June 2021

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

Version 10.0. This guidance document replaces the version of June 2020 and can be voluntarily applied from June 2021. The document must be applied from the dates given in the table starting on page 2.

Changes to the previous version are highlighted in yellow

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

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January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products	DK + expert groups	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

		4.3 Residues	expert group	1 November 2017
		4.4 Efficacy	expert group	1 November 2017
		4.5 Environmental fate and behaviour	expert group	1 November 2017
		4.6 Ecotoxicology	expert group	1 November 2017
May 2018	7.0	Seventh revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections:		
		All sections		1 November 2018
June 2019	8.0	Eighth revision of Guidance Document on Work-Sharing in the Northern Zone in the Authorisation of Plant Protection Products. Changes in the following sections:		
		All sections		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		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		1 November 2021

The correct reference for the NZ work sharing GD:
Northern Zone, 2021. Guidance document on work-sharing in the Northern zone in the authorisation of plant protection products. Version 10, June 2021.

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 substance 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 reapproval date from 1 January 2016.

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

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 sent to the applicant.

The procedures for new applications and re-authorisations are further described in Chapters 5. to 12.

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 III**: Contact points.

The steering committee has telephone 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. Chairs are responsible for drafting the agendas of the meeting of the steering committee, minutes of the meetings as well as to coordinate updating the list of applications with agreed zRMS and timelines and 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.

Incoming chairs year 2021 – 2027

Year	Country*
2021	Estonia
2022	Sweden
2023	Norway
2024	Denmark
2025	Finland
2026	Latvia
2027	Lithuania

*Iceland is excluded.

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.

Guidance on the 'risk envelope' approach is available at the EU level as detailed in **http://ec.europa.eu/food/sites/food/files/plant/docs/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 III**: Contact points

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 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 authorization

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 IV) 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:

- **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 IV:** Summary of national requirements. 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

- **Cover letter**, including a brief summary of the application content and a brief summary describing how the documentation is organised
- **The application form,** available at each authority's website.
- **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. Preferably organised in Caddy.xml format or another intuitive structure with folder and file names reflecting the content, see **Appendix VII** for a recommended structure. File directory should not exceed 100 letters, including the file name.
  Further guidance on data requirements can be found in EU Guidance document on the interpretation of the transitional measures for the data requirements for chemical active substances and plant protection products according to Regulation (EU) No 283/2013 and Regulation (EU) No 284/2013 (SANCO/11509 /2013– rev. 3).
  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.
- **Completeness check scheme**

- **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.
- **Labels,** all labels should also be submitted to the zRMS.
  - National labels in national languages
  - Master label in English containing a description of the use in the whole zone.
- **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).
- **Justification** for new data submitted and use of vertebrate studies.

- Complete reference list
  - 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
  - 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.

- Confidentiality claim – use template in appendix 10 of the EU Guidance document on zonal evaluation and mutual recognition, withdrawal and amendment of au-thorisations 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 the **Guidance document on the evaluation of new annex II data post-annex I inclusion of an active substance** (SANCO/10328/2004 (latest version)).

8 Administrative prolongations of authorisations

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

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

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

9 Renewal of products 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.

9.1 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 authorizations
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.

1. 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.
2. 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.

9.2 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:

- Cover letter
- List of Cat. 4 studies to be submitted with the full dossier
- 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.

10 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:

- 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)
- Submission of the dossier (study reports) that was submitted to the reference MS.
- The assessment which is being referred to should fulfil the current requirements concerning form and detail (e.g. Registration Report)
- Part A of the reference Member State
- National requirements must be addressed
- Compliance with the national agricultural and environmental standards
- National risk management measures must be considered.

11 Withdrawal and amendment of an authorisation based on zonal evaluations

11.1 Amendment of authorisation

Amendments shall be dealt with according to the zonal procedure, if applicable. Appendix 1 in EU Guidance documents on zonal evaluation and mutual recognition, withdrawal and amendment of authorisations under Regulation (EC) No 1107/2009 (SANCO/13169/2010) states which kind of applications that should be sent for commenting. 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.

Type of amendment	**Sections 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 The composition of the co-formulants needs to be submitted to all cMS to make commenting possible.
Significant* formulation change	- An updated part C - An updated part B1, 2, 4 or addenda - Updates/addenda of other necessary part B, e.g analytical methods (method specificity), tox, efficacy etc.
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

*It is up to the MS to decide whether a formulation change is significant or non-significant. MS assessment will be performed by comparing the new formulation to the formulation for which a complete risk assessment was performed. See flow chart in section 4.1.1 for details.

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.

11.2 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) should be followed.

12 Timelines

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

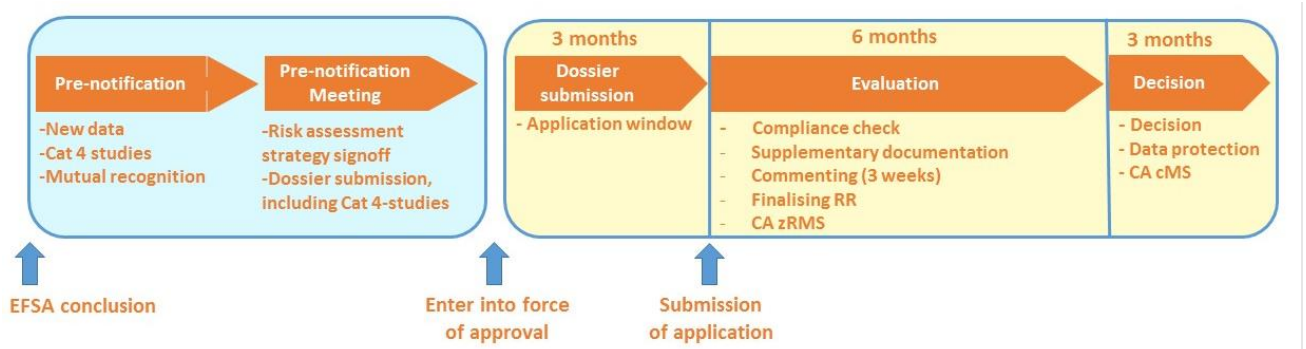
The allocation of the zonal RMS for the products within the Northern zone is initiated during the re-evaluation process (AIR-programs) of the active substances. The work is coordinated by one of the Northern zone MSs. The holder of the product authorisation will be notified of the zonal RMS for their 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 below.

SCHEME OF THE PROCESS FOR RE-AUTHORISATIONS



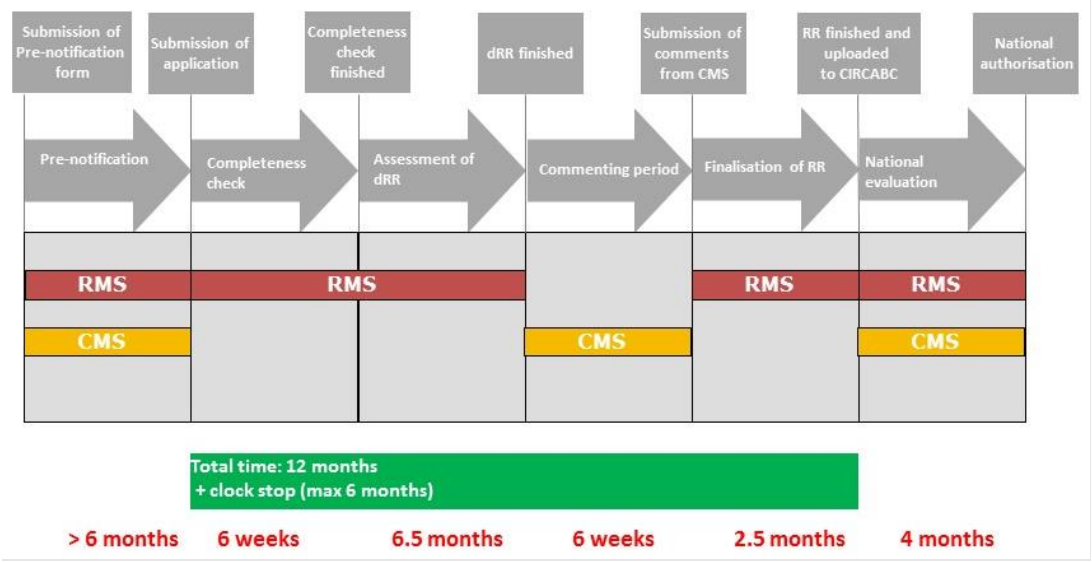
12.2 New product authorisations

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 below.

SCHEME OF THE PROCESS FOR ASSESSMENT OF APPLICATIONS FOR NEW PRODUCT AUTHORISATIONS



12.3 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).

12.4 Mutual recognition

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

12.5 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.

13 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.

14 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:** Reporting table and must be submitted before the agreed deadline (see timelines, section 12) 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.

15 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 see Appendix V: List of mitigation options available in the Member States in the zone.

16 Identity, physical chemical properties and analytical methods

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

- Manual on development and use of FAO and WHO specifications for pesticides. First edition - third revision, Rome, March 2016. http://apps.who.int/iris/bitstream/10665/246192/1/WHO-HTM-NTD-WHOPES-2016.4-eng.pdf?ua=1

- The International Code of Conduct on Pesticide Management, FAO Rome and WHO Geneva 2014. http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en/ / (March, 2015)
- United nations recommendations on the transport of dangerous goods (UN RTDG) manual of tests and criteria http://www.unece.org/fileadmin/DAM/trans/danger/publi/manual/Rev4/English/01E_intro.pdf
- ECHA guidance on the application of the CLP criteria http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp.
- SANCO/3030/1999, rev. 5, 22nd March 2019. Technical Material and Preparations: Guidance for generating and reporting methods of analysis.
- SANTE/2020/12830 Rev. 1, 24 February 2021. Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes SANCO/825/00 EU, rev. 8.1 and SANCO/3029/99 EU, rev.4), applicable from March 2021.
- Guidance document on the finalization of the reference specification for technical active substances after peer review (SANCO 6075/2009, rev.3, July 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, rev. 10.1, 13th of July 2012).
- Guidance document on significant and non-significant formulation changes, SANCO 12638/2011, 20th November 2012~~2~~
- Technical guideline on the evaluation of extraction efficiency of residue analytical methods, SANTE 2017/10632, rev.3, 22 November 2017.

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

16.1 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.

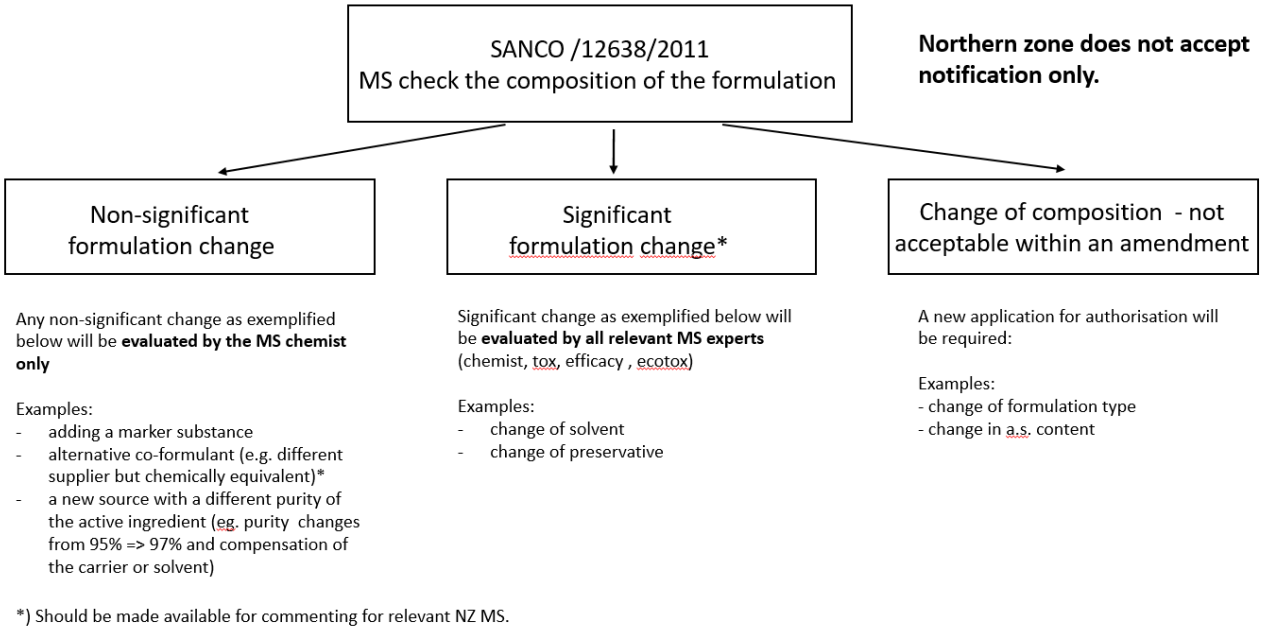
The acceptability of active substance's identity of every manufacturing source notified in the formulation shall be given with the precise reference (title of document, RMS, month, year of issue) to the EU relevant document (DAR/RAR Vol 4 Annex C, addendum to the DAR/RAR Vol 4 Annex C, Equivalence assessment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

The identity and content of safeners, synergists and co-formulants shall be given. For co-formulants, which are mixtures, the detailed complete composition shall be provided. 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. The trade name, where available, shall also be provided in part C of the dRR.

Information concerning suggested alternative co-formulants (e.g. from different suppliers) shall be included in the application. They must be chemically equivalent, and detailed composition for each alternative co-formulant is to be submitted to all cMSs for equivalence assessment. Chemical equivalence will be assessed on a case by case basis.

With regard to formulation changes, it is up to the MS in question to decide whether a formulation change is significant or non-significant. Northern zone does not accept notification only for formulation changes but always requires an application for amendment (see Section 11). MS assessment will be performed by comparing the new formulation to the formulation for which a complete risk assessment was performed. Please see figure below.

Northern zone - procedure for evaluation of formulation changes



Safety data sheets pursuant to Article 31 of Regulation (EC) No 1907/2006 as amended by Regulation (EC) No 453/2010 shall be provided and references to them included in Part C of the dRR.

16.2 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.

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 physico-chemical section.

Storage stability test at elevated temperature is always required independent of whether a 2-year storage stability test at ambient temperatures is available or not. 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.

If theoretically a relevant impurity could be formed during storage, then its content should be determined before and after storage (accelerated and shelf-life studies). If it could not be formed during storage, then determination of its content is only necessary before storage. If the relevant impurity is formed during manufacturing of the plant protection product then determination is also only necessary before storage. In cases where the relevant impurity cannot be formed upon manufacture or storage, then 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.

If tank mixing is recommended on the label, then the physical 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. Known non-compatibility shall be reported.

16.3 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. If new or old methods used for generation of data for risk assessment are submitted, a reason as to why these are needed should be provided with cross-references to the corresponding studies of the risk assessment (tox, ecotox, fate, residues or efficacy).

Validated methods, including those for the generation of data and for post approval 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.

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.

17 Toxicology

The most recent versions of the following guidance documents should be used for the core assessment:

- SANCO/10328/2004-rev 8 (24.01.2012). Guidance Document on the Evaluation of New Active Substance Data Post Approval
- SANCO/221/2000 –rev.10, 25 February 2003. Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC
- 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, 25 May 2018.

- SANCO/12638/2011. 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/EE[1]
- EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874, 55 pp., doi: 10.2903/j.efsa.2014.3874. (referred to as EFSA OPEX GD). The implementation schedule and applicability of this Guidance should follow SANTE-10832-2015 revised version 1.7, 27 January 2017.

Specific national requirements are listed for each country within the Northern zone in **Appendix IV**: Summary of national requirements and **Appendix V**: List of mitigation options available in the Member States in the zone.

17.1 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 was not according to CLP (Reg. 1272/2008). Likewise, if the study was evaluated according to previous data requirements that do not apply anymore.

When the hazard assessment for the PPP applied for is based on data for another similar formulation, the principles of Regulation (EC) No 1272/2008 (Annex I point 1.1.3) and SANCO/12638/2011 should be applied and a comprehensive bridging statement should be included in the dRR Part C.

The replacement of a study with an alternative approach under the CLP Regulation requires, according to the data requirements, that the specific toxicity of all components should be provided or reliably predicted. The applicant should provide a calculation of the classification from the information they have available. It is the responsibility of the applicant to ensure that the information about all the co-formulants, which is not available to the applicant, is provided by the supplier to the zRMS and cMS(s) in order to evaluate the calculation of the classification.

Acute Inhalation

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. See Appendix IV for national approaches on how to deal with this data requirement.

17.2 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.

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 cases, it may be necessary to perform additional exposure calculations for the lower application

[1] See section 16.

rates. This may apply if the experimentally determined dermal absorption value for a higher dilution is disproportionally larger than for a lower dilution.
In the EFSA calculator, the input parameter for water should be the minimum volume (L water/ha), given for the specific use, and the maximum application rate (L product/ha). The input for dermal absorption of the in-use dilution shall be based on the dilution corresponding to the highest application rate (L product/ha) diluted in the highest water volume (L water/ha) given for the specific use. As an example, if the amount of product is given as an interval of 0.5 – 1.5 L product/ha and the water volume is given as 100 – 300 L water/ha for the critical use, the highest application rate of 1.5 L product/ha and minimum water volume of 100 L water/ha should be entered in the EFSA calculator. The dermal absorption value for the in-use dilution, to be entered in the EFSA calculator, should cover the dilution of 1.5 L product/ha in the highest water volume of 300 L water/ha.

Acute risk assessment for operator and bystander exposure can be performed only when the AAOEL values for active substances are established at EU level. Acute worker exposure cannot be estimated as information in the EFSA Guidance 2014 is currently not suitable

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[2] 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.

17.2.1 Operator Exposure

The following exposure models are acceptable:

- EFSA GD Exposure Calculator
  (Available on https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3874)
- Dutch model (greenhouses)
  (Available on https://english.ctgb.nl/plant-protection/documents/assessment-framework-ppp/2016/10/27/calculation-model-operator-nl-greenhouse)
- Seed Tropex model (seed treatment)

[2] See Appendix IV for national requirements for Norway on adjuvants.

For all models a default body weight of 60 kg should be used while, as a first tier, the rest of the standard input parameters are not changed.

With regard to EFSA GD Exposure Calculator:
The values of treated area per day used for the estimation of operator exposure in EFSA GD Exposure Calculator should not be adjusted for smaller areas. Not even if less modern equipment is assumed, since the AOEM covers also less sophisticated techniques.

Initially, the assessment shall be made with the assumption that the operator is not using any PPE. However, regular workwear (as defined in the EFSA OPEX GD) is assumed. See Table 17.2.6-1 for an overview of the tiered approach, use of PPE and other risk mitigation measures applicable in the NZ.

For tunnel uses the Dutch greenhouse model should be used as it is considered the worst-case operator exposure scenario.

17.2.2 Non-professional user

The following exposure models are acceptable:

- 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 and will be evaluated on a case-by-case basis. A product applied both upward and downward outdoor should be assessed according to both the German and UK POEM model. Relevant tiered approach to exposure evaluation should follow table 17.2.2-1. 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 17.2.2-1 Models and input values for a tiered exposure assessment of non-professional users

		UK POEM	German model	Dutch greenhouse	UK Trigger[c]	PHED	Pufferpack[c]
		Solids/liquids	**Solids/liquids**		**Ready-To-Use**	**Solids**	**Solids**
Low target 1st tier	Work rate ha/day	0.1ha		0.1ha		0.1ha	
	Exposure duration	2h			2h		1h
Low target 2nd tier[a]	Work rate ha/day	0.01ha[b]		0.01ha			
	Exposure duration	0.5h[b]			0.5h[b]		0.5h[b]
High target 1st tier	Work rate ha/day		1 ha[b]	0.1ha			
High target 2nd tier[a]	Work rate ha/day		0.1ha	0.01ha			

[a] FI will assess 2nd tier on a case by case basis

[b] default value

[c] default work rate is ~0.01 ha/day

17.2.3 Worker Exposure

The following exposure calculations and input parameters are acceptable:

- EFSA GD Exposure Calculator to both outdoor and indoor scenarios (Available on https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2014.3874)
- Seed Tropex model - sowing

For tunnel uses the EFSA calculator indoor scenario should be used as it is considered the worst-case worker exposure scenario.

Inhalation exposure

The inhalation contribution should be taken into consideration for indoor uses. If inhalation exposure is not a part of the scenario used in the EFSA Calculator a realistic worst case should be applied. Consequently, the inhalation exposure contribution should be determined in the EFSA Calculator by applying roof fogging/low-volume mist for all uses other than ornamentals. For instance, in berries, spray application does not consider inhalation. Low volume mist or roof fogger are considered as worst case instead of taking into account other uses like ornamentals where spray application does account for the inhalation contribution.

Dissipation of the active substance on the foliage

A default dissipation half-life of 30 days should be used for organic substances only if no DT_{50} value or half-life data representative of the supported use(s) are reported[3].

Dislodgeable foliar residues (DFR)

[3] The DT50 or half-life values stated in EFSA OPEX GD 2014 Appendices C and D cannot be used to refine the default value of 30 days as otherwise stated in the GD. In the EFSA Technical Report 2014 (https://efsa.onlinelibrary.wiley.com/doi/pdf/10.2903/sp.efsa.2014.EN-681) comment 430 in page 75 it is clarified that experimental studies representative of the supported use(s) should be provided.

If data on the amount of dislodgeable foliar residues (DFR) under the proposed conditions of use are not available, default assumption (3 µg a.s./cm^2 of foliage/kg a.s. applied/ha;) shall be used.
Experimental data on DFR can be included, if all of the following is fulfilled:

- the study covers all the intended uses (GAP). This includes the application rate, number of applications, application efficiency, equipment, environmental conditions (i.e. relevant time of year and geographic location), crop type, physical and chemical properties of the applied PPP.
- an official guidance/guideline is applied and referred to (e.g. US EPA OPPTS Guidelines 875.2000; 875.2100, Guidance for determination of dislodgeable foliar residue, HS-1600 revised 2002, California EPA or comparable).
- the study follows GLP standards.

Data from a DFR study could provide a direct basis for the selection of protective measure as re-entry/waiting period (in hours or days).

Calculation of re-entry period and required interval for the use of gloves and/or work wear
Generally, the worker re-entry period is the time interval (in hours or days) during which entry into the treated crops, buildings or spaces and handling crops that have been treated with a PPP is not safe for workers even when they wear protective gloves and workwear.

Currently, the available data of EFSA Calculator for both outdoor and indoor scenarios allow calculations for re-entry only immediately after the application solution has dried. If worker exposure during re-entry activities (e.g. inspection, harvesting, reaching, picking, cutting, sorting etc.) exceeds the AOEL, even when wearing protective gloves and workwear, a re-entry period can be used as a risk mitigation measure.
The NZ has developed the 'NZ Worker Safe Re-entry Calculator' for the situations where a re-entry period can be calculated. A re-entry period should be calculated from the equation for dermal exposure with an extra factor for decay using dissipation half-life (DT_{50}) and assuming first order kinetics in accordance with the EFSA OPEX GD (section 6.2). Inhalation exposure is assumed to be negligible for outdoor uses. For indoor uses, inhalation exposure is assumed to be unchanged over time and is added without considering decay.
The NZ Worker Safe Re-entry Calculator is applicable to both outdoor and indoor scenarios and is available on
https://www.kemi.se/en/pesticides-and-biocides/plant-protection-products/apply-for-authorisation-for-plant-protection-products/plant-protection-products/plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products.

This calculator offers three calculation options and should be used for determining:

1) Re-entry period (the number of days after the application), after which worker re-entry activity is acceptable with gloves (PPE) and workwear.
2) The number of days after application for which gloves (PPE) and workwear are required.
3) The number of days where only workwear is required counting from terminating the use of gloves (PPE).

Acceptability of a re-entry period as a risk mitigation measure, determined by this calculator, as well as time restriction on the use of gloves and workwear is decided on by each MS (for details see Appendices IV and V).
It is necessary to note that some prerequisites have to be followed before applying the NZ Worker Safe Re-entry Calculator: the inhalation exposure contribution should be determined in the EFSA Calculator by applying roof fogging/low-volume mist for all indoor (greenhouses) uses other than ornamentals. The Calculator is only applicable to PPPs with low to moderate volatile substances. The Calculator is applicable for PPPs with both single and multiple active substances.
A noteworthy fact is that irrespective of calculating a re-entry period 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 V).

Transfer coefficient (TC)
At first, the assessment shall be made using available data with the assumption that the worker is not using any PPE: normal work clothing/workwear (coveralls or long-sleeved jacket and trousers) is assumed. Further refinement using gloves (PPE) is needed if the predicted exposure exceeds the AOEL. Each MS decides on appropriateness of using gloves as a refinement of exposure assessment (see Table 17.2.6-1).

17.2.4 Bystander & Resident Exposure

For long term risk assessment, the following approach, exposure calculations and input parameters are acceptable:

- **as a Tier I** EFSA GD Exposure Calculator 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 mean value of all pathways) 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 17.2.6-1).

- 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 calculator outdoor scenario should be used as it is considered the worst-case bystander and resident exposure scenario.

Recreational exposure
A risk assessment for recreational exposure is necessary for an application of a PPP on golf course, turf, other sports lawns or amenity turf/grassland areas where member of the public is likely to have access[4,5]. Additionally, for an application of a PPP on golf course, turf, lawns, grassland etc an assessment of re-entry/waiting periods has to be submitted in the core dRR. However, acceptability of a re-entry/waiting period will be decided on by each MS.

17.2.5 Field studies

In general, where no standardised **first tier method** of operators, workers, residents and bystander's 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** might 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. The respective requirements of EFSA OPEX GD chapter 4.3 should be followed.
A short summary describing the field study and the main parameters, including the application rate and specific application equipment, personal protective equipment, the frequency and duration of pesticide handling and the weather conditions should be included in the dRR.

[4] See Appendix IV for restrictions in Norway for the use of PPPs on areas accessible for the public.
[5] In the EFSA GD Exposure Calculator choose golf course, turf and other sports lawns to assess the risk of recreational exposure

A justification should be provided in the dRR (Part C if confidential) if the field study is performed on 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.
It should be noted that user conditions of field studies might affect the user conditions stipulated in the national product authorization.
In addition to these general requirements, the following requirements need to be met for field studies concerning operator exposure assessment and seed treatment assessment, respectively:

Specific requirements to field studies concerning operator exposure assessment

- Perform the study according to OECD Guidance no 9 and follow GLP standards (OECD guideline No 6)
- The study shall be conducted on the product applied for or a product with identical formulation type, similar physical chemical properties (pH, viscosity, density, surface tension and dustiness for solid), same tank mixture requirements including (but not limited to) mixing with other PPP, solvents and water. If conducted with another active substance, then the active substances should have similar relevant physical chemical parameters such as vapour pressure.
- Study parameters shall cover those specified in the NZ GAP table including (but not limited to) highest dose rate, application method, season, crop type, as well as relevant application equipment and temperature should be used.
- 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
- The data shall include all outliers in the data set as they represent realistic use

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.

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.

17.2.6 Risk mitigation measures

Table 17.2.6-1 gives an overview of the acceptable risk mitigation measures in each of the member states of the Northern zone. Information on risk mitigation measures for workers such as acceptability of a re-entry period, determined by the NZ Worker Safe Re-entry Calculator, and national requirements for waiting period(s) can be obtained in Appendices IV and V.

Concerning label requirements, there are different approaches. In some countries, the need for use of workwear and gloves is not put 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 new risk mitigation measures for the health risk assessment. Hence, not all MS are ready to accept these. 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 will be required on the label if required as risk mitigation measures.

Table 17.2.6-1 NZ approach[6] of choosing PPE and other risk mitigating measures in the EFSA calculator

	DK	NO	SE	FI	LT	LV	EE	Harmonized
Operator								
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 covered	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
Residents/ bystanders								
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								
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
Field use								
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear + 1. No PPE 2. Gloves	CbC***	Y	CbC***	Y	Y	Y	Y	N

*Under evaluation **Experience is needed before changing legislation ***Case-by-Case. Regarding field use/tiered approach gloves will be accepted case-by-case by DK and SE.

[6] See Appendix IV for National requirements and Appendix V for mitigation options available in the member states in the zone

17.3 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. The bridging statement should include a comparison of the composition of the two products and also 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 safe 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.

17.4 Formulation Changes

Evaluation of significant formulation changes[7] as indicated by SANCO/12638/2011 should consider:

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

17.5 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.

The assessment of the relevance should cover all the requirements in the GD (SANCO/221/2000 – rev.10) on the relevance of metabolites in groundwater. The full relevance assessment is to be presented in the core dRR, Part B section 6 and 10.

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

18 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):

- OECD (2009). 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 (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
- OECD (2008). Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96.
- OECD (2009). 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
- SANTE/2019/12752 – (23 November 2020). Appendix D - Data requirements for setting maximum residue levels, comparability of residue trials and extrapolation of residue data on products from plant and animal origin (Repealing and replacing the existing Guidance Document SANCO 7525/VI/95 Rev. 10.3.) will be applicable to applications submitted from 1 January 2021.
- SANCO/7039/VI/95 EN. 22 July 1997. Appendix I – Calculation of maximum residue levels and safety intervals
- MRL Calculator EU-OECD 2015
- SANCO/11187/2013 rev. 3. 31 January 2013. Appendix J – Nature of pesticide residues in fish
- SANTE/11956/2016 rev.9 14 September 2018 (Technical guidelines for determining the magnitude of pesticide residues in honey and setting Maximum Residue Levels in honey) will be applied to applications received at or after 1 January 2020.
- SANTE/2020/12830 Rev. 1, 24 February 2021 - Guidance Document on Pesticide Analytical Methods for Risk Assessment and Post-approval Control and Monitoring Purposes (Supersedes SANCO/3029/99 EU, rev.4 and SANCO/825/00 EU, rev. 8.1), becomes applicable on 1st March 2021
- 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)
- OECD (2007). 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 TEST GUIDELINES No. 501, 502, 503, 504, 506, 507, 508, 509

Specific national requirements are specified for each country in **Appendix IV**: Summary of national requirements .

18.1 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.

18.2 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.

18.3 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 analyzed
- 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*".

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.

18.4 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.

18.5 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.

18.6 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.

18.7 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.

In addition that the evidence should be scientific, no guidelines exist as to how consumer safety should be assessed. 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.

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 IV:** Summary of national requirements **.**

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

The rules for comparability, extrapolation, group tolerance and data requirements for pesticides residues in food and raw agricultural commodities, described in guidance document SANTE/2019/12752, 23 November 2020, 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, 23 November 2020.

18.9 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.

19 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 **Appendix IV**: Summary of national requirements **.**

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

1. 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. A dRR with all sections must be submitted.

2. The applicants can ask for label extension but only for use already authorized in at least one of the countries in the Northern zone.

3. The applicants are required to provide an overview of the current authorizations 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.

4. The countries in the Northern zone belong to two EPPO zones (Maritime and North-East) and if the applicant applies for authorization 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.

5. 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: Minimum number of trials to be conducted in the Northern Zone.

6. If the active substance is 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.

20 Environmental Fate and Behaviour

Disclaimer:

1. *This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases, specific national guidance must be consulted additionally. Specific national requirements are presented in* **Appendix IV:** Summary of national requirements **.**
2. 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 approval is not applied for in a specific country the specific national requirements do not need to be addressed.

The following guidance documents should be used for the core assessment:

- 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[8].
- Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (version 1.1, 18 December 2014): 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 version 2.0 (final). June 2006.
- Generic Guidance for Surface Water Scenarios (version 1.4, May 2015): 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 rev.2 (final), version 1.4, May 2015.
- SANCO/321/2000 rev.2. November 2000. FOCUS groundwater scenarios in the EU review of active substances.
- Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version 2.2, May 2014): 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 Journal 2014; 12(5):3662. 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[9].
- Guidance document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and

[8] Note that this guidance is not accepted by DK (see Appendix IV). For the assessment of groundwater exposure in DK, please see the Danish national guidance document.

[9] This guidance should be used for all a.s. which have been evaluated at the EU level after this guidance entered in to force. It may be used for other a.s. if this is the only way of demonstrating safe use. That means, recalculation of existing LoEP data on DT_{50} and Koc according to the guidance will not be required. Please note the new interception values, which should be used for all submissions.

crops grown under cover) to relevant environmental compartments, SANCO/12184/2014 rev. 5 (27 January 2015).

- Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach", SANCO/11244/2011 rev. 5 (14 March 2011).
- Guidance on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments, SANTE/12586/2020 – REV 0 (26 January 2021). *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 ground-water 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 IV). Exposure estimations are case-by-case decisions.
- **US EPA's Golf course adjustment factors (GCAF)** are accepted in Finland and Sweden for tees, greens, fairways and roughs[10]. GCAFs are used to refine the area that is sprayed and are found in the following web-page: https://archive.epa.gov/oppefed1/web/html/golf_course_adjustment_factors.html
- The **risk envelope** approach is acceptable for calculation of PECsoil, PECgw and PECsw modelling is more complex. The risk envelope approach may only be used 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.

20.1 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 Finnish temperature scenario, which is pre-implemented into the PECsoil 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 20.1-1). EFSA Guidance Document for evaluating laboratory and field dissipation studies (2014)[11] should be used to select the proper DT_{50} value.

Table 20.1-1 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 (°C)	Annual precipitation (mm)
Denmark[3]	5 -7	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	5 - 7	Below 10 (Ap layer)	ca. 4.3	627 – 650

[10] 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 partiular use

[11] 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.

Latvia[4]	4.5 - 7	1.5 - 5 (Ap layer)	5.2 - 7.4	600 - 850
Lithuania	4-8.2[7]		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 pH_{H2O} and organic carbon content (OC) derived from a database of 12 598 samples of arable topsoils systematically covering 92.7 % of arable land in Sweden, published in Jordbruksverkets Rapport 2015:19.

6) 10th and 90th spatial percentile of annual average air temperature and annual precipitations for agriculture-related land-use, derived from EFSA/ESDAC raster dataset.

7) Soil pH data from Lithuanian Geological Survey. pH given as pH_{H2O}.

8) Average annual air temperature (°C) and precipitation (mm) 1981-2010. Climate data from Lithuanian Hydrometeorological Service.

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 SFO=DT90/3.32).

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.

For the active substance(s), $PEC_{max\ (1st\ season)}$, $PEC_{21\ dayTWA}$ and PEC_{acc}[12] 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 20.2-4 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, a soil depth of 20 cm can be considered for the years before the last application if tilling practice is applicable. 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.
For the product, the PEC_{max} of the first year should be reported and referred to as $PEC_{product}$.

National cut-off criteria:
DK: For approval, 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 approval 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.

20.2 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.

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

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

Surrogate crops

When a crop is not parameterised in any of 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.

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 20.1-1) should be used for selection of appropriate input values for the groundwater simulations[13] (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[14] used as model input need to follow EFSA GD on $DegT_{50}$ (2014).

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[15]. 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.

National requirements for PECgw simulations

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{DOT}asp{AT}smhi{DOT}se; Tel 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

[13] 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.

[14] 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.

[15] Generic Guidance for Tier 1 FOCUS Ground Water Assessments, Version: 2.2, Date: May 2014; Implemented from 1 May 2015.

package that was downloaded from FOCUS DG SANTE so that all currently relevant (and requested) scenarios are included.

Table 20.2-1 National requirements for PECgw simulations. The newest model version should always be used, unless otherwise specified.

MS	Tier I - PELMO	Tier II – simulations with MACRO[16]			
		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[17] **≥ 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[18]** **Rustad[19]**	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 **< 0.1 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**			**Evaluation of MACRO/PELMO results**
		Triggered when	**MS specific comment**		
DK	FOCUS PELMO: Hamburg	a.s./any metabolite **> 0.001 µg/L**	As input the following shall be used: 80th percentile for the degradation (not geomean DT_{50}), 20th percentile for K_{foc} and 80th percentile for 1/n (not arithmetic mean) and number of years that exceed 0.1 µg/L out of 20 years as output (not 80th percentile). All metabolites need to be covered by the assessment. Further guidance available in the Danish national guidance: http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/		a.s./all metabolites **< 0.1 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.
MS	**Tier I – PEARL or PELMO**	**Tier II – simulations with PEARL or PELMO (Hamburg)**			**Evaluation of PEARL/PELMO results**
		Triggered when	**MS specific comment**		

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

[17] 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.

[18] 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.

[19] Rustad is only required for Norway. Relevant files and background information is available at www.mattilsynet.no or on request.

LT	FOCUS PEARL or 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 **< 0.1 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 or PELMO**			
FI[20]	FOCUS PEARL or PELMO: Hamburg and Jokioinen			
LV				
EE				

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

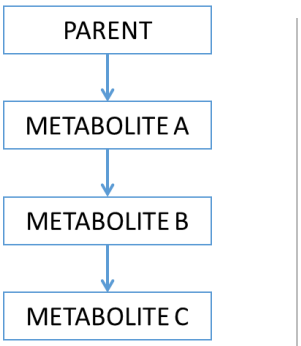
General guidance on simulating PECgw for metabolites in MACRO:

The purpose of the following text is to give practical advice on how to simulate PECgw 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 below). 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 below). 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.

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 true degradation or formation fraction data are available:

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 x (1-interception) x max observed x (Mw_{met} / Mw_{par})

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 20.2-2.

Table 20.2-2 Example of summary table for the PECgw results

Country	PECgw (80^{tt} percentile)		
	Compound	PECgw	model & scenario

If one or both of the limit values (0.1 µg/L for each individual substance[21] and 0.5 µg/L for the sum of substances[22]) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. field studies, and/or monitoring data[23]) 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")[24]. This is the official policy in the following Northern zone member states; EE, FI, LT, LV, NO, SE. For more information, see 20.5 Assessment of the relevance of metabolites in groundwater.

Information on crop rotation in each NZ MS

The crop rotation period represents the normal agricultural practice. When the value is 3 or more every third-year application can be used in modelling. Use every second/third/fourth year depends on crop and country (please refer to Table 20.2-3 for country specific crop rotation periods).

Table 20.2-3 Possible crop rotation period in years (for cells left blank an argumentation is required)

Crop	Country						
	Denmark	Estonia	Finland	Latvia	Lithuania	Norway	Sweden****
Potatoes	4	1*/3***	1/3***	2-3	4	1/3*	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**	
Cabbage	1	1/3*	1/3*	2-3		1	
Carrots	1	1/3*	1/3*	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	1	1/3*	1/5*	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	

1: every year. 2: every second year. 3: every third year etc.
* In early potatoes, cabbage, carrot and onion crop rotation may not necessarily be applied.
** Harvested as seed.
*** 3 years crop rotation is for seed potato
****The Swedish Board of Agriculture's Regulations SJVFS 2015:49 indicate that records sheets for pesticide treatments shall be kept at least three years (12 §). Sweden therefore 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. The values indicated in the column for Sweden are based on the current practices or recommendations in terms of crop rotation but capped to three years.

[21] Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.
[22] 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/.
[23] 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 IV.
[24] 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).

20.3 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. If older versions of Step 1 and 2 is used, Step 2 PEC calculations are sufficient for parents and metabolites If the resulting Toxicity-Exposure ratio trigger values for aquatic ecotoxicology are exceeded by a factor of 10. If the latest version is used of Step 1 and 2, Step 2 PEC calculations for metabolites are sufficient without the resulting Toxicity-Exposure ratio trigger values for aquatic ecotoxicology being exceeded by a factor of 10. The table below lists the different cases that can occur and what rule should apply in each of these cases:

Table 20.3-1 Coupling between the PEC_{SW} obtained at FOCUS Step 1 and 2 and the ecotoxicology assessment.

Focus step 1-2 version	parent-substance	metabolite
≥ 3.2	Step 3 not required if $TER_{step\ 1\ or\ 2,Parent} \geq (AF * 10)$	Step 3 not required if $TER_{step\ 1\ or\ 2,Metabolite} \geq AF$
< 3.2	Step 3 not required if $TER_{step\ 1\ or\ 2,Parent} \geq (AF * 10)$	Step 3 not required if $TER_{step\ 1\ or\ 2,Metabolite} \geq (AF * 10)$

Where $TER_{Step1\ or\ 2}$ = Toxicity / $PEC_{SW,step1\ or\ 2}$ and AF = Assessment Factor = trigger value.

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 20.3-2).

Surrogate crops

When a crop is not parameterised in any of 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.

Input parameters

For DT_{50} in soil, sediment and water, modelling endpoints in accordance with the recent version 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 (see Table 20.1-1 and text in chapter 20.2 - Groundwater). 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 chapter 20.2 - 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).

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:

Table 20.3-2 Member State specific requirements for FOCUS scenarios considered in the assessment of surface water and sediment exposure

Country	Scenarios								
	D1	D3	D4	D5	D6	R1	R2	R3	R4
Denmark#		X	X						
Estonia###	X	X	X			X			
Sweden*	X		X						
Norway##	X	X	X	X	X	X	X	X	X
Lithuania	X	X	X			X			
Latvia###	X	X	X			X			
Finland**	X		X			X			

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.
In case a surrogate crop is used, simulations must be conducted for all the scenarios that contain the surrogate crop.
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.
*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.
** 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 20.3-3 Possible surface water mitigation measures in the Member States of the Northern zone

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

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 20.3-4.

Table 20.3-4 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

[25] 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)

Country	Comp.	Appl.	Step 2		Step 3			Step 4		
			PECsw	PECsed	Scenario	PECsw	PECsed	Mitigation measure	PECsw	PECsed
		S								
		M								
		S								
		M								

S = single application, M =multiple applications

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.

20.4 Monitoring data

Available monitoring data from the zone (see Table 20.4-1) 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 IV). 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 20.4-1 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 IV.

20.5 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"[26], the upper limit value is 10 µg/L.

The assessment of the relevance should cover all the requirements in the GD (SANCO/221/2000 – rev.10) 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.

21. Ecotoxicology

Disclaimers:

1. *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 IV**: Summary of national requirements **.**
2. The present guidance for the environmental risk assessment regarding applications for approval of plant protection products in the Northern Zone highlights parts which MS in Northern Zone disagrees with in EU and EFSA Guidance Documents mentioned below. 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 product may also be used as surrogate for another product, if valid bridging studies can support this.
- Endpoint according to product data requirements (284/2013), if not covered by LoEP.

The following guidance documents should be used for the core assessment:

- 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. The most recent version.
- 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 rev. 2 final. 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.* [27]
- 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

[26] 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).

[27] Not relevant for Estonia, Latvia and Lithuania

- 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 would not accept modelling data based on unofficial FOCUS-model versions (see section 20.3).

21.1 Mixture toxicity

Mixture toxicity should always be considered for acute and long-term risk assessment for all non-target species, using the concentration addition approach.

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:

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

If SUM < 1 the risk assessment is acceptable

Where:

- ”Trigger-value” represents the uncertainty factor of chemical A, B etc.
- TER is the Toxicity Exposure Ratio calculated from the substance specific effect concentration (e.g. EC50, EC10 or NOEC) divided by the expected environmental exposure.

21.2 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 IV**: Summary of national requirements for national criteria for non-professional use.

21.3 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).

21.4 Vertebrate testing

Generating new studies on vertebrate animals should be avoided whenever possible[28], and duplication of vertebrate tests is not accepted[29]. 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.

21.5 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[30] with a few amendments.

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. A geometric mean with only two species is not considered sufficiently protective[31]. If endpoints from two species are available, the lowest endpoint should be used in the risk assessment. 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. Please follow the procedure for the GM and DA approach used for algae and aquatic plants (21. 6 Aquatic ecosystems).

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.

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

[28] 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.

[29] Regulation (EC) No1107/2009, Chapter V, Article 62.

[30] In EFSAs guidance document (EFSA Journal 2009; 7(12) 1438) it is mentioned that for the acute risk assessment a geometric mean of the acute toxicity data can be used in a refined risk assessment. Denmark, however, does not accept the use of this geometric mean approach. Therefore, for the risk assessment the lowest endpoint available could be used to cover for the whole zone. If the geometric mean approach is used this should be clearly highlighted by the rapporteur in the core assessment. Denmark always uses the lowest endpoint and takes account of additional toxicity data by an ad-hoc assessment.

[31] 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.

should always be considered also for long-term risk assessment including risk from secondary poisoning[32]. 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 21.1 should be used for the long-term risk assessment[33]. 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/.

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 DT_{50} in plants are available. Please refer to the Northern Zone higher tier guidance document, section 4.4 (available at the Danish EPA webpage regarding Pesticides; https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-11/cooperation-in-the-north-zone/ for Northern Zone requirements concerning refinement of DT_{50}.

When further refinements of the risk assessment are necessary, the Northern Zone higher tier guidance document describing relevant scenarios to be used in a higher tier risk assessment 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 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.

21.6 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[34]. 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 VI**. 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 PECsw based on spray drift of formulation.

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

[32] for all a.s. in a product and metabolites with log Pow > 3

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

[34] 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.

An excel based Aquatic MixTox calculation tool has been developed in order to ensure correct calculations and can be accessed at the Danish EPA webpage regarding Pesticides; https://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/cooperation-in-the-north-zone/. Applicants shall use this tool and report the results in the format given in the Aquatic MixTox tool. If the mixtox calculation is based on active substance endpoints i.e. ETRmix-ca, and it shows unacceptable mixtox 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.

If refinements are needed in the aquatic risk assessment, the following must be considered in the core assessment:

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 20.3). 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[35] regarding use of PEC_{TWA}. 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.

Refinement by using detailed analysis of exposure profiles is not accepted (Chapter 9.1, parts of chapter 9.2 and chapter 10.3.10 in EFSA AGD)
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.

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

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 in Table 21.6-1 below.

Table 21.6-1 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+
	Long-term	Not accepted (see below)			

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

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[36] 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).

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 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 RAC_{GM} (RAC_{GM} = geometric $mean_{acute}$ / 100), RAC_{DA} should be used in the risk assessment. Here, the RAC_{DA} is the

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

endpoint of the most sensitive species divided by a **default AF of 20 for invertebrates and 30 for fish**[37].

- (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, RAC_{DA} should be used in the risk assessment. Here, the RAC_{DA} is the endpoint of most sensitive species divided by a default AF of 60[38].

- (iii) When the endpoint of the most sensitive species tested is lower than the derived geometric mean value by a factor between 1 and 10, the RAC_{GM} should be used in the RA (RAC_{GM} = geometric $mean_{acute}$ / 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 RAC_{GM} (RAC_{GM} = geometric $mean_{LT}$ / 10), the RAC_{DA} should be used. Here, the RAC_{DA} is the is the endpoint of most sensitive species divided by a default AF of 6[39].
- (ii) When the endpoint of the most sensitive species tested is equal to or higher than the RAC_{GM} (RAC_{GM} = geometric $mean_{LT}$ / 10), compare RAC_{GM} to the RAC_{DA} and use the lowest RAC for the risk assessment. Here, the RAC_{DA} is the is the endpoint of most sensitive species divided by a default AF of 8[40].

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 IV 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[41].

[37] 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.

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

[39] 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.

[40] 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.

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

21.7 Bees

Interim approach for the risk assessment of bees pending revision of the EFSA guidance document

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 "honey bees", 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)[42] only takes into account acute toxicity data on honey bees.

The new EFSA guidance document for bees (EFSA, 2013)[43] contains a risk assessment scheme for the chronic risk to adult honey bees and honey bee larvae, and for the risk to bumble bees and solitary bees. However, the guidance document has not yet been taken note of in the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF). To manage this discrepancy of the entry into force of Commission Regulation (EU) No 284/2013 and the EFSA guidance document, the following interim approach for the risk assessment of bees is required for applications in the Northern zone[44].

First-tier risk assessment

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

The test guideline for acute oral and contact toxicity to bumble bees has been ring-tested and is considered suitable for risk assessment purposes. 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 21.6.2. For the time being, a tier 1 risk assessment using HQ acute oral and HQ acute contact should be presented for bumble bees[45] 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.

Chronic risk assessment
Chronic toxicity studies with adult honey bees and honeybee larvae should always be submitted. The chronic risk assessment for adult honey bees and honey bee 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:

[42] SANCO, 2002. Guidance Document on Terrestrial Ecotoxicology Under Council Directive 91/414/EEC (Working Document, SANCO/10329/2002 rev 2 final, 17 October 2002).
[43] EFSA, 2013. Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees), revision of July 4th 2014).
[44] Estonia, Latvia and Lithuania will require only that the new studies described in this interim approach are submitted, but risk assessment needs not to be conducted.
[45] The HQ for bumble bees is reasonable pragmatic interim solution.

The chronic risk assessment of solid applications (granules and seed treatment) may be conducted according to the EPPO (2010)[46] risk assessment scheme. This scheme is cited in the Regulation (EC) 1107/2009 (EU 2009) as a current risk assessment scheme. For spray applications we accept the use of EPPO modified by ECPA (2017)[47] approach. The ECPA (2017) risk assessment scheme may also be accepted for seed treatment products.

The chronic risk assessment for adult bees and larvae from solid and spray applications may also be conducted according to the EFSA bee guidance (2013)[48]. 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/10.2903/j.efsa.2013.3295.

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)".

Chronic risk assessment of spray formulations honey bee adult and larvae
In view that there are no agreed risk assessment schemes for the chronic risk assessment of spray formulations, 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 corrected with respect to the units (g to microgram). The corrected calculations are used in the Nordic calculator tool for chronic bee risk assessment.

Chronic risk assessment for solid applications (granules and seed treatments) honeybee adult and larvae:
Following the **EPPO (2010) risk assessment scheme**, the NOED[49] 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[50] µg a.s./larva/day. These values are based on a worst-case residue value of 1 mg a.s./kg plant matrix and the worst-case sugar intakes of bee foragers and drone larvae of 128 mg sugar/bee/day and 15.1 mg sugar/larva/day, respectively (Rortais *et al.*, 2005). The sugar content of nectar and product specific application rate is thus not included in the risk assessment.

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

For an overview of test methods/guidelines that are considered suitable, see **Table 21.7.1** below.

Table 21.7-1: List of available test guidelines for bees

[46] 2010 OEPP/EPPO, Bulletin OEPP/EPPO Bulletin 40, 323–331
[47] 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)
[48] EFSA Journal 2013;11(7):3295
[49] In EPPO NOEDD is expressed as NOEL, here for consistency the term NOEDD is used.
[50] 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.

Reference to Part A of the Annex to regulation (EU) No. 284/2013	Test methods
10.3.1.1.1 **Acute oral toxicity**	*Honey bees:* • OECD Test Guideline 213: Honey bees, acute oral toxicity test • EPPO Standard PP1/170[51] (2010). Test methods for evaluating the side-effects of plant protection products on honey bees *Bumble bees:* • OECD Test Guideline 247. Bumblebee, acute oral toxicity test
10.3.1.1.2 **Acute contact toxicity**	*Honey bees:* • OECD Test Guideline 214: Honey bees, acute contact toxicity test • EPPO Standard PP1/170 (2010). Test methods for evaluating the side-effects of plant protection products on honey bees. *Bumble bees:* • OECD Test Guideline 246: Bumble bee, acute contact toxicity test
10.3.1.2 **Chronic toxicity to bees**	*Honey bees:* • OECD Test Guideline 245: Honey bee chronic toxicity test (10-day feeding) • Aupinel et al. (2007): A new larval in vitro rearing method to test effects of pesticides on honeybee brood. Redia XC: 87-90 • Oomen, P.A., de Ruijter, A., van der Steen, J. (1992). Method for honeybee brood feeding tests with insect growth - regulating insecticides. Bulletin OEPP/EPPO Bulletin 22, 613-616.
10.3.1.3 **Effects on honeybee development and other honeybee life stages**	*Honey bees:* • OECD Guidance Document 239 on Honey Bee Larval Toxicity Test following Repeated Exposure • OECD Guidance Document 75 on the honey bee (*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 honey bee 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[52]**	*Honey bees:* • 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 honey bee (*Apis mellifera* L.) brood test under semi-field conditions
10.3.1.5 **Cage and tunnel tests**	*Honey bees:* • EPPO Standard PP1/170. Test methods for evaluating the side-effects of plant protection products on honey bees
10.3.1.6 **Field tests with honeybees**	*Honey bees:* • EPPO Standard PP1/170. Test methods for evaluating the side-effects of plant protection products on honey bees

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

[51] 2010 OEPP/EPPO,OEPP/EPPO Bulletin 40, 313–319

[52] 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.

are not required for the time being, and no chronic risk assessment for bumble bees and solitary bees is needed.

Higher tier risk assessment

If the first-tier risk assessment for honey bees 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 the field to forage on flowering weeds and bees foraging in the off-field may be exposed via spray drift.

For **bumble bees**, there are currently no agreed higher tier test guidelines. Although there are differences between bumble bees and honey bees, in the interim period, if the risk assessment demonstrate safe use with regard to the risk to honey bees (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[53]. In case there is still a concern, risk mitigation measures should be considered.

Risk mitigation

A common mitigation option for all Member States is either a restriction in timing of application or restriction of use in flowering crop, 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 the Northern Zone Guidance document, **Appendix V**: List of mitigation options.

Waiving

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 21.7.2**

Table 21.7-2: Acceptable waiving of formulation toxicity studies on bees in the Northern zone

Formulation data	Acceptable waiving	
	Formulations containing one active substance	**Formulations containing two or more active substances**
Acute oral and contact toxicity for honey bees	• If the toxicity of the formulation can be reliably predicted to be the same or lower than the active substance**	• -

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

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 honey bees 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 risk assessment based on surrogate mixture toxicity of the active substances*

Plant protection products containing only one active substance

It is not necessary to perform chronic toxicity studies on honey bees 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[54] 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.

Plant protection products containing more than one active substance

For products containing more than one active substance, a surrogate endpoint for the mixture toxicity of active substances with known endpoints can be calculated, based on the concept of dose additivity[55].

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.

21.8 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.

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

[54] 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.*"

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

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 (see **Appendix V**: List of mitigation options available in the Member States in the zone. 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.

21.9 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.

The endpoints (LC50 and NOEC/EC10) 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, unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of organic carbon content in soil. Hence, the endpoint must be divided by a factor of 2 even if the toxicity tests are performed with soil containing less organic matter than 10%.

Risk assessment for the active substance and metabolites should be performed with PECsoil,acc 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.
If a formulation contains more than one active substance, mixture toxicity should also be calculated using the equation given in the paragraph below. The calculations should always be based on the PECsoil,acc 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. Formulation endpoint can only be used to cover the risk assessment for the first season.

Mixture toxicity risk should be calculated based on the model of concentration addition using the following equation:

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

If SUM < 1 the risk assessment is acceptable

Where:

- ”Trigger-value” represents the uncertainty factor of chemical A, B etc.
- TER is the Toxicity Exposure Ratio calculated from the substance specific effect concentration (e.g. EC10 or NOEC) divided by the expected environmental exposure.

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 Northern zone conditions. 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.

In addition, refinement of the PEC_{soil} based on crop interception (see fate section) is acceptable for the core assessment. At present use of $PEC_{pore\ water}$ in the soil risk assessment is not accepted.

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.

For risk mitigation options, see **Appendix V: List of mitigation options available in the Member States in the zone.**

National requirement (Denmark): Specific requirements for persistent substances[56]; Field effect studies for substances with DT50 soil between 3 and 6 months (further details can be found in the Danish Framework for Risk Assessment of Plant Protection Products, see **Appendix IV:** Summary of national requirements).

21.10 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

[56] 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.

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. See **Appendix V**: 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.

21.11 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 5). Metabolites recorded in food items (see core dRR, Part B section 3) 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 covered by the a.s. risk assessment. The relevant EU guidance documents should be followed, if nothing else is stated in this guidance.

21.12 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 product. 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 of intended authorisation or re-authorisation activity

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).

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

Appendix II: Reporting table

Active substance:
Trade name:
Formulation type:
Rapporteur:

Annex III point	Country	Comment	Reply rapporteur	Accepted Yes/No
General				
Section 0 – Product Background, Regulatory Context and GAP information				
Section 1 – Identity				
Section 2 – Physical and chemical properties				
Section 3 – Efficacy data and information				

Section 4 – Further information				
Section 5 – Analytical methods				
Section 6 – Toxicology				
Section 7 – Metabolism and Residues				
Section 8 – Environmental fate				
Section 9 – Ecotoxicology				
Section 10 – Relevance of metabolites				

Confidential Commenting table

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

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

Appendix III: Contact points

Pre-notifications and applications should be submitted to:

Country	e-mail	Postal Address
Denmark	pesticider@mst.dk	Pesticider & Biocider Miljøstyrelsen Tolderlundsvej 5 DK - 5000 Odense C Denmark
Estonia	mariann.leps@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_zonal@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 [57]	postmottak@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

[57] Address for transfer of documentation: Norwegian Food Safety Authority, National Registration Department, Glynitveien 30, NO-1400 Ski, Norway Norway.

CONTACT POINTS OF FOR STEERING COMMITTEE IN THE NORTHERN ZONE

MS	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:** Mariann Leps **Authority:** Agriculture and Food Board **Address:** Teaduse 2, Saku 75501 Estonia **Tel:** +372 5324 6604 **E-mail:** mariann.leps@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_zonal@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 authorization 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 IV: Summary of national requirements

Denmark				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
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 VIII. • 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. • For products intended for use in the home, an ad hoc risk assessment for toddlers/small children is required. • DK does not accept the use of re-entry times as a refinement for risk assessment of recreational residence.	Yes Danish/English	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**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		• The NZ Worker Re-entry Period Calculator can be used for calculating re-entry as a risk mitigation measure with or without gloves (alternative 1) and for limiting the time using gloves (alternative 2). The applicant shall justify the use of alternative 1 and 2. • 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 (Regulation no. 1272/2008[58]), may not be used in private gardens, public areas and similar areas which are accessible to the public, areas around residential buildings, childcare institutions and similar, or to treat vegetation on borders with public roads or private gardens. In addition,		

[58] 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

Denmark				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		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		

Denmark				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		owners without a spraying certificate or spraying permit. • Non-professional users are assumed to use handheld spray equipment and have no PPE to protect them.		
Residues	Dossier must cover Danish conditions			
Efficacy	Dossier must cover Danish conditions. Bridging studies required for similar products.			
Fate and behaviour	Specific persistency assessment Specific groundwater modelling – including all metabolites	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 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.	Yes Danish/English	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/
Ecotoxicology	**General** **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	Danish/English	Find guidance in the latest Danish risk assessment framework at the respective webpages: Danish:

Denmark				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
	Aquatic organisms Specific aquatic risk assessment	Specific assessment principles for mesocosm studies		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**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
Toxicology	YES	Non-professional use: Authorization 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		

Estonia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		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 Regulation (EC) No 1272/2008: - 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. - Respiratory sensitisation (Resp sens 1) H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.		

Estonia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		- Specific organ toxicity (STOT SE 1, 2; STOT RE 1, 2) H370 Causes damage to organs. H371 May cause damage to organs. H372 Cause damage to organs through prolonged or repeated exposure. H373 May cause damage to organs through prolonged or repeated exposure. - Mutagenic, carcinogenic or toxic to reproduction (Muta 1A, 1B, 2; Carc 1A, 1B, 2; Repr 1A, 1B, 2) H340 May cause genetic defects. H341 Suspected of causing genetic defects. H350 May cause cancer. H351 Suspected of causing cancer. H360 May damage fertility or the unborn child. H361 Suspected of damaging fertility or the unborn child. - Toxic by aspiration (Asp tox 1) unless childproof packaging has been used H304 May be fatal if swallowed and enters airways		

Estonia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		- The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL. Acute Inhalation Toxicity: EE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix VIII. Default waiting period in greenhouses Default waiting period in greenhouses/tunnels (greenhouse/tunnel is closed-off/locked) after application is 18 hours. EE accepts using the NZ Worker Safe Re-entry Calculator for determining the number of days after application when worker re-entry is acceptable with protective gloves and work wear (alternative 1) and time restriction of PPE use (alternative 2 and 3 in the Calculator).		
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**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
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. Non-professional use:	No	

Finland				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		Authorization of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be authorized for non-professional users if those have any of the following characteristics: - Product is explosive - Extremely flammable, highly flammable or flammable - Fatal or toxic if swallowed, in contact with skin or if inhaled - Skin corrosive - Causes serious eye damage or is irritating to eyes - Causes respiratory or skin sensitisation - Carcinogenic, toxic to reproduction, mutagenic or fulfils criteria for specific target organ toxicity - 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			

Finland				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Fate and behaviour	NO	No specific requirements		
Ecotoxicology	NO	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 authorized for non-professional users if those have any of the following characteristics: - Products containing an active substance listed as candidate for substitution at the EU level - Products with several or far-reaching conditions for use. This may, for example, mean requirements for safety distances, restriction of use in the ground water areas, restriction of use in the consecutive years (if risk for the soil organisms occurs after use in consecutive years) - Products which are particularly harmful to pollinating insects - Products (granules) which are particularly harmful to birds and mammals.		

Latvia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	**NO**			
Toxicology	**Yes**	The following products cannot be accepted for non-professional use: - classified with any of the following (Acute Tox. 1, 2) H300; (Acute Tox. 3) H301; (Acute Tox. 1,2) H310; (Acute Tox. 3) H311; (Eye Dam. 1) H318; (Acute Tox. 1, 2) H330; (Acute Tox. 3) H331; (Muta. 1A, 1B) H340; (Muta. 2) H341; (Carc. 1A, 1B) H350; (Carc. 2) H351; (Repr. 1A, 1B) H360D; (Repr. 1A, 1B) H360F; (Repr. 2) H361d; (Repr. 2) H361f; (Lact.) H362; - if operator risk during use of PPP or after it when not using individual personal equipment exceeds allowable value PPP can not be authorised for non-professional use;	Yes, national regulation, Latvian	2012.gada 24.jūlija MK noteikumi Nr.509 „Noteikumi par augu aizsardzības līdzekļu laišanu tirgū saskaņā ar Regulu Nr.1107/2009"
Residues	NO			
Efficacy	No			
Fate and behaviour	**Yes**	See core text in chapter 20.2		
Ecotoxicology	**No**			

Lithuania				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	No			
Toxicology	Yes – for waiting period and non-professional uses	**Acute inhalation toxicity requirements:** Until a change in condition i) of the data requirement for inhalation toxicity of Regulation (EU) No 284/2013 has been made, or a harmonised EU interpretation of this condition has been established, an acute inhalation toxicity study should not be required if the applicant can justify an alternative approach under Regulation (EC) No 1272/2008. 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. **Non-professional use:** - 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 and for specific target organ toxicity (H370, H371, H336, H372 and H373).	No Yes	Lithuanian: https://www.e-tar.lt/portal/lt/legalAct/26596c906f4611ea-bee4a336e7e6fdab

Lithuania				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		- Re-entry periods after an application of a PPP on turf, lawns, grassland etc. is not acceptable for non-professional use. **Waiting period** in the greenhouses/tunnels/warehouses/empty warehouses after indoor application of PPP until re-opening is 24 hours without ventilation.	Yes	Lithuanian: https://www.e-tar.lt/portal/lt/legalAct/TAR.19431CB8A7D7/asr
Residues	No			
Efficacy	Dossier must cover Lithuanian conditions.			
Fate and behaviour	Yes **Non-professional use:** Plant protection products may not be authorised if risk mitigation measures are required to protect groundwater from contamination.	See core text in chapter 20.2	No	
Ecotoxicology	No			

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	No	<u>The following plant protection products may not be authorised for use by non-professional users:</u> - Products that are explosive (E) or oxidizing (O).	Yes, in Norwegian	
Toxicology	No	<u>Acute Inhalation Toxicity:</u> 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). <u>The directions for approval of non-professional use:</u> Important issues are: -use of substitutional principle - evaluation regarding storage of the plant protection product - evaluation regarding personal protection equipment for non-professional users lacking skills in handling plant protection products.	Yes, in Norwegian	

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		<u>The following plant protection products may not be authorised for use by non-professional users:</u> Products that are acutely toxic category 1-2 (deadly) or category 3 (toxic); that are corrosive for the skin and eyes or can cause serious eye damage; that may cause allergy or asthma symptoms or breathing difficulties if inhaled; that may or possibly may give cancer, genotoxic effects or impair fertility or the unborn childs (CMR-substances) or that cause or may cause damage to organs by single or repeated exposure. Thus, plant protection products in Norway for non—professional use labelled with one or more of the following risk phrases according to Regulation (EC) No 1272/2008 (CLP), will not be approved: - H300 Fatal if swallowed. - H301 Toxic if swallowed. - H310 Fatal if in contact with skin. - H311 Toxic if in contact with skin. - H314 Causes severe skin burns and eye damage. - H218 Causes serious eye damage. - H330 Fatal if inhaled. - H331 Toxic if inhaled.		

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. - 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. - 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, repro-toxic 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.		

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		The following products can be accepted for non-professional use: Ready for use: Plant protection products without classification/labelling, or with irritating characteristics (if there are no better alternatives). These products will not be approved if there is extensive need for personal protection equipment. Concentrate: Plant protection products with irritating characteristics may be approved. Products labelled as harmful to health may be approved if there are no better alternatives (health). These products will not be approved if there is extensive need for personal protection equipment. Powder soluble in water: Powder soluble in water is not suitable for non- professional use because of the danger for exposure. But if the products are delivered in small disposable packages as water soluble bags they may be accepted for non-professional use.		
Residues	No			
Efficacy	Dossier must cover Norwegian conditions		No	The Norwegian Food Safety Authority is the responsible authority.

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
				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	No	Directions for approval 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. Directions for labelling of PPPs toxic to bees: A pictogram of a bee may be required on the label*. Directions for labelling of PPPs authorised for use in permanent greenhouses:		

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		Greenhouse products may, depending on their environmental profile, be identified as a "spesialpreparat for veksthus"*.		
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).		

*Criteria for requiring a bee pictogram and for defining a ppp as "spesialpreparat for veksthus" are under development. The criteria and a bee pictogram will be published at: https://www.mattilsynet.no/planter_og_dyrking/plantevernmidler/godkjenning_av_plantevernmidler/hvordan_soke_godkjenning_av_plantevernmidler.34036

Sweden				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
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.			

Sweden				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
	(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 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. In all cases, 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. In all other cases, 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	Products solely containing, approved low risk substances, or active substances stated in appendix 15 of the Agency regulation KIFS 2008:3, 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.			

Sweden				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
Toxicology	SE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix VIII.			
Residues	NO			
Efficacy	NO			
Fate and behaviour	NO			
Ecotoxicology	NO			

Appendix V: List of mitigation options available in the Member States in the zone

Denmark	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology		
Operator exposure Worker exposure Bystander and resident exposure	- limits on spraying methods authorized - requirements on special permits for spraying personnel - requirements on special packaging (dimensions, design, possibly water-soluble packaging) - specific requirements concerning use of protective equipment - waiting periods before entry into treated areas - re-entry periods before working in/with treated crops - specific requirements concerning use of protective equipment - buffer zone for spraying See also Table 17.2.6-1 on the use of risk mitigation measures in the EFSA GD exposure 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.	
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*
Bees	Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise.	
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*
Soil organisms	Restrictions of use, dose and frequency	

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	**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.	
Toxicology		
Operator exposure 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. EE accepts using the NZ Worker Safe Re-entry Calculator for determining the number of days after application when worker re-entry is acceptable with protective gloves and work wear (alternative 1) and time restriction of PPE use (alternative 2 and 3 in the Calculator). - specific requirements on the use of protective equipment	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 improvement systems, 1 meter from the water boundary of artificial recipients of land improvement systems with a catchment area of less than 10 km^2 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.	
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.	
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
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
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	**Mitigation options**	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology	FI accepts using NZ Worker Safe Re-entry Calculator (described in 17.2.3) for determining **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 the product may not be used in the classified groundwater areas used or suitable for water supply (groundwater area classes I and II). 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.	
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
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.	
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
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).	-
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	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology	Latvia accepts mitigation options as shown in **Table 17.2.6-1: NZ approach of choosing PPE and other risk mitigating measures in the EFSA calculator.**	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.	
Aquatic organisms 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
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.	
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.
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.	
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	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology		
	Lithuania accepts mitigation options as shown in *Table 17.2.6-1: NZ approach of choosing PPE and other risk mitigating measures in the EFSA calculator*. Lithuania accepts using the NZ Worker Safe Re-entry Calculator (described in 17.2.3) for determining **re-entry period** (Option1) and for required interval for the use of gloves (PPE) and/or workwear (Option 2 and 3) on case by case basis. **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.	
Aquatic organisms 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
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.	
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
Soil organisms	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
Non-target plants	Buffer zones: min – 5 m, calculating on every 5 meters. From currently registered PPP maximum buffer zone is 10 m. Drift reducing nozzles can be used to further reduce the risk from spray drift.	Nozzles with 50, 75 and 90 % reduction

Norway	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 Safe Re-entry Calculator for time restriction of PPE use (alternative 2 and 3 in the Calculator). See also Table 17.2.6-1 on the use of risk mitigation measures in the EFSA GD exposure 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.	
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)
Bees	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
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)
Soil organisms	No additional national mitigation options are available other than those listed in Commission Regulation (EU) No 547/2011.	
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)
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	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology	Sweden accepts mitigation options as shown in **Table 17.2.6-1: NZ approach of choosing PPE and other risk mitigating measures in the EFSA calculator.** SE accepts using the NZ Worker Safe Re-entry Calculator for time restriction of PPE use (alternative 2 and 3 in the Calculator). SE may accept alternative 1 on a case-by-case basis. The applicant shall justify the use of alternative 1. 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.	
Aquatic organisms 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: http://sakertvaxtskydd.se/sv/Bibliotek/Mitigating-spray-drift-in-Sweden1/ The surface water mitigation measures that are accepted in Sweden are listed in table 20.3-3 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%

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 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”.	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
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%
Soil organisms	In addition to risk mitigation option 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.	
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 VI: 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**			**RAC_{sw}**	**Is PEC_{sw} max > RAC_{sw}?**
	Worst-case scenario (ditch, stream or pond)	**PEC_{sw} 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 VII: Recommended structure for the documentation

Caddy.xml format (dRR format according to ***SANCO/6895/2009***):

- Part A - Risk Management
- Part B - Data Evaluation and Risk Management
  - Section 1 - Identity, physical and chemical properties and further information
    - Section 1/001 - [Product code/name] - Part B Section 1
  - Section 2 - Analytical methods
    - Section 2/001 - [Product code/name] - Part B - Section 2
  - Section 3 - Mammalian toxicology
    - Section 3/001 - [Product code/name] - Part B - Section 3
  - Section 4 - Metabolism and Residues
    - Section 4/001 - [Product code/name] - Part B - Section 4
  - Section 5 - Environmental fate
    - Section 5/001 – [Product code/name] - Part B - Section 5
  - Section 6 - Ecotoxicological studies
    - Section 6/001 - [Product code/name] - Part B - Section 6
  - Section 7 - Efficacy data and information
    - Section 7/001 - [Product code/name] - Part B - Section 7
  - Section 8 - Assessment of the relevant metabolites in groundwater
    - Section 8/001 - [Product code/name] - Part B - Section 8
  - Part C - Confidential Information
    - Confidential Part C/001 - [Product code/name] - Part C
    - Confidential Part C/002 - Safety data sheet –
- Part K - Individual test and study reports *(should following the structure of the dRR)*
  - KIIIA 1 - Identity of the Plant Protection Product
  - KIIIA 2 - Physical, Chemical and Technical Properties of the
  - KIIIA 3 - Data on Application
  - KIIIA 4 - Further Information on the Product
  - KIIIA 5 - Methods of Analysis
  - KIIIA 6 - Efficacy Data and Information (including Value Data)
  - KIIIA 7 - Toxicological Studies and Exposure Data and Information
  - KIIIA 8 - Metabolism and Residues Data
  - KIIIA 9 - Fate and Behaviour in the Environment
  - KIIIA 10 - Ecotoxicological studies on the plant protection product
  - KIIIA 12 - Assessment of the relevant metabolites in groundwater

Caddy.xml format (dRR format version 2015):

- Part A - Risk Management
- Part B - Data Evaluation and Risk Management
  - Section 0 - Product Background, Regulatory Context and GAP information
    - Section 0/001 - [Product code/name] - Part B Section 0
  - Section 1, 2, 4 - Identity, physical and chemical properties and further information
    - Section 1, 2, 4/001 - [Product code/name] - Part B Section 1, 2, 4
  - Section 3 - Efficacy data and information
    - Section 3/001 - [Product code/name] - Part B Section 3
  - Section 5 - Analytical methods
    - Section 5/001 - [Product code/name] - Part B - Section 5
  - Section 6 - Mammalian toxicology
    - Section 6/001 - [Product code/name] - Part B - Section 6
  - Section 7 - Metabolism and Residues
    - Section 7/001 - [Product code/name] - Part B - Section 7
  - Section 8 - Environmental fate
    - Section 8/001 – [Product code/name] - Part B - Section 8
  - Section 9 - Ecotoxicology
    - Section 9/001 - [Product code/name] - Part B - Section 9
  - Section 10 - Assessment of the relevance of metabolites in groundwater
    - Section 10/001 - [Product code/name] - Part B - Section 10
  - Part C - Confidential Information
    - Confidential Part C/001 - [Product code/name] - Part C
    - Confidential Part C/002 - Safety data sheet – [xxx]
- Part K - Individual test and study reports *(should following the structure of the dRR)*
  - KIIIA 0 - Product Background, Regulatory Context and GAP information
  - KIIIA 1 – Identity
  - KIIIA 2 - Physical, Chemical and Technical Properties of the plant protection product
  - KIIIA 3 - Efficacy Data and Information (including Value Data)
  - KIIIA 4 - Further Information on the Product
  - KIIIA 5 - Methods of Analysis
  - KIIIA 6 - Toxicological Studies and Exposure Data and Information
  - KIIIA 7 - Metabolism and Residues Data
  - KIIIA 8 - Fate and Behaviour in the Environment
  - KIIIA 9 - Ecotoxicological studies on the plant protection product
  - KIIIA 10 - Assessment of the relevant metabolites in groundwater

Folder structure (dRR format according to *SANCO/6895/2009*):

1. Admin (Cover letter, application form)
2. dRR
    a. Part A
    b. Part B
        i. dRR section 1 (Identity, physical and chemical properties and further information)
        ii. dRR section 2 (Analytical methods)
        iii. dRR section 3 (Mammalian toxicology)
        iv. dRR section 4 (Metabolism and Residues)
        v. dRR section 5 (Environmental fate)
        vi. dRR section 6 (Ecotoxicological studies)
        vii. dRR section 7 (Efficacy data and information)
        viii. dRR section 8 (Assessment of the relevant metabolites in groundwater)
    c. Part C
        i. dRR Part C
        ii. Other confidential documents
    d. Part K (KIIIA test and study reports)
        i. Section 1 (Identity, physical and chemical properties and further information)
        ii. Section 2 (Analytical methods)
        iii. Section 3 (Mammalian toxicology)
        iv. Section 4 (Metabolism and Residues)
        v. Section 5 (Environmental fate)
        vi. Section 6 (Ecotoxicological studies)
        vii. Section 7 (Efficacy data and information)
        viii. Section 8 (Assessment of the relevant metabolites in groundwater)
3. GAP (Master GAP, GAP for each country)
4. Label (Master label, country specific labels)
5. Letter of Access (if relevant)
6. Additional documents

Folder structure (dRR format version 2015):

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

Appendix VIII: Acute inhalation toxicity – pre-evaluation of products (spraying only)

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[59] 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[60] with unknown acute inhalation toxicity. It is also based on a theoretical[61] 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 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 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 1-3 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.

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 the acceptable amount of components with a 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. The 5 mg/l reflects the upper limit of cat. 4 classification and hence if above, the dilution is not classifiable:

   Acceptable amounts [Aa] of components with unknown and cat 1 classification:
   Aa % $< \frac{dilution\ x\ 0.005\ mg/l}{5\ mg/l} x100\%$.

   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.

[59] This approach is not accepted by NO, FI and LT. Please refer to Appendix IV for national requirements.

[60] 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.

[61] 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.

3) It is possible to refine the assumptions of worst case by assuming an ATE of 0.05 mg/L when the component is not considered orally acute toxic (LD_{50}>2000 mg/kg bw). Then the acceptable amount of components with a classification of acute inhalation tox cat. 1 and unknown acute inhalation toxicity can be calculated using the following equation:

   Acceptable amounts [Aa] of components with unknown and cat 1 classification:
   Aa % $< \frac{dilution\ x\ 0.05\ mg/l}{5\ mg/l} x\ 100\%$.

   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 100% or less.