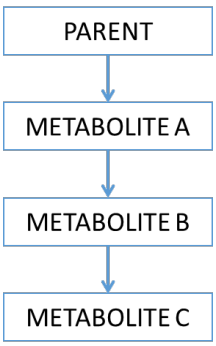
The purpose of the following text is to give practical advice on how to simulate PEC_{gw} for metabolites in MACRO. MACRO can only handle one parent compound and one metabolite in a single simulation. Hence, additional simulations are required if several metabolites are formed. Depending on the quality 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 10). However, if the degradation pathway includes a chain of degradation where a metabolite is formed from another metabolite, the PECgw 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 10). 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 10. 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:

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

21.2.7 Presentation of results from PECgw model simulations:

The documentation must be well structured and transparent in order to demonstrate which models and scenarios that have been used for each country. An example of a summary table is given in Table 11.

Table 11 Example of summary table for the PEC_{gw} results

PEC_{gw} (80^{tt} percentile)			
Country	**Compound**	**PEC_{gw}**	**Model & scenario**

If one or both of the limit values (0.1 µg/L for each individual substance[27] and 0.5 µg/L for the sum of substances[28]) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. field studies, and/or monitoring data[29]) convincingly demonstrate that unacceptable leaching will not occur in a Northern Zone 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 Northern Zone conditions.

Metabolites for which the PECgw 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")[30]. This is the official policy in the following Northern zone member states; EE, FI, LT, LV, NO, SE. For more information, see Assessment of the relevance of metabolites in groundwater 21.5.

21.2.8 Information on crop rotation in each NZ MS

The crop rotation period represents the normal agricultural practice. (please refer to Table 12 for country specific crop rotation periods). When the value in Table 12 is 3 or more, every third-year application can be used in modelling.

[27] Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.
[28] Sum of substances in a sample refer to all active substances + metabolites stated as relevant. For DK please refer to the latest national guidance: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/.
[29] 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.
[30] Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under Council Directive 91/414/EEC. Sanco/222/2000 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 8).

Table 12 Possible crop rotation period in years (for cells left blank an argumentation is required) The numbers in the table indicate 1: every year. 2: every second year. 3: every third year etc.

Crop	Denmark	Estonia	Finland[E#]	Latvia	Lithuania	Norway	Sweden[D****]
Potatoes	4	1[A*]/3[C***]	1/3[C***]	2-3	4	1/3[A*]	Up to 3
Sugar beets	3	1	1	2-3	4	-	
Winter cereals	1	1	1	2-3	1	1	
Beans	4	3	3	2-3	4	6[B**]	
Cabbage	1	1/3[A*]	1/3[A*]	2-3		1	
Carrots	1	1/3[A*]	1/3[A*]	2-3		1	
Linseed	1	1	1	2-3		-	
Maize	1	1	-	2-3	3	-	
Spring OSR	4	3	4	2-3	2-3	6	Up to 3
Winter OSR	4	3	4	2-3	2-3	6	Up to 3
Onions	5	1/3[A*]	1/5[A*]	2-3		4	
Peas	4	3	5	2-3	4	4	
Spring cereals	1	1	1	2-3	1	1	
Strawberries		1	1	2-3		5	

[A]*In early potatoes, cabbage, carrot and onion crop rotation may not necessarily be applied.
[B]**Harvested as seed.
[C]***3 years crop rotation is for seed potato
[D]****Every fourth-year simulations are not accepted by the Swedish Chemicals Agency 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.
[E]# Risk assessment modelling results for annual application are required for all uses and all crops. Modelling for biennial and triennial applications may be provided for any crop to demonstrate acceptable use. 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. For maize no specific information on crop rotation is available.

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 13 lists when Step 3 is not required:

Table 13 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 D1, D3-D6 and R1-R4 in accordance with the country specific requirements (Table 14).

21.3.1 Surrogate crops

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.

21.3.2 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 concerned member states should be applied in the simulations[31] (see Table 8 and text in chapter 21.2 – ground water). 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. 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).

21.3.3 Application dates

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. Thus, for the drainage scenario D1, for winter cereals at BBCH 20, the application window suggested for BBCH 21 by AppDate should be used. For BBCH 21-29 the application windows suggested by AppDate should be used. For BBCH 30 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.

All scenarios in which a crop is parameterised should be simulated. 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-off scenarios not relevant for DK and SE; see MS specific scenarios in table below).

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

[31] Latvian requirement: if acidic soils do not represent worst case conditions for PECsw, the whole data set (acidic and alkaline merged) can be used.

Table 14. Member State specific requirements for FOCUS scenarios considered in the assessment of surface water and sediment exposure.

Scenarios									
Country	**D1**	**D3**	**D4**	**D5**	**D6**	**R1**	**R2**	**R3**	**R4**
Denmark[1]		X	X						
Estonia[2]	X	X	X			X			
Sweden[3]	X		X						
Norway[4]	X	X	X	X	X	X	X	X	X
Lithuania[2]	X	X	X			X			
Latvia[2]	X	X	X			X			
Finland[5]	X		X			X			

1. In case a crop is not included in the D3 and D4 scenario, a similar crop must be selected instead so that both scenarios are always modelled.
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, simulations with a surrogate crop are only needed if the crop in the proposed GAP is neither parameterised in D1 nor in D4.
4. For Norway, 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 by Norway.
5. For Finland, in case a crop is not parameterised in D1, D4 and R1 scenarios, a similar crop must be selected for simulation in R1 and in either D1 or D4, to obtain a result for at least one drainage scenario and one run-off scenario.

Table 15. Possible surface water mitigation measures in the Member States of the Northern zone

Width of non-spray buffer zones to mitigate drift (m)							
Driftmitigate (m)	**Denmark**	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden***
2	FVOB	-	-	-	-	-	-
3	-	-	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)**							
	Denmark	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden***
Buffer zone (m)	-	10	10	10	10	10	-
Drift reducing nozzles (%) *							
nozzles (%)	**Denmark**	**Estonia**	**Finland**	**Latvia**	**Lithuania**	**Norway**	**Sweden***
25	-	-	-	-	-	-	O
50	-	Yes	Yes	Yes	Yes	FVOB	FVOB
75	-	Yes	Yes	Yes	Yes	FV	FVOB
90	-	Yes	Yes	Yes	Yes	FV	FVOB
99	-	-	-	-	-	-	O

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

* Spray-free buffer zone ("*Hjälpredan"/"the Helper*") is to be used as first option for off-field risk mitigation. If necessary, drift reducing equipment could be used in combination with spray-free buffer zones to further reduce the exposure. See further information in Appendix V.

**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[32]. The use of the VFSmod tool is not accepted.

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 PECsw are to be used in the aquatic risk assessment. An example of a summary table is given in Table 16.

Table 16 Example of a summary table for the obtained maximum PECsw [µg/L] and PECsed [µg/kg] which are to be used in the risk assessment.

			Step 2		Step 3			Step 4		
Country	**Comp.**	**Appl.**	**PECsw**	**PEC_{sed}**	**Scenario**	**PEC_{sw}**	**PEC_{sed}**	**Mitigation measure**	**PEC_{sw}**	**PEC_{sed}**
		S								
		M								
		S								
		M								

S = single application, M =multiple applications

[32] 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)

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} values should always be provided. Other output files shall be made available when requested from the regulatory authority.

For products containing more than one active substance, a mixture toxicity assessment must be performed in addition to the risk assessment for each active substance. For more details refer to the corresponding section in the ecotoxicological part of this guidance document.

21.3.4 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 17) concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products should be reported. The data might, in some Member States, be used in support of the groundwater and surface water modelling. Note that monitoring data is not accepted as a higher tier by member states 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 17 Monitoring programmes in the Northern zone.

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	-

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 Northern Zone 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"[33], the upper limit value is 10 µg/L.

The assessment of the relevance should cover all the requirements in the GD (SANCO/221/2000) on the relevance of metabolites in groundwater. The full relevance assessment is to be presented in the core dRR, Part B section 8 or 10. 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.

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 Northern Zone 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 Northern Zone.

Ecotoxicological data used for risk assessment in the Northern zone:

- List of endpoints data including data from the representative product if that product is applied for in the Northern Zone. Endpoint for the representative or other similar formulation may also be used as surrogate for product applied for, if valid bridging studies can support this.
- Endpoint according to product data requirements (284/2013), if not covered by LoEP.

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

[33] SANCO/221/2000 rev.10 (final). 25 February 2003. 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 8).

- Guidance of EFSA Risk assessment for birds and mammals. EFSA Journal 2009; 7(12) 1438.
- Pesticide Risk Assessment for Birds and Mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone 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 (abbreviated as EFSA AGD in this NZ GD).
- SANCO/10329/2002 Guidance Document on Terrestrial Ecotoxicology. Under Council Directive 91/414/EEC.
- For chronic risk assessment for bees, EPPO 2010, OEPP/EPPO Bulletin 40, 313–319: Side effects for honeybees and ECPA 2017: POS/17/LO/28028; modified EPPO for chronic RA for adult honeybees from spray applications.
- Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods (ESCORT 2; Candolfi et al. 2001).
- 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 (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.

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 draft registration report.

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 Northern zone (see section 21.5). In addition, the Northern Zone does not accept modelling data based on unofficial FOCUS-model versions (see section 20.3).

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[34]:

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

$$\text{if } SUM < 1 \; the \; risk \; is \; acceptable$$

Where "Trigger value" represents the uncertainty factor of chemical A,B etc and TER is calculated as follows:

$$\text{TER} = \frac{\text{substance specific effect conce. (e.g. EC50, EC10 or NOEC)}}{\text{Expected environmental exposure}}$$

22.2 Non-professional use/Home gardens

No harmonized approach for risk assessments of non-professional/home garden products have yet been agreed within the Northern zone. 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 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

A risk assessment for birds, mammals, bees, non-target arthropods, and non-target plants should be performed assuming the same exposure as for an outdoor-field use, unless it is indicated that the uses will be restricted to permanent greenhouses. For this purpose, it is recommended that Member States request clarification on the representative use during the admissibility check i.e., the type of protected structure the representative use will be made under, should be clear at the very early stage of the risk assessment. The environmental fate exposure assessment will advise on the need for a risk assessment for aquatic organisms and soil dwelling organisms.

For substances with Log Pow > 3, secondary poisoning evaluation (for birds and mammals) is necessary even if products are applied in permanent greenhouses (if fate evaluation indicate exposure to surface water and/or soil). The max $PEC_{soil, twa}$

[34] Exception being bumble bees, see Section 21.7 Bees for details.

(max. 21 d) from the 20 years Nordic PEC_{soil} calculations should be used in the risk assessment for earthworm-eating birds and mammals.

22.4 Vertebrate testing

Generating new studies on vertebrate animals should be avoided whenever possible[35], and duplication of vertebrate tests is not accepted[36]. In cases where generating new vertebrate studies is considered an option by the applicant, they 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 should be presented in the core assessment. The EFSA guidance document for birds and mammals i.e. EFSA 2009 (EFSA Journal 2009; 7(12) 1438) should be used for the screening and tier 1 assessments with a few amendments.

22.5.1 Geometric mean

EFSA 2009 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 northern zone, 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[37]. If endpoints from two species are available, the lowest endpoint should be used in the risk assessment.

22.5.2 Willow warbler in late growth stages of maize

If a product will be used in late growth stages of maize (BBCH ≥30), the bird species willow warbler has to be added to the package of species presented in the EFSA guidance document. The reason for this is that this species is frequently detected in late growth stages of maize in the Northern Zone and it is not covered by the species presented in the EFSA guidance document. A shortcut value (SV) of 52.2 shall be used for assessment of acute risk and SV = 20.3 for assessment of long-term risk for willow warbler.

[35] 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.
[36] Regulation (EC) No1107/2009, Chapter V, Article 62.
[37] 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 Mixture toxicity assessment

The mixture risk assessment for birds and mammals shall follow the Appendix B of Guidance of EFSA Risk assessment for birds and mammals (EFSA Journal 2009; 7(12) 1438). It should be noted that mixture toxicity should always be considered also for long-term risk assessment including risk from secondary poisoning[38]. Different mode of action of the active substances is not a valid reason for not assessing combination effects.

To decrease complexity of the assessment the concentration addition equation presented in section 22.1 should be used for the long-term risk assessment[39]. To facilitate these calculations, an excel based Mixtox Calculator tool for birds and mammals can be accessed at the Danish EPA webpage regarding Pesticides:

http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/cooperation-in-the-north-zone/

22.5.4 Tier 1 refinement options

No refinements of the EFSA tier 1 assessment scenarios are accepted, except that MAF and the TWA factor may be refined if adequate substance specific data on DT50 in plants are available. For Northern Zone requirements concerning refinement of DT50, please refer to the Northern Zone Bird and mammals higher tier guidance document, section 4.4 (available at the Danish EPA webpage regarding Pesticides:

https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Feng.mst.dk%2Fmedia%2F218368%2Fbirds-and-mammals-higher-tier-risk-assesment-northern-zone-december-2020-ver-2-1-1.docx&wdOrigin=BROWSELINK

22.5.5 Higher tier risk assessment

When further refinements of the risk assessment are necessary, the Northern Zone 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 Northern Zone 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 Northern Zone, where some of the generic focal species are rare or missing and the niches of the remaining focal

[38] For all a.s. in a product and metabolites with log Pow > 3

[39] I.e., the method given in Appendix B: EFSA Journal 2009; 7(12):1438 should not be used for the long-term risk assessment.

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 in this NZ GD) should be presented. The terminology used in the EFSA AGD 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 20.3) divided by RACs should be included[40]. The risk assessment tables shall contain all country specific scenarios and relevant mitigation measures for the countries in which authorization is applied for. Examples of how the aquatic step 4 risk assessment should be presented are given in Appendix VII. It is important to present all calculations made in the risk assessment in a transparent way, also those calculations not included in the example tables.

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 7.3.5.1 of EFSA AGD.

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 21.3, Table 13.

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.

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.

[40] See section 20.3 regarding extra safety factor of 10 if older version than FOCUS Step 1&2 (version 3.2) is used for PEC estimation.

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 PECsw based on spray drift of formulation and formulation endpoint. Formulation toxicity is already considered in Aquatic MixTox tool. 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[41]:

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

$$n = number\ of\ mixture\ components$$

$$i = index\ from\ 1 \ldots n\ mixtures\ components$$

$$PEC_i = PEC\ of\ component\ i$$

$$RAC_i = RAC\ of\ component\ i$$

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 Member State specific buffer zones in section 21.3). Other nationally specific mitigation options (run-off reduction and spray drift reducing nozzles) are accepted in some Member States. 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 Member state.

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[42] regarding use of PECTWA. In addition to fulfilling the conditions of the decision scheme regarding use of $PEC_{sw;twa}$ in the EFSA AGD , it has to be clearly demonstrated, that the boundary conditions of reciprocity and latency of effects are fulfilled for the relevant twa period.

[41] 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)

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

Refinement by using detailed analysis of exposure profiles

Chapter 9.1 of the EFSA AGD 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 is, however, not accepted for refined risk assessments in the Northern Zone. 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. Some of these variable parameters affecting the exposure profiles are described in the EFSA AGD, 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) 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 Northern Zone, 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.

Likewise, chapter 10.3.10 in EFSA AGD utilizes detailed analysis of exposure profiles to refine the worst case PEC_{mix} in risk assessments of 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 is not accepted to be used in refined risk assessments within the Northern zone.

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 recommendations, for algae, aquatic plants and invertebrates. For fish, however, exceptions are given in Table 18 below.

Table 18 **Method accepted (marked with X) in the Northern zone 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. However, use of geometric mean for long-term invertebrate risk assessment requires both that the EFSA AGD is respected[43] 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 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

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

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[44].
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[45.]
iii. When the endpoint of the most sensitive species tested is lower than the derived geomeric 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) and should not be merged in the assessment.

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 end-point of most sensitive species divided by a default AF of 6[46.]
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

[44] 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.

[45] $AF_{overall}$ = 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**.

[46] 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.

RACDA is the is the endpoint of most sensitive species divided by a default AF of 8[47]

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

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 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. 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. 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 Northern Zone Member States[48].

22.7 Bees

Please observe that this is an interim approach awaiting the EFSA guidance documents on bees.

An acceptable acute and chronic risk and risk to colony survival and development must be demonstrated. According to Regulation (EU) No. 284/2013, chronic 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 Northern zone 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)[49] only takes into account acute toxicity data on honeybees.

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[47] 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.

[48] In particular Sweden, Finland and Norway tend to have slightly acidic surface water.

[49] SANCO, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (Working Document, SANCO/10329/2002 rev 2 final, 17 October 2002).

To manage the discrepancy between the data requirements of Commission Regulation (EU) No 284/2013 and the guidance in SANCO GD (2002), the following interim approach for the risk assessment of bees is required for applications in the Northern zone 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 SAN-CO/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 20. For the time being, a tier 1 risk assessment using HQ acute oral and HQ acute contact should be presented for bumblebees[50] 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)[51] risk assessment scheme. This scheme 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)[52] approach. The ECPA (2017) risk assessment scheme may also be accepted for seed treatment products.

[50] The HQ for bumble bees is reasonable pragmatic interim solution.
[51] 2010 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 40, 323–331
[52] 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)

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)[53]. 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://doi.org/10.5281/zenodo.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 Northern Zone (mst.dk)" Cooperation in the Northern Zone (mst.dk).

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 formula-tions, the Northern zone 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 correct-ed 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[54] 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.

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[55]. 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.

[53] EFSA Journal 2013;11(7):3295
[54] In EPPO NOEDD is expressed as NOEL, here for consistency the term NOEDD is used.
[55] 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.

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 Northern Zone B&M GD version 2.1, 2020[56], 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 19 below.

Table 19. List of available test guidelines for bees

Datapoint[57]	Test methods
10.3.1.1.1 Acute oral toxicity	*Honeybees:* • OECD Test Guideline 213: Honeybees, acute oral toxicity test • EPPO Standard PP1/170[58] (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
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

[56] Northern Zone 2020. Pesticide risk assessment for birds and mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009.

[57] Reference to Part A of the Annex to regulation (EU) No. 284/2013.
[58] 2010 OEPP/EPPO,OEPP/EPPO Bulletin 40, 313–319.

	• 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[59]	*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 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 Northern zone 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

[59] 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.

the field to forage on flowering weeds and bees foraging in the off-field 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[60]. 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 Member States is either a restriction in timing of application or restriction of use in flowering crop[61], these mitigation measures can therefore be used in the core assessment. However, Member States 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.
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 Northern zone is given in Table 20**.**

Table 20. Acceptable waiving of formulation toxicity studies on bees in the Northern zone

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**	-

[60] 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.
[61] 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.

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[62] 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.

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[63] and compared with the acute formulation endpoint[64] (both expressed in terms of µg sum a.s./bee). It is recommended to use

[62] 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."

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

[64] 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.

the "waiving calculation" sheet in the "Chronic bee calculation tool", which can be downloaded at the Danish Environmental Protections Agency's website: Cooperation in the Northern Zone (mst.dk).

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 20 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

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

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

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 2019). Experts at EFSA (2019) agreed on VDF of 5 instead. The VDF is therefore set to 5 in the Northern zone as an interim approach.

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 Member state.

In the off-field risk assessment, in-field non-spray buffer zones should be used if required. For spray-drift values[65] 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. See Appendix VI: List of mitigation options available in the Member States in the zone, for relevant buffer zones in each Member State 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. However, data on acute effects on earthworms are no longer required according to Regulation 284/2013. Instead, the risk assessment should be based on sublethal effects for earthworms together with studies on *Folsomia candida* and *Hypoaspis aculeifer* where relevant. According to Regulation 284/2013, studies on *Folsomia candida* and *Hypoaspis aculeifer* are required whenever the product is applied directly to soil either as a spray or as a solid formulation and if first tier risk assessment for foliar treatments on non-target arthropods other than bees results in HQ above the trigger 2.

[65] Please notice that also 3 m buffer zone is relevant for arable crops and should be reported for Finland (drift values for arable crops at 3 m can be calculated by replacing 1 with 3 in cell A4 in the excel sheet).

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

Risk assessment for the active substance and metabolites should be performed with PEC_{acc}[66] values obtained by using Nordic PECsoil Calculator to take into account the possible accumulation of the active substance in the soil during the 20 years period. Risk assessment for the product should be performed with PEC_{max}, product of the first year of the spraying season. Formulation endpoint can only be used to cover the risk assessment for the first season.

22.9.3 Mixture toxicity assessment

If a formulation contains more than one active substance, mixture toxicity should be calculated. using the equation in section 22.1. The calculations should always be based on the PEC_{soil}, acc values obtained by using Nordic PEC_{soil} Calculator to

[66] PECacc: the highest concentration in soil (PEC max) during a period of 20 years including all applications from the last year.

consider the possible accumulation of the active substances in the soil during the 20 years period.

22.9.4 Higher tier risk assessment

22.9.4.1 Field studies

If required, also 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 of the Dutch platform for the assessment of higher tier studies, Guidance for summarizing earthworm field studies, RIVM 2006). 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 Member state. If field studies from other zones are used in the risk assessment, it must be shown that the exposure profile is representative for the uses applied for and Northern zone conditions, (see Table 8). If a new field study is performed it is recommended that the concentration of the active substance in the soil is measured and presented. 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 Refined PEC

In addition, refinement of the PECsoil based on crop interception (see fate section) is acceptable for the core assessment. At present use of PECpore water in the soil risk assessment is not accepted.

22.9.4.3 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 Member States in the zone.

National requirement (Denmark): Specific requirements for persistent substances[67]; Field effect studies for substances with DT50 soil between 3 and 6 months (further

[67] Persistent active substances can affect the environment over long periods of time as such substances can be distributed and accumulated within and outside the areas in which they are used. Persistent substances constitute a long-term and difficult-to-quantify risk of spreading in the environment and effects on organisms (standard ecotoxicological endpoints may not capture the full effects of prolonged exposure). Persistent substances can also cause effects on and lead to residues in subsequent crops. This also applies to the metabolites of an active substance.

details can be found in the Danish Framework for Risk Assessment of Plant Protection Products, see Appendix V: Summary of national requirements).

22.10 Non-target terrestrial plants

In the core assessment, a risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002 rev 2 final) 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 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 rev 2 final is not accepted in the Northern Zone 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 and the drift value must be according to Appendix III and IV in "Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods" (ESCORT 2; Candolfi et al. 2001). 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 Northern Zone 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[68] 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

[68] Please notice that also 3 m buffer zone is relevant for arable crops and should be reported for Finland (drift values for arable crops at 3 m can be calculated by replacing 1 with 3 in cell A4 in the excel sheet).

from where the latest version of Rautmann values in English (excel sheet) can be downloaded. See Appendix VI: List of mitigation options available in the Member States in the zone, for relevant buffer zones in each Member State 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 Assessment of the relevance of metabolites

The metabolites deemed relevant for ecotoxicological risk assessment in the NZ are given in the fate section (see core dRR, Part B section 8). Metabolites recorded in food items (see core dRR, Part B section 7) that might be eaten by birds or mammals should also be addressed in the risk assessment. The risk assessment is in principle similar to the assessment for the a.s., if not already covered by the a.s. risk assessment. The relevant EU guidance documents should be followed, if nothing else is stated in this guidance.

If toxic data is not available for a metabolite in question or an assessment of toxicity in accordance with EFSA AGD (chapter 10.2 in EFSA AGD) is not present, a risk assessment where the toxicity of the metabolite is considered 10x more toxic than the parent substance is accepted. This procedure is considered acceptable for all groups of organisms. If there exist evidence, e.g. from other sections (tox/ecotox) or from read-across, another factor than 10x may be applied on a case by case basis.

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 is given in FAQ to Aquatic Mixtox tool:

https://zenodo.org/record/4593676

22.12 Use of non-testing methods (e.g. QSAR)

It has been agreed in the Northern zone not to accept use of models such as QSAR for extrapolating the potential toxicity of the formulated product, metabolites or any other product ingredients.

However, QSAR models are accepted to be used for estimating the potential toxicity of metabolites and other ingredients in a particular formulated product if those particular models have been used and harmonized on EU-level for that particular substance. Hence, a QSAR endpoint for a metabolite could be accepted if it has earlier been accepted at EU level.

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	pesticider@mst.dk	Pesticider & Biocider Miljøstyrelsen Tolderlundsvej 5 DK - 5000 Odense C Denmark
Estonia	Rauno.Aljas@pta.agri.ee with copy to everiin.lill@pta.agri.ee	Agriculture and Food BoardPlant 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	The Environment Agency of Iceland 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 with copy to kristina.valioniene@vatzum.lt.	State Plant Service under Ministry of Agriculture Ozo str.4A LT-08200 Vilnius, Lithuania
Norway [69]	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	kemi@kemi.se	Kemikalieinspektionen P.O Box 2 SE-172 13 Sundbyberg, Sweden

[69] 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/

Appendix IV. Contact points of for Steering Committee in the Northern zone

Member State	CONTACT POINT
Denmark	**Title:** Coordinator for National Approvals **Name:** Vibeke Møller **Authority:** Danish EPA **Address:** Tolderlundsvej 5, 5000 Odense C, Denmark **Tel:** + 45 72544578 **E-mail:** vm@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:** Head of Unit **Name:** Kaija Kallio-Mannila **Authority:** Finnish Safety and Chemicals Agency (Tukes) **Address:** P.O. Box 66, FI-00521 Helsinki, Finland **Tel:** +358 29 5052000 **E-mail:** kaija.kallio-mannila@tukes.fi **and E-mail:** ppp@tukes.fi
Iceland	**Title:** Advisor **Name:** Helga Ösp Jonsdottir **Authority:** Environment Agency of Iceland **Address:** Sudurlandsbraut 24, 108 Reykjavik **Tel (direct):** 00354 591 2000 **E-mail:** helga.jonsdottir@ust.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	No	N.A.	N.A.
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. - 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	Danish: http://mst.dk/kemi/pesticider/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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 - -fatty acids - sulphur or iron - microbiological agents - pheromones for insect confusion - Products for non-professional users: Products which can be purchased 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.	

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- 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.	
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: http://mst.dk/kemi/pesticider/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/
Fate and behaviour	Specific groundwater modelling – including all metabolites	The following requirements should be included in the core assessment: Makro Danish scen. or PELMO Hamburg + specific input and output values All metabolites that are not inherently non-relevant needs to be covered by the assessment.	Danish: http://mst.dk/kemi/pesticider/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English:

Denmark			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
			http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/
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/kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed/ English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/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/kemi/pesticider/godkendelse-af-pesticider/vurderingsrammer-for-miljoe-og-sundhed/ English: https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/

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. - Severely damaging to to eyes (Eye Dam 1) - H318 Causes serious eye damage.	

Estonia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- 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. - 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.	

Estonia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
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**
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 **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 all necessary data about the co-formulants is provided by the supplier to the competent authority	
Toxicology - Exposure assessment		National work rate / day for barley is 40 ha. Dutch model is applied to greenhouse uses. In 2014 the *EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products* was published. Tukes has decided to implement this Guidance for all applications for plant protection products that are submitted from **1 January 2016.** 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		Authorization of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be	

Finland			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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. - 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	

Finland			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- 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	National regulation, Latvian 2012.gada 24.jūlija MK noteikumi Nr.509 „Noteikumi par augu aizsardzības līdzekļu laišanu tirgū saskaņā ar Regulu Nr.1107/2009”

Latvia			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- 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.	
Residues	No		
Efficacy	No		
Fate and behaviour	Yes	See core text in section 20.2	
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	

Lithuania			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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.	
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. - 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.	Lithuanian: 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.		

Lithuania			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
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).	
Toxicology-non-professional use		The directions for authorisation of non-professional use: 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		The following plant protection products may not be authorised for use by non-professional users: 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	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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 - 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.	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		- 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. 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	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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.
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	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		to protect bees or other pollinating insects according to the interim methodology in the Northern Zone. Furthermore, the plant protection product shall be labelled with the bee pictogram if the acute oral or contact LD50 for the product, active substance or relevant metabolites is lower than or equal to 11 µg/bee. 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).	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
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. 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?	

Norway			
Section	**Supplementary data Requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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. 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	

Sweden			
Section	**Supplementary data requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
		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 PECgw 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. 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	No		

Sweden			
Section	**Supplementary data requirements for Annex III dossier Yes/No**	**Goal(s) of Guidance document**	**Reference**
Toxicology		SE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix IX.	
Residues	No		
Efficacy	No		
Fate and behaviour	No		
Ecotoxicology	No		

Appendix VI. List of mitigation options available in the Member States in the Northern zone

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 See also Table 7 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 7 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 7 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 7 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 7on 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 7 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 20.3-3).	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.	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.	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.	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.	
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 20.3-3).	Nozzles with 50, 75 and 90 % reduction
Ecotoxicology- Bees	If the substance is toxic to bees and other pollinating insects, use nearer than 60 m to the beehives is forbidden without the beekeeper's permission. Restrictions of use during flowering and foraging activity including restrictions in time: plants may be sprayed after the flying time of bees between 21 and 6 o'clock.	

Finland		
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.	Nozzles with 50, 75 or 90% reduction
Ecotoxicology- Soil organisms	A restriction on the use in the consecutive years can be set for the plant protection products, if risk for the soil organisms occurs after use in consecutive years (calculated according to the Nordic PEC soil calculator).	-
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

Latvia		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology	Latvia accepts mitigation options as shown in Table 7 **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. 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, 50 m for orchards, 40 m for bush berries & nurseries. Mitigation of run-off: 10 m of vegetative buffer zone is acceptable. Drift reducing nozzles can be used to further reduce the risk from spray drift.	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	Buffer zones for off-field risk reduction can be applied if needed. Buffer zones calculating on every 5 meters which are based on toxicity to non-target arthropods is set as minimum of 5 m. 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 not an option.
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	Risk refinement has to be done with HC5 approach or risk mitigation with buffer zones. There is no limit for the maximum buffer zone width set in the national legislation. Buffer zones calculating on every 5 meters is set as minimum of 5 m.	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 7 *NZ approach of choosing PPE and other risk mitigation measures.* **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 organisms and surface water	Buffer zones, which are based on toxicity to water organisms. Min – 5m, max – 20 m for field crops and vegetable, 40 m for orchards. Calculating on every 5 meters. Mitigation of run-off: 10 m of vegetative buffer zone is acceptable. Drift reducing nozzles can be used to further reduce the risk from spray drift.	Nozzles with 50, 75 and 90 % reduction
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.	

Lithuania		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology - Non-target arthropods	Buffer zones for the off-field non-target arthropods. Min – 5m, max – 15m for field crops and vegetable, 30 m for orchards. Calculating on every 5 meters. Drift reducing nozzles can be used to further reduce the risk from spray drift.	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	Buffer zones: min – 5 m, calculating on every 5 meters. Drift reducing nozzles can be used to further reduce the risk from spray drift.	Nozzles with 50, 75 and 90 % reduction

Norway		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Toxicology - Worker exposure	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. NO accepts using the NZ Worker Acceptable Re-entry Calculator for time restriction of PPE use (alternative 2 and 3 in the Calculator). See also Table Table 7on the use of risk mitigation measures in the EFSA OPEX online calculator.	
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 20.3-3.	Yes (see table 20.3-3)
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 20.3-3)
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 20.3-3)

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%, …? %)**
Chemistry	Sweden may set the self-life of the PPP based on acceptable interim data from ambient self-life study.	
Toxicology	Sweden accepts mitigation options as shown in Table 7**: 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
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.	

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
Ecotoxicology - Aquatic organisms and surface water	In Sweden, adjusted buffer zones are used as a complement to fixed buffer zones to reduce spray drift. The use of buffer zones is regulated in regulation **NFS 2015:2**, where it is stated that the person who uses pesticides is obliged to establish spray-free buffer zones based on the current conditions on the site (e.g. temperature and wind). In order for the operator to determine adjusted spray-drift buffer zones, "Hjälpredan" ("the helper"= Buffer Zone Calculator) has been developed. The "Hjälpredan" enables pesticide users to decide the size of the buffer zone at the point in time when the pesticide is going to be applied by combining information on current weather conditions and their sprayer configuration. The use of "Hjälpredan" is equivalent to a (fixed) maximum FOCUS step 4 spray-free buffer zone of 15 m in field crops or 20 m in orchards. Consequently, if it is identified in the risk assessment that a FOCUS step 4 spray-free buffer zone up to 15 m in field crops or up to to 20 m in orchards is needed, this will result in a condition of use saying that the label shall include a requirement to use "Hjälpredan" in order to calculate and keep proper spray-free buffer zones. "Hjälpredan" (i.e. spray-free buffer zone) is to be used as first option for off-field risk mitigation. If the risk assessment indicates that spray-free buffer zones wider than 15/20 m are necessary in order to maintain a low risk to non-target organisms, "Hjälpredan" is not sufficient. Additional risk management measures may then be needed to fulfil the requirement for authorisation, for example drift-reducing equipment. However, it has to be established that the use of drift reducing nozzles does not impair on the efficacy of the product. - More information about the "Hjälpredan" is available at: Säkert växtskydd in English (sakertvaxtskydd.se) The surface water mitigation measures that are accepted in Sweden are listed in table Table 15 Conditions of use linked to SPe 2 and SPe 4 in Commission Regulation (EU) No 547/2011 are currently not used in Sweden.	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
Ecotoxicology - Bees	Risk mitigation options in SPe 8 in Commission Regulation (EU) No 547/2011 are accepted with the exception of restrictions related to beehives, where in-field spray-free buffer zones are accepted to avoid exposure of beehives outside the field.	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%

Sweden		
Area concerned	**Mitigation options**	**Drift reduction equipment e.g. nozzles (if yes 50%, …? %)**
	Restrictions of use regarding flowering crops always include weeds. Furthermore, in-field spray-free buffer zones could be used to reduce off-field risk to bees outside the field, maximum 15 m in field crops and 20 m in orchards. If necessary, also drift reducing equipment could be used in combination with spray-free buffer zones to further reduce the risk (if the efficacy is maintained). See further details above in point "Surface water".	
Ecotoxicology - Non-target arthropods	In-field spray-free buffer zones could be used to reduce off-field risks, maximum 15 m in field crops and 20 m in orchards. If necessary, also drift reducing equipment could be used in combination with spray-free buffer zones to further reduce the risk (if the efficacy is maintained). See further details above in point "Surface water".	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
Ecotoxicology - Soil organisms	Accepted risk mitigation option as described in Spe1 in Commission Regulation (EU) No 547/2011 where a restriction of use in the consecutive years can be set for the plant protection product, ~~a refined RA to reduce treated area may be possible with banded application~~.	
Ecotoxicology - Non-target plants	In-field spray-free buffer zones could be used to reduce off-field risks, maximum 15 m in field crops and 20 m in orchards. If necessary, drift reducing equipment could be used in combination with spray-free buffer zones to further reduce the risk (if the efficacy is maintained). See further details above in point "Surface water". Conditions of use linked to SPe 4 in Commission Regulation (EU) No 547/2011 are currently not used in Sweden. .	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%

Appendix VII. Template for Aquatic Risk Assessment including mitigation measures

Example Table 1: Risk assessment of the reproductive risk for fish based on FOCUS step 4 after use of Substance X in winter cereals.

Intended use **Application regime (single or multipel)**	Winter cereals Single application
Active substance	Substance X
Organism **Reproductive endpoint [µg/L]** **Assessment factor**	Fish *(O. mykiss)* 8 µg/L 10

Country	**FOCUS Step 4**			**RACsw**	**Is PECsw max > RACsw?**
	Worst-case scenario (ditch, stream or pond)	**PECsw max (µg/L)**	**Risk mitigation measure**		
Sweden	D1				Yes/No
	D4				
Denmark	D3				
	D4				

Finland	R1				
	D1				
	D4				
Estonia	R1				
	D1				
	D3				
	D4				
Lithuania	R1				
	D1				
	D3				
	D4				
Latvia	R1				
	D1				
	D3				
	D4				

Norway	R1				
	R2				
	R3				
	R4				
	D1				
	D3				
	D4				
	D5				
	D6				

Example Table 2: The long-term mixture toxicity risk assessment for fish and aquatic invertebrates after use of substance X and substance Y in winter cereals.

Intended use		Winter cereals						
Application regime (single or multiple)		Single application						
Active substances		Substance X and Substance Y						
Organisms		Fish ***(****O. mykiss)* and aquatic invertebrates (*D. magna*)						
Reproductive endpoints for *O. mykiss* [µg/L][1]		8 µg Substance X/L and 6 µg Substance Y/L or $NOEC_{mix-CA}$						
Reproductive endpoints for *D. magna* [µg/L][1]		6 µg Substance X /L and 4 µg SubstanceY /Lor $NOEC_{mix-CA}$						
Assessment factor used in the RAC calculation to derive RQ_{mix}[2]								
Assessment factor used in the RQ_{mix} or ETR_{mix-CA} calculation[3]								
Country	**Worst-case combination scenario[4]**	**Substance**	**FOCUS step**	**PEC_{SW} max (µg/L)**	**Mitigation measure**	**PECmix[5]**	**ETR_{mix-ca} or RQ_{mix}**	**Is risk acceptable?**
Fish								

Sweden	D1 stream	Substance X	Step 3		--			Yes/No
		Substance Y	Step 2		--			
Denmark	D3 ditch	Substance X	Step 4		20 m non-spray buffer			
		Substance Y	Step 4		20 m non-spray buffer			
Finland	D4 stream	Substance X	Step 3		--			
		Substance Y	Step 2		--			
Estonia								
Lithuania								
Latvia								
Norway								
Invertebrates								
Sweden								
Denmark								

Finland								
Estonia								
Lithuania								
Latvia								
Norway								

[1.] Endpoints of the single active substances should be reported if the risk assessment is based on RQ_{mix}. Endpoint of $NOEC_{mix-CA}$ should be reported if the risk assessment is based on ETR_{mix-ca} calculation

[2] Assessment factor used in RAC calculation will only be relevant if the risk assessment is based on RQ_{mix-CA}.

[3] If the risk assessment is based on ETRmix-ca calculation the assessment factor should be according to the ETR trigger value. If the risk assessment is based on RQmix, the assessment factor is set to 1.

[4] For the active substances there may be different worst-case scenarios, for example R1 for active substance no 1 and D1 for active substance no 2. The applicant must therefore show why a certain scenario is chosen to be the worst-case scenario for the combination of both active substances. Hence, it is the combination scenario giving the highest RQmix and ETR_{mix} that shall be presented in the table (not the scenarios with the highest PEC_{sw} values for each active substance).

[5] PECmix column will only be relevant if the risk assessment is based on ETRmix-ca calculation.

Appendix VIII. 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 IX. 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[70] as described below before gathering further information on acute inhalation toxicity.

The pre-evaluation is based on the dilution rate of the GAP and a worst case assumption of acute inhalation toxicity cat. 1 classification of the product and of the components[71] with unknown acute inhalation toxicity. It is also based on a theoretical[72] classification of the spray dilution. The outcome of the pre-evaluation is either A) the spray is theoretically classifiable or B) the spray is not theoretically classifiable:

A) The spray dilution is theoretically classifiable
If the spray is theoretically classifiable based on the worst case assumption (see scenarios 1-3 below for the assessment), further information on acute inhalation toxicity will be required, according to the data requirements, to address the classification of the product.
The information should be given according to the step-wise approach in the CLP Regulation: 1) available test data for the whole mixture, 2) bridging principle, 3) calculation of classification (however 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 product, MS will decide whether the product can be authorised for professionals and specific conditions for use will be set.

B) The spray dilution is not theoretically classifiable
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 below 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.

[70] This approach is not accepted by NO, FI and LT. Please refer to Appendix V for national requirements.
[71] 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.
[72] 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 as to whether acute inhalation toxicity of the product is relevant for situations in which the product is to be applied by spraying.

The following scenarios will not lead to a theoretical classification of the spray-dilution:

1) More than 1000 times dilution of the product (assume ATE 0.005 mg/L).
2) If less than 1000 times dilution and the component(s) of unknown inhalation toxicity are considered orally acute toxic (LD_{50}< 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 dilution is theoretically not classifiable:

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

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

   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) If less than 1000 times dilution and the component(s) of unknown inhalation toxicity are not considered orally acute toxic (LD_{50}> 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] of components with unknown and cat. 2 classification:

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

   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 less than 1000 times dilution and the PPP 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 can be used:

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

$n = the\ number\ of\ components\ fulfilling\ scenario\ 2$
$m = the\ number\ of\ components\ fulfilling\ scenario\ 3$
$C_{2i} = concentration\ (\%)\ of\ component\ i\ with\ oral\ LD50 > 2000\ mg/kg\ bw$
$C_{3j} = concentration\ (\%)\ of\ component\ j\ with\ oral\ LD50 > 2000\ mg/kg\ bw$

Appendix X. 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 e.g, data available in the Section 11 Toxicological information.
- 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[73], 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.

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

- 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.

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

Appendix XI. 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 exposure of 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 Northern Zone. The countries in the Northern zone 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 ($\chi 2$) %[74]
- A t-test and/or confidence interval for the rate constant (k)[75]

[74] If the visual fit is satisfactory, $\chi 2 > 15$ % may be accepted, especially for field studies where variation generally is higher.
[75] 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.