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

Version 7.0. This guidance document replaces the version of May 2017 and can be voluntarily applied from 25. May 2018. 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 Registration 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January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Registration of Plant Protection Products	DK + expert groups	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 Registration 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 Registration 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 Registration 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 Registration 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 Registration 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 Registration 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 Registration of Plant Protection Products. Changes in the following sections:		
		All sections		1 November 2018

The correct reference for the NZ work sharing GD:
Northern Zone, 2018. Guidance document on work-sharing in the Northern zone in the authorization of plant protection products. Version 7, May 2018.

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 under regulation (EC) No 1107/2009 and Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009. It is intended that it should be used in the context of zonal evaluations of applications for registration of plant protection products in order to reduce the workload for both applicants and authorities and to promote the harmonisation in the Northern zone. Where the transitional measures of Regulation (EC) No 1107/2009 apply the work-sharing is conducted on a **voluntary basis** with the aim to improve mutual recognition and facilitate the development of a registration work-sharing program. The procedures in this document will be applied for re-authorisation of products containing active substances with a submission deadline 31 October 2010 or later.

For applications of new authorisations submitted after 14 June 2011 the provisions of the EU guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 applies.

The document might be updated once a year to take account of 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 applicants 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 the comments received 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 procedures for new applications and re-registrations are described in more details in the Chapters 3.3, 3.5 and 3.8.

3.1 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 updating of this document. The chair of the steering committee is also the primary contact point for the Central- and Southern zones. The chair and incoming-chair are members of the Inter-zonal committee.

Incoming chairs year 2018 – 2023:

Year	Country*
2018	Finland
2019	Latvia
2020	Lithuania
2021	Estonia
2022	Sweden
2023	Norway

*Iceland is excluded.

3.2 Prerequisites for work-sharing

3.2.1 Re-registration for authorised products

Formulations and GAP should be harmonised as much as possible in the Member States where re-registration is to be applied. This will allow a 'risk envelope' approach to the assessment, whereby only the worst case exposure scenarios for each area of the risk assessment are evaluated, with other 'less risky' scenarios being deemed acceptable. Different formulations may be covered by the same risk assessment if bridging studies and scientific justifications are available. Guidance on the 'risk envelope' approach is available at the EU level as detailed in
http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf

To facilitate work sharing and the allocation of ZRMS, the pre-notification form available at Commission web site (see **Appendix I**) should be completed by the applicant.

3.3 Submission of application

3.3.1 Pre-submission notifications

All applicants are requested to submit a pre-notification at the latest 6 months before submission of the dossier (applies for new applications). A pre-notification shall also be submitted for renewals if the applicant requests cat. 4 data.

The pre-notification must be submitted to all concerned MS using the form available at the Commission web site (see **Appendix I**).

3.3.2 Renewal of authorised products

An application for renewal of authorisation shall be submitted to the appointed ZRMS within 3 months from the date of enters into force of the re-approval of the active substance. 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.

3.3.3 New products authorisation

The applicant should submit an application to all Member States within the zone where they wish to gain an 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 under Regulation (EC) No 1107/2009 (SANCO/13169/2010) should be followed as well as the Northern zone guidance document.

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.

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**

3.4 How is the zonal RMS appointed?

Whilst the applicant's preference for choice of the ZRMS may be taken into consideration, the decision on the ZRMS allocation should take into account:

- the identity of the original RMS for the evaluation of the active substance (noting that in the Northern zone it will only in few cases be possible to allocate the work to the original RMS)

- the relevance/importance of the products in each country
- the resource availability in each country.

The decision will be made by the zonal steering committee.

3.5 Communication with applicants

Applicants are encouraged to make early contact with the respective contact point listed in **Appendix III**: Contact points. 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 the **Appendix III**).

The appointed ZRMS will be communicated to the applicants. After appointment of ZRMS, communication regarding the application should be between the applicant and the ZRMS, unless it concerns national addenda only relevant for cMS.

3.6 Format for the application

Applicants are requested to submit documentation as specified below and a draft Registration Report. 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 guidance is not required for AIR II substances).

The core draft Registration Report should just cover the conditions and requirements for the Northern zone as described below, and be specific to these conditions.

The common working language for the preparation and assessment of registration reports is English.

3.6.1 General documentation requirements for an application

The application and documentation must include the following:

- **Cover letter**, including brief summary of the application, number of CDs and a brief description of the content of each CD.

  Documentation on CD
  The application and documentation should meet the following criteria:
  - Should be submitted on CD with 3 copies of each CD
  - Preferably submission in Caddy.xml format
  - When possible, using a maximum of 100 letters in the file directory (including the file name)

  The submitted documentation should be structured and intuitive to navigate through. The folder structure should be simple and the naming of folders and documents should be clear and reflect the content.

  See **Appendix VII** for a recommended structure for the documentation.

- Northern Zone **Application form** in English and/or in the language of the relevant MS. The form is available at each authority's website.

- **Completeness check** scheme

- **Labels**
  - National labels in national languages
  - Master label in English containing a description of the use in the whole zone.

  All labels should be submitted to the ZRMS.

- **Product dossier** – study reports preferably in Caddy.xml format and **Draft Registration Report (dRR)** in word format for all sections:
  - Part A,
  - Part B as a Northern zone core,
  - Part C
  - If applicable, national addenda.

  All Part As and national addenda for all cMS in the zone should also be submitted to the ZRMS.

  Dossier content:
  - 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.

- **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.

- **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).

- **Individual test and study reports.** Further guidance on which data requirements that are applicable in a certain case 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).

- **Justification** for new data submitted and use of vertebrate studies.

- 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.

For uses not considered for approval of the active substance, an assessment using established endpoints and by the application of the Uniform Principles is required. Where different or additional endpoints are proposed, these must be supported by appropriate data/information.

Any areas highlighted in the Review Report as requiring particular attention at Member State level must be addressed.

3.7 Evaluation of the dossier

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 to address 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 weeks 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.

3.7.1 Proposal for new endpoints in the risk assessment

Where different or additional endpoints not in accordance with the List of Endpoints are proposed, these must be supported by appropriate data/information.
Endpoints deviating from the List of End points can only be accepted if they are required to achieve acceptable risk or if the endpoint shows that the active substance is more adverse than what was documented by the endpoint listed in the List of Endpoints. It is not acceptable to use new endpoints in order to avoid risk mitigation measures. Prior to the submission the applicant must present a clear case to show that a risk assessment based on the established endpoint will not support their application.

The guidance document SANCO/10328/2004 (latest version) **Guidance document on the evaluation of new annex II data post-annex I inclusion of an active substance** must be taken into account.

3.8 Administrative prolongations of authorisations

If the active substance is prolonged on EU-level, then the products can be prolonged until the same date, plus 1 year (according to article 32). SE, LV and EE ~~FI~~ 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 a letter or 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 it has been extended to. Ordinary periods of grace for retail sale and use can be granted, according to Art. 46. If amendments of the product are such that the product will be considered as a new product, the old product will expire as explained above.

3.9 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.

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 3.6.1 unless it is agreed with zRMS that the complete dossier should be submitted later.

The ZRMS notify the applicant for the receipt of the application and an agreement on the date for the submission of a complete dossier for renewal.

3.9.1 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 dossier 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 4.1.1.

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.

3.10 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. 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 CAT4 data prior to submission of the application will not be accepted as CAT4 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.

Before the date of application for renewal (according to the renewal regulation), the applicant submit a formal application for renewal and 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
- Indication of when the full dossier will be submitted (no later than 3 months after the final CAT 4 study is finalised)

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

3.11 Commenting procedures for zonal evaluations

Concerned Member States of the zone 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, and on new studies submitted to address data gaps identified in the review report or to cover 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, 3.12) in order to be

taken into consideration by the ZRMS. Bilateral discussions among experts during the evaluation are encouraged.

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

It is voluntary for the ZRMS to ask for comments by the applicant in cases of an application for re-registration under transitional measures.

3.12 Decision making

The risk assessments and registration reports (RR) prepared by ZRMS should be used by the others in order to prepare evaluation for 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.

3.13 Timelines

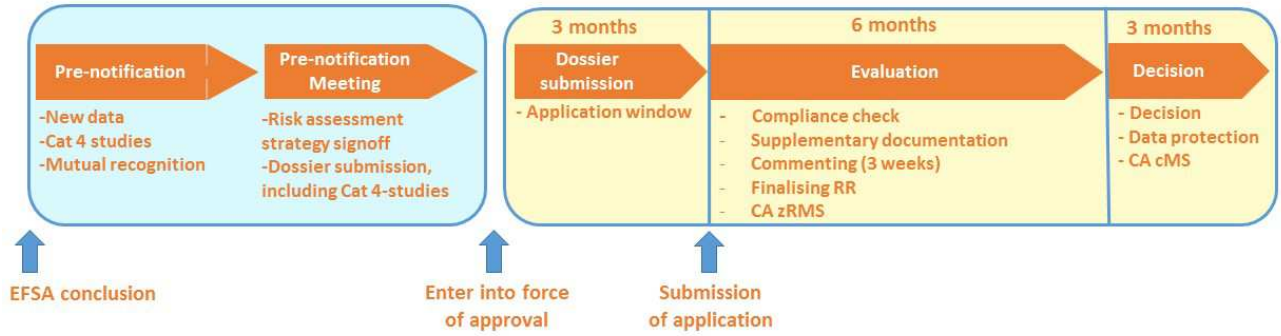
3.13.1 Application for renewal of products (article 43)

Within 2 months following the publication of the EFSA conclusion, the authorisation holders must submit:

- The pre-notification form to notify intended zonal applications
- Indication of agreement on the studies which are needed and where possible an expected timeframe; If there are CAT 4 studies, it has to be approved by the ZRMS and cMS.
- Indication of which parts of the risk assessment need updating (to be agreed in pre-submission meetings with ZRMS)
- Indication of amendments of the GAP or formulation changes (to be agreed in pre-submission meetings with ZRMS);
- A "data matching list" regarding references relied upon (where relevant).

Six months before the date of application for renewal, the notification form including the GAP should be submitted to the proposed ZRMS and all cMS's. If the applicant aim to apply for changes in connection with the renewals, the information should be submitted at least 6 months before the date for application of renewal and discussed with ZRMS and if needed with cMS.

SCHEME OF THE PROCESS FOR RE-AUTHORISATIONS



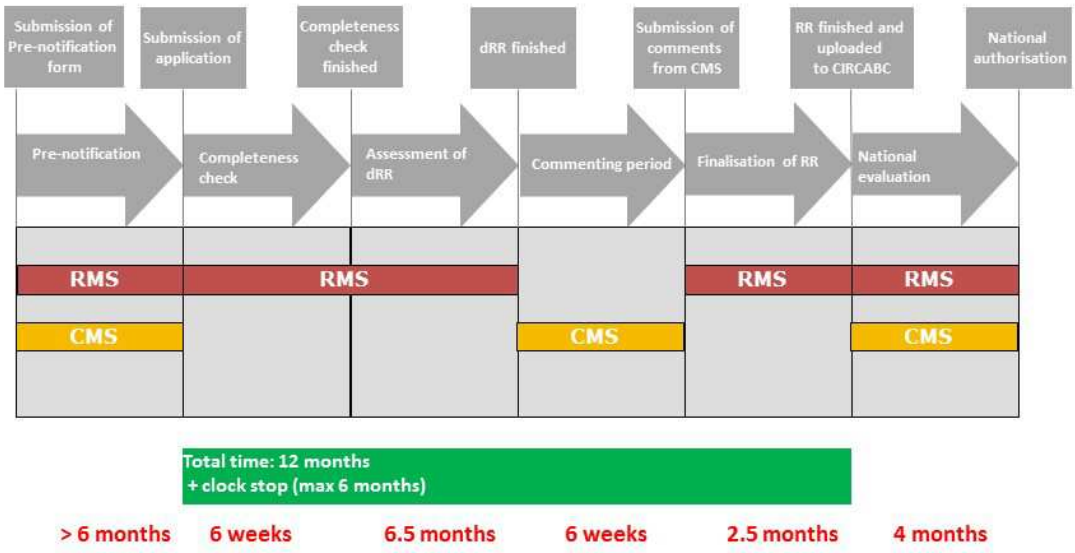
3.13.2 New product authorisations

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

A six weeks 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 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.

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



3.14 Inter-zonal uses

The EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed.

3.15 Applications for mutual recognitions

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

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

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

3.16 Provisional authorisations

In principle, applications for provisional authorisations will be dealt with in the same way as applications for new authorisations. The provisions for provisional authorisations (Article 30.1 and 30.2) are no longer valid since according to article 30.3 the provisions shall only apply until 14 June 2016.

3.17 Withdrawal and amendment of authorisation based on zonal evaluations

The SANCO/13169/2010 (or later version) of **Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009** should be followed.

3.17.1 Amendment of authorisation

Amendments should be dealt with according to the zonal procedure, if applicable. Different types of amendments require various information/ documentation to be submitted. Furthermore, relevant sections of the latest registration report should be updated. Depending on the changes revised sections or addenda should be submitted, the format should be agreed with zRMS. In the table below it is shown which sections of the dRR that needs to be revised.
All changes should be highlighted in each section, 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 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 or addenda - Updates/addenda of other necessary part B, e.g analytical methods, tox, efficacy etc.
Change 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 of source of product	- An updated section, as it was originally submitted, part B1 or part C
Label extensions (crops, pests etc.)	- Updates/addenda for relevant part B's, depending on the amendment (could be all parts except B1, B2, B4)
Administrative changes (authorisation holder, name of product etc.)	National application only - No updated dRR necessary

*It is up to the MS that 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.

Evaluation time should be appropriate to the kind of amendment being assessed, 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.
The SANCO/13169/2010 (or later version) of **Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009** should be followed.

4 Assessment

Applicants are required to submit a full dossier according to the data requirements for products that is valid for the application (regulation 284/2013). In the format specified in the format of the draft registration Report – version 2015[1].

Compared to what was used in the past the following changes have been introduced:

I. Applicants are required to prepare dossiers reflecting all intended uses in Northern zone.

II. National data requirements concerning the specific problems in a country, as indicated in **Appendix IV:** Summary of national requirements, have to be respected and data submitted for evaluation in the national addenda.

III. An assessment should be conducted by applicants for the identification of worst case use(s)/scenarios following the risk envelope approach according to SANCO/11244/2011. Uses with similar characteristics can be assessed group-wise and that the risk assessment for different use groups can be simplified by focusing on the group with worst-case characteristics as a representative for other use groups.

Insofar, the concept requires:

- grouping of the intended uses according to certain criteria (e.g. crop, application rate, number of applications, timing, etc.) and
- sorting of those groups according to their estimated risk levels as determined by the target of the respective assessment.

It should be noted that this will often result in different grouping and sorting of results for the different sections of the dossier and even for the different areas of the environmental risk assessment, which needs to be documented transparently. It is very important that all worst case uses/scenarios are included in the dossier.

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.

[1] The latest version from 20. March 2015 should be used for applications submitted after 1. January 2016. However the previous version may be used for applications for renewal of products containing AIR II activesubstances.

Duplication of vertebrate studies shall not be accepted by MS according to Article 62 (2). Additionally, 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, vertebrate studies shall not be accepted. Vertebrate studies generated for authorisation in a regulatory jurisdiction outside the EU, should not be accepted.

4.1 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. 4, 11th July 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis.
- SANCO/825/2000, rev. 8.1, 16th of November 2010, Guidance document on pesticide residue analytical methods.
- 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).
- Chemicals Regulation Directorate DATA REQUIREMENTS HANDBOOK http://webarchive.nationalarchives.gov.uk/20151023155227/http:/www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook. A new EU guidance document based on this document is under development.
- 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]

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

4.1.1 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, full details of the differences shall be provided. Each product code number shall be specific to a unique plant protection product.

[2] Not accepted in NO. Formulation changes will be assessed on a case-by-case basis.

The identity and content of the technical active substance (based on the 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.

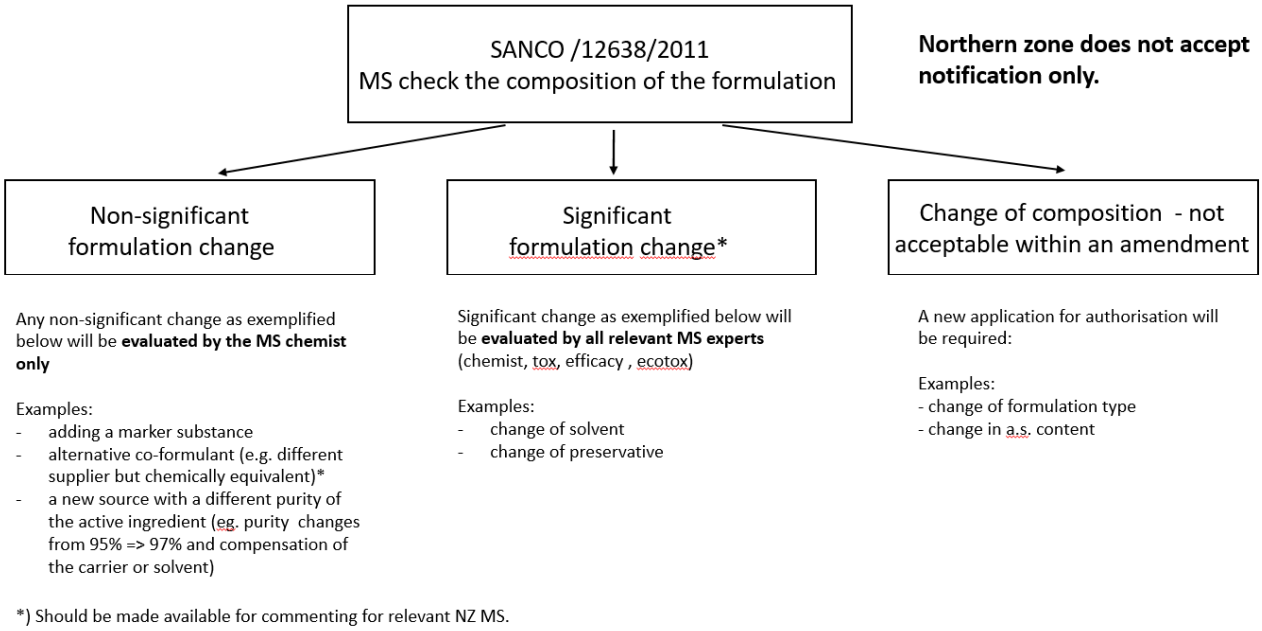
The zRMS conclusion on the acceptability of active substance's identity of every manufacturing source notified in the formulation shall be given with the precise reference to the EU relevant document (DAR Vol 4 Annex C, addendum to the DAR Vol 4 Annex C, Equivalence report, RMS, month, year of issue).

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. 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.

Suggested alternative co-formulants (e.g. from different suppliers), if any, shall be included in the application. They must be chemically equivalent[3] and detailed composition for each alternative co-formulant must be submitted to MS for equivalence assessment. Northern zone does not accept notification only. If the applicant wants to add an alternative co-formulant at a later time, an application must be submitted for the alternative co-formulant to be assessed by the competent authorities and an updated Part C must be provided. Chemically 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. 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.

[3] Only insignificant differences can be accepted.

4.1.2 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 is claimed to be used with an adjuvant then the physical-chemical properties are requested for the product mixed with the adjuvant in question.

Storage stability test at elevated temperature is always required independent of whether a 2-year storage stability test at ambient temperatures is available. 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. Where appropriate, data on the content of relevant impurities, before and after storage, shall be provided. 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 not required before and after storage. In cases where the relevant impurity cannot be formed upon 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 required.

If tank mixing is recommended on the label 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 efficacy section of the dRR (see also section 4.4 of this guidance). Known non-compatibility shall be reported.

4.1.3 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 previously been submitted to the MS, evaluated and accepted at EU-level this should be indicated with reference to its assessment. If new methods are submitted a reason as to why these are needed should be provided.

The methods to be available are:
- the analysis of the formulation;
- 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.

Methods should be provided for the formulation that is intended to be authorised. The analytical method for the determination of the relevant impurity (including those that are specified in the FAO specification) in the formulation is a data requirement independently of whether the relevant impurity is formed or not during storage according to Commission Regulation (EU) No 284/2013. 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 higher LOQ.

4.2 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 Panel on Plant Protection Products and their Residues (PPR), 2012. Guidance on Dermal Absorption, EFSA Journal 2012; 10(4):2665
- 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/EEC[4]
- 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.

4.2.1 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 the co-formulants 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.

4.2.2 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.

[4] See section 4.1.1

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[5] 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.

Where no standardised first tier method of exposure assessment is available and a PPP application scenario is not covered by the exposure models and provisions mentioned below, an appropriate *ad hoc* method might be applied and respective requirements of EFSA OPEX GD should be followed.

4.2.2.1 Operator Exposure

The following exposure models are acceptable:

- EFSA GD Exposure Calculator (latest version)
- Dutch model (greenhouses)
- Seed Tropex model (seed treatment)

As a first tier the models should be used as they are with standard input parameters. For all models a default body weight of 60 kg should be used.

With regard to EFSA Guidance 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 4.2.2.5-1 for an overview of the tiered approach, use of PPE and other risk mitigation measures applicable in the NZ.
Acute risk assessment for operator exposure is possible only when the AAOEL values for active substances are derived by EFSA and MS during the peer review, unless guidance on setting an AAOEL has been adopted by the Standing Committee on Plants, Animals, Food and Feed (SCPAFF).

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

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

4.2.2.2 Non-professional user

The following exposure models are acceptable:

- UK POEM
- German model (75th percentile)
- Dutch model (greenhouses)
- PHED (available on http://www.pesticides.gov.uk)
- Puffer pack model (available on http://www.pesticides.gov.uk)
- UK Trigger Spray model (available on http://www.pesticides.gov.uk)

The assessment of products for 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 4.2.3.2-1. 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 4.2.2.2-1. Models and input values for a tiered exposure assessment of home & garden 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

4.2.2.3 Worker Exposure

The following exposure calculations and input parameters are acceptable:

- EFSA GD Exposure Calculator (latest version) to both outdoor and indoor scenarios
- 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 it is not a part of the EFSA calculator a realistic worst case should be applied. For instance in berries, spray application does not take inhalation into consideration. Low volume mist or roof fogger are considered as worst case instead of taking into account another use 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.

Dislodgeable foliar residues (DFR)
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 basis for the selection of protective measure as re-entry/waiting period (in hours or days). However, acceptability of a re-entry/waiting period for particular PPP is decided on by each MS[6].

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 4.2.2.5-1).

4.2.2.4 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 (latest version) for resident. For PPPs with no potential acute systemic toxicity the longer term risk assessment for bystander is covered by the risk assessment for resident. If the estimated resident exposure (all pathways (mean)[7]) exceeds the AOEL no higher tier risk refinements are available, unless increasing of buffer zones and the

[6] See Appendix IV for National requirements and Appendix V for mitigation options available in the member states in the zone.
[7] All pathways may not always be relevant

use of drift-reducing nozzles could be considered. These risk mitigation measures may be accepted by some MS.

- When no safe use can be identified for resident (and for bystander simultaneously) EUROPOEM II Bystander Exposure to Pesticides[8] for bystander and German Guidance (Martin et al.[9]) for resident may be considered by some MS[10] using 60 min duration of exposure for EUROPOEM II and the other values as suggested for the respective model.

Acute risk assessment for bystander exposure is possible only when the AAOEL values for active substances are derived by EFSA and MS during the peer review.

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

A risk assessment for recreational residence 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 are likely to have access[11,12]. 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.

4.2.2.5 Risk mitigation measures

Table 4.2.2.5-1 gives an overview of the acceptable risk mitigation measures in each of the member states of the Northern zone.

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.

[8] Bystander exposure to Pesticides – Report of the Bystander working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002

[9] Martin S, Westphal D, Erdtmann-Vourliotis M, Dechet F, Schulze-Rosario C, Stauber F, Wicke H and Chester G, 2008. Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application; J. Verbr. Lebensm. 3 (2008): 272 – 281.

[10] These models are not accepted in Denmark

[11] See Appendix IV for restrictions in Norway for the use of PPPs on areas accessable for the public.

[12] In the EFSA GD Exposure Calculator choose golf course, turf and other sports lawns to assess the risk of recreational residence.

Table 4.2.2.5-1: NZ approach 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	N	Y**	N	N
Residents/ bystanders								
Buffer strip	Y	N	Y	N	Y*	Y	Y	N
Drift reducing equipment	Y	N*	Y	Y	N	Y	N	N
Both buffer strip + drift red.	Y	N*	Y	N	N	Y**	N	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
Re-entry period	Y	Y	Y	CbC***	Y	Y	Y	N
Field use								
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear + 1. No PPE 2. Gloves	N****	Y	N****	Y	Y	Y	Y	N
Re-entry period	CbC***	Y	N	CbC***	Y	N	Y	N

*Under evaluation **Experience is needed before changing legislation ***Case by Case
**** Gloves will be accepted case by case.

4.2.3 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.

4.2.4 Formulation Changes

Evaluation of significant formulation changes[13] as indicated by SANCO/12638/2011 should consider:

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

4.2.5 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.

4.3 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 283/203 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)

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

- 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
- SANCO/7525/VI/95 rev. 10.1 December 2015. Appendix D – Comparability, extrapolation, group tolerance and data requirements
- SANCO/7039/VI/95 EN. 22 July 1997. Appendix I – Calculation of maximum residue levels and safety intervals
- OECD MRL calculator (2011)
- SANCO/11187/2013 rev. 3. 31 January 2013. Appendix J – Nature of pesticide residues in fish

- SANCO/3029/99 EU, rev.4, 11 July 2000- Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements
- SANCO/825/00 EU, rev. 8.1, November 2010, Guidance document on pesticide residue analytical methods (post-registration monitoring and control)
- 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 .

4.3.1 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.

4.3.2 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.

4.3.3 Residue trials (supervised field trials)

Supervised field trials from Northern residue zone, defined in guidance document SANCO/7525/VI/95, 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 SANCO/7525/VI/95 rev. 10.1, 01 December 2015). Indicate if the methods include analysis of all substances included in the residue definition for both monitoring and risk assessment.

4.3.4 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.

4.3.5 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.

4.3.6 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.

4.3.7 Estimation of Exposure through Diet and Other Means

It should be demonstrated that the uses of the evaluated plant protection product does 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 taken into account 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 EFSA model (PRIMo rev 2.0) using 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 EFSA model (PRIMo rev 2.0 or later) 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 **.**

4.3.8 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 SANCO/7525/VI/95 rev. 10.1, 01 December 2015., should be used.

The extrapolations 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 SANCO/7525/VI/95 rev. 10.1, 01 December 2015.

4.3.9 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.

4.4 Efficacy

The guidance for the efficacy section is available at
http://agro.au.dk/en/public-sector-consultancy/guidance-on-requirements-for-efficacy-data/

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

4.4.1 Efficacy issues related to renewal of products (article 43)

1. Applicants are strongly encouraged to submit a BAD. 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 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 uses 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 extrapolation 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.

6. If the active ingredient 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.

4.5 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[14].
- 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.

[14] 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.

- 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[15].
- Guidance document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments, SANCO/12184/2014 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).

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.
- The interpretation of the acceptability/representativeness of a field study for the specific agricultural landscape and protection goals should be done for each country[16] since climatic and soil conditions vary and **field data** might not be valid/representative for all Member States.
- 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 the 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.

4.5.1 Soil

Only $PEC_{max\ (1st\ season)}$[17], $PEC_{21\ dayTWA}$, PEC_{acc}[18] and $PEC_{plateau}$ 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.

If representative field data are available, the worst case DT_{50}field (non-normalized) should be applied. If no representative field data are available a worst case DT_{50}lab (normalized) should be used.
If field studies are used it must be scientifically justified that these are representative for conditions in the Northern zone as a whole (among others, with regard to soil type, pH and climate). It has to be described

[15] 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.

[16] Latvia generally accept the field studies from central zone. This also apply 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.

[17] $PEC_{max\ (1st\ season)}$: maximum PECsoil in the first season taking into account all applications = PEC_{ini} in the Finnish PECsoil calculator.

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

which parts of the Northern Zone the field studies represent. Field studies must follow the EFSA GD (2014) on $DegT_{50}$ for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil.

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 $PEC_{max\ (1st\ season)}$ and PEC_{TWA} a soil depth of 5 cm shall be used. For $PEC_{plateau}$ calculations, a soil depth of 20 cm can be considered for the years before the last application if tilling practice is applicable. For the last year considered in the calculations, a soil depth of 5 cm shall be used. Hence it is assumed that no tilling is performed the final year. Examples of crops where this refinement cannot be used are no-tillage farming systems, orchards and golf courses.

The Nordic PECsoil calculator (tool and user manual available at http://www.kemi.se/en/directly-to/pesticides/application-guide/plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products) shall be used for the Northern Zone core assessment. 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.

Nordic PEC_{soil}-calculator:
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. $PEC_{plateau}$ can be calculated for applications every year, every 2nd or every 3rd year. Please see table 4.5.2-4 for possible crop rotations periods in years for each member state. 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.

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.

4.5.2 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 have to be used in PEC calculations.

When triggered, as specified in Table 4.5.2-2, the core assessment should contain modelling with all national scenarios for the Member States where authorisation is applied.

The risk envelope approach may only be used in cases where the worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised should be modelled. When a crop is not parameterised in any of the relevant scenario(s), the user should select a crop resembling the intended

crop based on expert judgement. The choice of crop should be justified. In addition to the summary in the dRR, the modelling report with representative files should always be provided in document K. Other output files shall be made available when requested from the regulatory authority.

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 4.5.2-1) should be used for calculation of appropriate input values for the groundwater simulations[19]. 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 the worst case conditions for parent compounds or precursors.

Table 4.5.2-1 Representative soil pH values for Northern Zone Member States

Country	Soils pH		Further comments
	Acidic (<7)	Alkaline (>7)	
Denmark	yes		Most Danish agricultural soils have pH < 7, only a few have pH >7
Estonia	yes		Most Estonian agricultural soils have pH of 4.5 – 7, only a few have pH >7
Sweden	yes	yes	Wide range of pH. Swedish arable land: minimum 4.2 and maximum 8.7
Norway	Yes		Most Norwegian agricultural soils have a pH of 5 – 7.
Lithuania	yes	yes	Arable land pH (H_2O): minimum 4 and maximum 8.2.
Latvia	yes		Most Latvian agricultural soils have a pH of 4.5 - 7
Finland	yes		Finnish agricultural soils have pH 5 – 7. Risk assessment for acidic soils should be provided

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

Regarding the transpiration stream concentration factor (sometimes referred to as plant uptake factor), a value of 0 should be used unless Briggs equation is applicable or another value has been accepted in an EFSA conclusion after 2014 (in accordance with Generic Guidance for Tier 1 FOCUS Ground Water Assessments Version: 2.2 Date: May 2014).

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

Table 4.5.2-2 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[20]			
		Triggered when	**The following scenarios shall be used**	**Comment to MACRO assessment**	**Evaluation of MACRO results**
SE and NO	FOCUS PELMO: Hamburg	a.s./relevant metabolites/non-assessed metabolites[21] **> 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** Risk of leaching to GW is listed as an area of concern in the EU review report	**Krusenberg** **Önnestad** **Näsbygård**[22] **Rustad**[23]	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** → 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 at Danish: 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**		
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

[20] Information about the different versions of the MACRO model and their bugs is available at: http://esdac.jrc.ec.europa.eu/projects/macro.
[21] 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.
[22] 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.
[23] Rustad is only required for Norway. Relevant files and background information is available at www.mattilsynet.no or on request.

MS	Tier I – PEARL or PELMO	step 5 in EU assessment **< 10 µg/L** → ok Non-relevant metabolites evaluated up to step 4 in EU assessment **< 0.75 µg/L** →ok Non-relevant metabolites evaluated up to step 4 in EU assessment **≥ 0.75 µg/L and < 10 µg/L** → Step 5 of relevance assessment needed
FI[24]	FOCUS PEARL or PELMO: Hamburg and Jokioinen	
LV		
EE		

[24] 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:

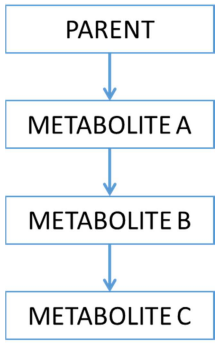
The purpose of the following text is to give practical advice on how to simulate PECgw for metabolites in MACRO. MACRO can only handle one parent compound and one metabolite in a single simulation. Hence, additional simulations are required if several metabolites are formed. Depending on the quality 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 ($Mw_{met\ B}$ / $Mw_{met\ C}$)
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 4.5.2-3.

Table 4.5.2-3 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[25] and 0.5 µg/L for the sum of substances[26]) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. lysimeter studies, field studies, and/or monitoring data[27]) 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 not covered by the "non-relevance-approach" in the guidance document on the assessment of the relevance of metabolites in groundwater[28]. This is the official policy in the following Northern zone member states; EE, FI, LT, LV, NO, SE.

Use every second/third/fourth year depends on crop and country (please refer to Table 4.5.2-4 for country specific crop rotation periods).

Table 4.5.2-4 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***	2-3	4	1/3*	
Sugar beets	3		1	2-3	4	-	
Winter cereals	1		1	2-3	1	1	
Beans	4		3	2-3	4	6**	
Cabbage	1		1/3*	2-3		1	
Carrots	1		1/3*	2-3		1	
Linseed	1		1	2-3		-	
Maize	1		-	2-3	3	-	
Spring OSR	4		4	2-3	2-3	6	
Winter OSR	4		4	2-3	2-3	6	
Onions	1		1/5*	2-3		4	
Peas	4		5	2-3	4	4	
Spring cereals	1		1	2-3	1	1	
Strawberries			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

4.5.3 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.

PECsw is to be calculated with the FOCUS STEP3 scenarios D1, D3-D6 and R1-R4 in accordance with the country specific requirements (Table 4.5.3-1). The risk envelope approach may only be used in cases where the

[25] Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.
[26] Sum of substances in a sample refer to all active substances + metabolites stated as relevant. In DK though, all metabolites are defined as relevant.
[27] 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.
[28] 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.

worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised should be modelled. When a crop is not parameterised in any of the relevant scenarios, the user should select a crop resembling the intended crop based on expert judgement.

For calculations at Step 1 and 2 the latest version (version 3.2) should be used[29].

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 4.5.2-1 and text in chapter 4.5.2 - Groundwater). FOCUS default values should be applied where appropriate. All input values used for the simulations have to be reported, including the application window chosen for the step 3 & 4 simulations.

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

Table 4.5.3-1 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			

D1 and R1 should always be simulated for use on field crops. When a crop is not parameterised for these specific scenarios, use a surrogate crop.

* In case a crop is not included in D1 and D4 in the FOCUS SW list of associated crops and scenarios, a similar crop must be selected for simulation in either D1 or D4, in order to obtain a result for at least one drainage scenario. If a crop is present in both D1 and D4, simulations must be conducted for both scenarios.

** All scenarios in which a crop is parameterised should be simulated. In case a crop is parameterised only for run-off or only for drainage, a similar crop (surrogate) must be selected based on expert judgement in order to obtain results for at least one drainage and one run-off scenario. Simulations must be conducted for all the scenarios that contain the surrogate crop.

*** In case a crop is not included in D1, D4 and R1 in the FOCUS SW list of associated crops and scenarios, a similar crop must be selected for simulation in R1 and in either D1 or D4, in order to obtain a result for at least one drainage scenario and one run-off scenario. If a crop is present in both D1 and D4, simulations must be conducted for both scenarios.

[29] If older versions of Step 1 and 2 is used Step 2 PEC calculations are sufficient for parents and metabolites IF the resulting Exposure–toxicity ratio threshold 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 Exposure–toxicity ratio threshold values for aquatic ecotoxicology being exceeded by a factor of 10.

Table 4.5.3-2 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		OB			
40	O		O				
45							
50	O		O				
Runoff vegetative buffer zone (m)**							
	-	10	10	10	10	10	-
Drift reducing nozzles (%) *							
25	-	-	-	-	-	-	O
50	-	-	Yes	Yes	-	-	FVOB
75	-	-	Yes	Yes	-	-	FVOB
90	-	-	Yes	Yes	-	-	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[30]

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 4.5.3-3.

In addition to the summary in the dRR, the modelling report with representative files should always be provided in document K. Other output files shall be made available when requested from the regulatory authority.

Table 4.5.3-3 Example of a summary table for the obtained maximum PECsw [µg/L] and PECsed [µg/kg] which are to be used in the risk assessment

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

S = single application, M =multiple applications

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.

[30] 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)

4.5.4 Monitoring data

Available monitoring data from the zone (see Table 4.5.4-1) 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 refinement 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 4.5.4-1 Monitoring programmes in the Northern zone.

Member state	Monitoring programme
Denmark	The Danish Pesticide Leaching Assessment Programme (PLAP)
Estonia	-
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.

4.5.5 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 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.

4.6 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[31].
- 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 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.
- Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods (ESCORT 2; Candolfi et al. 2001).
- 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.

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 as a mean of higher tier refinement of environmental risk assessments is not considered appropriate until commonly agreed models are available at European level and guidance documents with criteria for assessing model output are available.

4.6.1 Mixture toxicity

If formulation toxicity data are not available, mixture toxicity should always be considered for acute and long-term risk assessment for all non-target species, preferably using the concentration addition approach.

Further details on how mixture toxicity should be assessed are found e.g. in the Aquatic Guidance Document (EFSA Journal 2013; 11(7): 3290) and in the guidance document for birds and mammals in appendix B of Guidance of EFSA Risk assessment for birds and mammals (EFSA Journal 2009; 7(12) 1438). It should be noted that mixture toxicity should always be considered also for long-term risk assessment for birds and mammals (though not recommended in the EFSA Guidance Document). The active substances can jointly contribute to the same adverse effects on non-target species or to different adverse effects which together cause higher toxicity.

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

[31] Sweden will consider all information from LoEP, including endpoints from representative products.

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.

4.6.2 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.

National requirements (Norway)
When evaluating products for non-professional use/home gardens, toxicity to bees and persistence are especially taken into account. Products that are very toxic too bees/pollinating insects (LD50 <1.0 µg/bee) will not be authorised for outdoor use.

4.6.3 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 LogPow>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).

4.6.4 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 (EFSA Journal 2009; 7(12) 1438) should be used for the screening and tier 1 assessments[32] with a few amendments. 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.

[32] 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.

It should be noted that mixture toxicity should always be considered also for long-term risk assessment. 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 4.6.1 should be used for the long-term risk assessment[33].

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; http://eng.mst.dk/chemicals/pesticides/applications-for-authorisation-after-14-june-2011/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 the risk should be assessed for all focal species. All species required for the crop and growth stage in question according to the Northern Zone higher tier guidance document are relevant, even if the 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 species may thus be broader. Higher tier TER calculations are however not required for species which passed the trigger by a factor of 2 or more at tier 1.

4.6.5 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 use 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 4.5.3) 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 and the aquatic mixture toxicity 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.

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 4.5.3). 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}

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

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 to cover all sensitive life stages or all species in the field, since the effect of e.g. a pulsed exposure is highly species specific and dependent on sensitive life stages and/or different life strategies. Consequently, in the Northern Zone, time-variable exposures derived from the FOCUS modelling cannot be used to refine the aquatic risk assessment as described in chapter 9.1 and parts of chapter 9.2 of the EFSA AGD.

Likewise, chapter 10.3.10 in EFSA AGD utilizes detailed analysis of exposure profiles to refine the worst case PEC_{mix} in risk assessments of combinations of active substances in formulations. Based on the high uncertainty considering detailed analysis of FOCUS peaks (see above), chapter 10.3.10 in EFSA AGD is not accepted to be used in refined risk assessments within the Northern zone.

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

Valid toxicity data from additional species, exceeding data requirements (Regulation (EU) No 283/2013) can be used to refine the aquatic risk assessment. There are two possible options to refine the toxicity endpoint used in the risk assessment, which depends on the amount of additional data. 1.) the use of geometric mean (GM) and 2.) the use of Median Hazardous Concentration 5 % (Median HC5) from a species sensitivity distribution (SSD). A compilation of when the two different methods are considered acceptable is presented in Table 4.6.4-1 (for further details, see text below). The number (N) of species required to derive a geometric mean, may vary in accordance with the data requirements.

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

Table 4.6.4-1. Method accepted (marked with X) in the Northern zone for refinement of toxicity data when more data than required is available.

Aquatic organism	Acute/Long-term	Geometric mean	N_{GM} *	Median HC5	N_{HC5}
Algae		X	3-7	X	8+
Aquatic plants		X	3-7	X	8+
Invertebrates	Acute	X	3-7	X	8+
	Long-term	X	3-7	X	8+
Fish	Acute	X	3-4	X	5+
	Long-term				

* Geometric mean = GM.

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 and that only EC10 appearing in the List of Endpoints (LoE) 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. Guidance on how a deterministic approach (DA) is performed is given below for the acute risk assessment and 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 (AFspec) and other uncertainties (AF_{other}). The latter includes e.g. inter-laboratory variation and lab to field extrapolation for both acute and chronic situations. However, for chronic tests, it can be assumed that the AFspec has a larger weight than AFother since the uncertainties remaining in AFother are reduced. Indeed AFother does not to the same extend need to account anymore for the extrapolations from acute to chronic effects.

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: $AF_{overall} = AF_{spec} \times AF_{other}$.

For the acute assessment:

- (i) When the endpoint of the most sensitive species tested is lower than the derived geometric mean value by a factor 100 for acute endpoints, the RAC_{DA} should be used: The most sensitive endpoint divided by an overall AF >10, i.e. $AF_{overall} = 10$ (AF_{other}) x AF_{spec}. As a default value for the AF_{spec} a value of 2 at minimum is proposed, leading to a **default $AF_{overall}$ of 20**. I.e. acute RAC_{DA} = most sensitive $endpoint_{acute}$ / 20. Compare RAC_{GM}(geomean/100) with the RAC_{DA} (most sensitive endpoint/20) and use the lowest RAC for the risk assessment.

- (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 for acute endpoints, the RAC_{DA} should be used:

$AF_{overall}$ = 10 (AF_{other}) x AF_{spec}. As a default value for the AF_{spec} a value of 6 at minimum is proposed, leading to a **default $AF_{overall}$ of 60**. I.e. acute RAC_{DA} = most sensitive $endpoint_{acute}$ / 60. Compare RAC_{GM} (geomean/100) with the RAC_{DA} (most sensitive endpoint/60) and use the lowest RAC for the risk assessment.

- (iii) When the most sensitive species tested is more sensitive than the derived geometric mean value by a factor between 1 and 10 for acute endpoints, the geometric mean should be divided with the standard AF of 100 to derive an acute $RAC_{GM.}$ I.e. acute RAC_{GM} = geometric $mean_{acute}$ / 100.

For the long-term 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 geometric mean value by a factor 10 (i.e lower than RAC_{GM}), the RAC_{DA} should be used, i.e. the lowest species endpoint tested divided by an $AF_{overall}$ of 6[36].

- (ii) In the other cases, compare RAC_{GM} to the RAC_{DA} (lowest species tested divided by a default $AF_{overall}$ of 8) and use the lowest RAC for risk assessment.

The approach (i.e. either geometric mean or deterministic) that leads to the lowest RAC (i.e. RAC_{GM} or RAC_{DA}) shall be used in the aquatic risk assessment.

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 if the recovery period is maximum 4 weeks and an AF of 5 is used (see Denmark in Appendix IV for further details).

4.6.6 Bees

In the core assessment a first tier risk assessment using HQ acute oral and HQ acute contact should be presented. If necessary, also a higher tier risk assessment should be presented, including the evaluation of higher tier studies, e.g. semi-field or field studies. Under Regulation (EC) No. 1107/2009, an acceptable chronic risk and risk to colony survival and development must also be demonstrated. The procedures for risk assessment should be in agreement with the recommendations in the Guidance Document on Terrestrial Ecotoxicology (Working Document SANCO/10329/2002 rev 2 final, 17 October 2002).

[36] 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.

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. Furthermore, other potential exposure routes may include exposure via honeydew, succeeding crops, guttation and drinking water sources.

The interpretation of the acceptability/representativeness of field studies for specific agricultural landscape(s) and protection goals in Member states should be done on a country specific basis.

A common mitigation option for all Member States is the restriction in timing of application, this mitigation measure can therefore be used in the core assessment. However the Member States differ in their view on whether flowering weeds should be considered when restrictions on application in flowering stages are implemented as mitigation, see **Appendix V**: List of mitigation options available in the Member States in the zone.

4.6.7 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. The evaluation of field studies and the higher tier risk assessment should also be presented in the core assessment according to the guidance document of the Dutch Platform for the Assessment of Higher Tier Studies (de Jong, Bakker, Brown, Jilesen, Posthuma-Doodeman, Smit, van der Steen, van Eekelen; http://www.rivm.nl/bibliotheek/rapporten/601712006.pdf).

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

In the off-field risk assessment, in-field non-spray buffer zones of 5, 10, 15 and 20 m should be used if required (see **Appendix V**: List of mitigation options available in the Member States in the zone). If further mitigation (i.e. other than buffer zones) is needed, the risk assessment implementing nationally specific mitigation options should be presented in the national addenda.

4.6.8 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. 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%.

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 reevaluated 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.

National requirement (Denmark): Specific requirements for persistent substances[37]; 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).

4.6.9 Non target plants

In the core assessment, a risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002 rev 2 final) should be presented[38]. If a probabilistic risk assessment is used, endpoints from at least 10 species are required. Unacceptable effects must be excluded for all species tested. Hence, the HC5 must not exceed the EC50 of the most sensitive species in the SSD. If so, a deterministic risk assessment should be used instead.

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

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

The MAF and the drift value must be according to Appendix III and IV in "Guidance Document on Regulatory Testing and Risk Assessment Procedures for Plant Protection Products with Non-Target Arthropods" (ESCORT 2; Candolfi et al. 2001). A default MAF based on degradation in leaf substrates (i.e. T½ : spray interval is 2.3 : 1) is acceptable for exposure calculations in the risk assessment for non-target plants.

The Northern Zone does not accept the use of interception as refinement for lowering the exposure concentration in the risk assessment of non-target plants. Instead, non-spray in field buffer zones could be used as risk mitigation measure. See **Appendix V**: List of mitigation options available in the Member States in the zone, for relevant national specific buffer zones in each Member state.

If further mitigation (i.e. other measures than buffer zones) is needed, then the risk assessment implementing nationally specific mitigation options should be presented in the national addenda.

4.6.10 Assessment of the relevance of metabolites

[37] 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.

[38] Finland and Estonia do not accept an assessment factor of 1 in probabilistic risk assessment of non-target plants. An assessment factor of 3 is required in the probabilistic risk assessment in national addendum for Finland and an assessment factor of 2 is required in the probabilistic risk assessment in national addendum for Estonia.

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.

4.6.11 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.

5 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 and Article 43 of Regulation (EC) No 1107/2009** (SANCO/12544/2014).

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0ahUKEwi7mc7s3ZbbAhWIZVAKHUqEAWoQFggmMAA&url=https%3A%2F%2Fec.europa.eu%2Ffood%2Fsites%2Ffood%2Ffiles%2Fplant%2Fdocs%2Fpesticides_aas_guidance_template_notification_form_rev_0.doc&usg=AOvVaw18jKMwiWeUtuluPVXdan8-

6 Appendix II: Reporting table

Active substance:
Trade name/Formulation type:
Rapporteur:
cMS:
Send for comments:
Deadline:

dRR point	Country	Comment	Reply rapporteur	Accepted Yes/No

7 Appendix III: Contact points

Pre-notifications and applications should be submitted to:

Country	e-mail	Postal Address
Denmark	pesticider@mst.dk	Pesticider & Biocider Miljøstyrelsen Haraldsgade 53 DK - 2100 København Ø Denmark
Estonia	Maris.Raudsepp@pma.agri.ee with copy to eva.lind@pma.agri.ee	Estonian Agricultural Board Plant 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 [39]	postmottak@mattilsynet.no with copy to pesticider@mattilsynet.no	Norwegian Food Safety Authority, National Registration Department, Felles postmottak, P.O.Box 383, N-2381 Brumunddal, Norway
Sweden	kemi@kemi.se	Kemikalieinspektionen P.O Box 2 SE-172 13 Sundbyberg, Sweden

[39] Address for transfer of documentation: Norwegian Food Safety Authority, National Registration Department, Moerveien 12, N-1430 Ås, 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:** Haraldsgade 53, 2100 Copenhagen Ø, Denmark **Tel:** + 45 72544578 **E-mail:** vm@mst.dk
Estonia	**Title:** Chief specialist of Plant Protection Department **Name:** Eva Lind **Authority:** Estonian Agricultural Board **Address:** Teaduse 2, Saku 75501 Estonia **Tel:** +372 6712 619 (direct) (ext. 612 for teleconference) **E-mail:** eva.lind@pma.agri.ee
Finland	**Title:** Senior Officer **Name:** Heini Paloheimo **Authority:** Finnish Safety and Chemicals Agency (Tukes) **Address:** P.O. Box 66, FI-00521 Helsinki, Finland **Tel:** +358 29 5052000 **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:** 00371 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:** Smelio str.8, LT-11324 Vilnius, Lithuania **Tel:** +370 5 26 24 940 **E-mail:** kristina.valioniene@vatzum.lt
Norway	**Title:** Head of Department **Name:** Tor Erik Jörgensen **Authority:** Norwegian Food Safety Authority **Address:** P.O.Box 3, N-1431 Ås **Tel:** +47 22 77 91 26 or +47 95 04 12 83 **E-mail:** tejor@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

8 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. • DK does not accept the use of re-entry times as a refinement for risk assessment of recreational residence. • DK does not accept the EU definition of non-relevance of metabolites. Denmark generally considers all metabolites as relevant, but in some cases, and after evaluation by DEPA (see the Danish na-	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**
		tional 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[40]), may not be used in private gardens, public areas and similar areas which are accessible to the public, areas around residential buildings, childcare institutions and similar, or to treat vegetation on borders with public roads or private gardens. In addition, these products cannot be sold to or be used by non-professional users. A minimum buffer strip of 2 meter to bystander and resident should be stated on the label when used by professionals. • Buffer strips of 1, 2, 5 or 10 meter due to risk assessment for the bystander and resident may be necessary on the label (see the Danish national guidance).		

[40] 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**
		• 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). • Products for non-professional users: Products which can be purchased and used by everyone, including garden 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 +	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**
		specific input and output values All metabolites that are not inherently non-relevant needs to be covered by the assessment.		
Ecotoxicology	**General** **Birds and Mammals** Higher tier guidance on risk assessment for birds and mammals **Aquatic organisms** Specific aquatic risk assessment	 Danish refinement options for: FS, PD, PT, RUD, DT_{50} and interception Specific assessment principles for mesocosm studies	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/

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	NO	EE does not automatically require a vertebrate study on acute inhalation toxicity when the product is sprayed. Please see Appendix VIII.		

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
Residues	NO			
Efficacy	NO			
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.**	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**
		Margin of safety (MOS) between the carcinogenicity and reproductive NOAEL and AOEL shall be approximately 1000. In case where MOS is too small, extra assessment factor is used. <u>Non-professional use:</u> 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		

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**
		- Waiting period exceeds 7 days - The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL.		
Residues	NO			
Efficacy	Dossier must cover Finnish conditions			
Fate and behaviour	NO	No specific requirements		
Ecotoxicology	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 ingredient 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		

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**
		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 can not 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 per-	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”

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**
		sonal equipment exceeds allowable value PPP can not be authorised for non-professional use;		
Residues	NO			
Efficacy	No			
Fate and behaviour	**Yes**	See core text in chapter 4.5.2		
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	**Acute inhalation toxicity requirements:** A clear and robust justification for waiving the acute inhalation toxicity study required by Regulation No. 284/2013 should be provided, if the applicant cannot justify an alternative approach under Regulation (EC) No 1272/2008, i.e. acute inhalation toxicity of all		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**
	components cannot be provided or reliably predicted with a validated method. **Professional use:** When long term risk assessment for bystander & resident using EFSA GD Exposure Calculator indicates no safe use, EUROPOEM II Bystander Exposure to Pesticides for bystander and German Guidance (Martin et al.) for resident may be considered using 60 min duration of exposure for EUROPOEM II and the other values as suggested for the respective model. **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. - Re-entry periods after an appli-			

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**
	cation of a PPP on turf, lawns, grassland etc. may not be accepted for non-professional use.			
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 4.5.2	No	
Ecotoxicology	No **Non-professional use:** Plant protection products may not be authorized for non-professional use if those are systemic products with insecticidal properties and if buffer zone to protect aquatic organisms is large than 10 m or VFS buffer zone is required.			

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	The following plant protection products may not be authorised for use by non-professional users: - Products that are explosive (E) or oxidizing (O).	Yes, in Norwegian	
Toxicology	No	Acute Inhalation Toxicity: Until a change in condition i) of the data requirement for inhalation toxicity of Regulation (EU) No 284/2013 has been made, or a harmonised EU interpretation of this condition has been established, an acute inhalation toxicity study should be required according to the old data requirement on testing for inhalation toxicity (Regulation (EU) No 545/2011). The directions for approval of non-professional use: Important issues are: -use of substitutional principle - evaluation regarding storage of the plant protection product - evaluation regarding personal protection equipment for non-professional users lacking skills in handling plant protection products. The following plant protection products may not be authorised for use by non-professional users: Products that are acutely toxic category 1-2 (deadly) or category 3 (toxic);	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**
		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. - H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled. - H340 May cause genetic defects. - H341 Suspected of causing genetic defects.		

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**
		- 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. <u>The following products can be accepted for non-professional use:</u> <u>Ready for use:</u> 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		

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**
		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 the 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. 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		

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**
		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 µg/bee) will not be authorised for out-door use.		
Overall	Yes	National requirements for approval of adjuvants (see https://www.mattilsynet.no/language/english/plants/plant_protection_products/Approval_plant_protection_products/adjuvants.22424).		

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:			

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**
	(a) Monitoring data from the Danish PLAP is available for the active substance and any potentially relevant metabolite at the time of application. (b) The proposed conditions of use of the product in Sweden are directly comparable to the experimental condition of application of the product in the Danish PLAP. The applicant needs to provide a factual argumentation regarding this 'comparability', if necessary using a risk-envelope. (c) The results from MACRO In FOCUS simulations with the Swedish scenario Näsbygård and/or Önnestad indicate a non-acceptable leaching risk for the active substance or potentially relevant metabolites, while they indicate an acceptable leaching risk with the Swedish scenario Krusenberg. The Swedish Chemicals Agency considers that environmental conditions of the Danish PLAP fields do not cover the Krusenberg-scenario. In such cases, the results of the Danish PLAP, as published by the Geological Survey of Denmark and Greenland (GEUS), can be used by the applicant as higher tier assessment, as a complement for the simulation results. To be 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	Plant protection products are not suitable to be placed in authorisation class 3 (non-professional			Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg,

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**
may be used by non-professional users	use products) if they have any of the following characteristics: - Products containing a 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, waiting periods or personal protective equipment - Products that have the following classification according to Regulation (EC) No 1272/2008: Acutely toxic or acutely harmful (Acute tox. 1-4), requiring hazard statement H300 Fatal if swallowed H301 Toxic if swallowed H310 Fatal in contact with skin H311 Toxic in contact with skin H330 Fatal if inhaled H331 Toxic if inhaled H302 Harmful if swallowed H312 Harmful in contact with skin H332 Harmful if inhaled Highly corrosive (Skin corr 1a, 1B, 1C) requiring hazard statement H314 Causes severe skin burns and eye damage Severely damaging to to eyes (Eye Dam 1), requiring hazard statement H318 Causes serious eye damage Respiratory sensitisation (Resp sens 1), requiring hazard statement H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled Causing skin allergy (Skin sens 1; unless it can be shown that exposure is negligible) requiring hazard statement H317 May cause an allergic skin reaction Mutagenic, carcinogenic or toxic to reproduction (Muta 1A, 1B, 2; Carc 1A, 1B, 2; Repr 1A, 1B, 2) requiring hazard statement H340 May cause genetic defects H341 Suspected of causing genetic defects H350 May cause cancer H351 Suspected of causing cancer			+46 8 519 41 100, kemi@kemi.se

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**
	H360 May damage fertility or the unborn child H361 Suspected of damaging fertility or the unborn child H362 May cause harm to breast-fed children Specific organ toxicity (STOT SE 1, 2; STOT RE 1, 2) requiring hazard statement H370 Causes damage to organs H371 May cause damage to organs H372 Causes damage to organs H373 May cause damage to organs Toxic by aspiration (Asp tox 1) requiring hazard statement H304 May be fatal if swallowed and enters airways; unless they have childproof packaging - If the calculation of user exposure (without protective clothing) in or after application in "normal" use exceeds the AOEL (Acceptable Operator Exposure Level) - The products are formulated as concentrates and require dilution before use (unless products with particularly low risk are concerned*) - The products are packed in containers or are to be spread using containers which pose a special risk of spillage and misuse (unless low-risk substances are concerned) - The environmental risk assessment shows no or only a small margin to unacceptable effects in "normal" use Pack size and concentration are taken into account in allocating to an authorisation class. KemI generally recommends that authorisation class 3 products (non-professional use products) are sold as ready-to-use solutions in packs of 10 kg or 10 L or less. *In accordance with KIFS 2016:3, products formulated as concentrates that require dilution prior to use can only be accepted if they are of particularly low risk. According to the Swedish Chemicals Agency, particularly low risk is defined as follows: - The toxicity of the active substance is considered too low for an ADI, AfRD or AOEL to be determined. - The product is not harmful to bees such that labelling as SPe 8 has been considered necessary according to Regulation (EU) no 547/2011: SPe 8 Dangerous to bees			

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**
	- The product does not fulfil the criteria for the following classification according to Regulation (EC) No 1272/2008: Classification for physical hazards Environmental hazards, except H412 Harmful to aquatic life with long lasting effects H413 May cause long lasting harmful effects to aquatic life Health hazards, except H315 Causes skin irritation H319 Causes serious eye irritation EUH208 'Contains (*name of sensitising substance*). May produce an allergic reaction'.			
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			

9 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 for re-entry into treated areas - specific requirements concerning use of protective equipment - buffer zone for spraying See also Table 4.2.2.5-1 on the use of risk mitigation measures in the EFSA GD exposure calculator.	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		
Surface water	Buffer zones, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards	Not accepted*
Non-target arthropods	Buffer zones to protected areas, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards	Not accepted*
Bees	Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise	
Birds and	Restriction in timing – only fall application, dose and frequency restrictions, collection of spills	

mammals		
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	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**
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 - specific requirements on the use of protective equipment
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	- Buffer zone
Bees	- Person must notify the user of a plant protection product of the existence of his or her apiary (whose apiaries are located at a distance of up to two kilometers from the field where it is planned to use the plant protection product) at least 48 hours before starting spraying. - It is prohibited to spray areas where there are blooming flowers with a PPP unless there is a notation on the labeling of the

	packaging of the plant PPP that the PPP may be used during the blooming period of flowers and fluttering period of bees.

Finland	**Mitigation options**	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	Buffer zones, max width 20 m for field crops, 30 m for bush berries, nurseries and 50 m for orchards. Drift reducing equipment can be used to further reduce the risk from spray drift.	Nozzles with 50, 75 and 90 % reduction, certain types of air assistant sprayers
Non target arthropods	No specific national requirements.	-
Non target plants	Spray drift buffer zones alone or in combination with drift reducing equipment could be used to reduce the risk.	Nozzles with 50, 75 or 90% reduction, certain types of air assistant sprayers
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. The beekeepers within a radius of 3 kilometres must be informed not later than 24 hours before application.	-
Birds and mammals	For seed treatments: mitigation options that can be applied - removals of spills. Other uses: no use during breeding season.	-
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 Finnish PEC soil calculator).	
Fate and behaviour		-
Ground water	If the substance/the metabolite is mobile in the soil: the product may not be used in the 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.	

Latvia	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	There is no limit for the maximum buffer zone width set in the national legislation. 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. From currently registered PPP maximum buffer zone is 40m in orchards and 30m for field crops.	Nozzles with 50, 75 and 90 % reduction
Non target arthropods	Buffer zones for off-field risk reduction can be applied if needed. There is no limit for the maximum buffer zone width set in the national legislation. From currently registered PPP maximum buffer zone is 10m for field crops, 20m for orchards. For glasshouse uses option not to introduce pollinators or beneficial arthropods for certain period of time after application is used.	Not an option.
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. From currently registered maximum PPP buffer zone is 5 m for field crops.	Nozzles with 50, 75 and 90 % reduction
Bees	-According to Cabinet Regulations No. 950 a person using PPP with phrase “Toxic to bees” or R57 in its instruction for use, informs those beekeepers that have bees in radius of 2km and that have registered their hives according to cabinet regulations for registering animals, livestock etc. -In other cases (other phrases than “toxic to bees” or R57) user has to comply with Spe8 requirements in PPP instructions of use. 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.	
Birds and mammals	For seed treatments: mitigation options that can be applied - removals of spills. Other uses: no use during breeding season.	

Lithuania	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology		
Bystander & resident exposure Worker exposure	- when long term risk assessment for bystander & resident using EFSA GD Exposure Calculator indicates no safe use, buffer zone of 5 or 10 meters could be considered - re-entry periods after an application of a PPP on golf course, turf, lawns, grassland etc. could be considered - if the predicted worker exposure exceeds the AOEL using gloves as a refinement of exposure assessment could be considered	Drift reducing nozzles are not accepted
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		
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. Step 4 modelling must be provided with SWAN.	Drift reducing nozzles are not accepted
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.	-
Non target plants	Buffer zones: min – 5 m, calculating on every 5 meters. From currently registered PPP maximum buffer zone is 10 m.	-
Bees	If product is toxic to bees label signify as “dangerous to bees” (safety phrase). 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. Restrictions of use on flowering weeds: no use on flowering weeds/destroy weeds before flowering. Cover bee hives during spraying time for a (indicate time). Regulation of	

Lithuania	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
	use PPP: to inform beekeepers those have bees in radius of 2.5km not later than 48 hours before application.	
Birds and mammals	For pellets and seed treatments: fully insert in to the soil; remove off spills. Other uses: no use during breeding season.	
Soil organ-isms	If product is toxic to earthworms, soil macro- or micro- organisms, or if there is a possibility that product will accumulate in soil, use a restriction in time and rate: don't use product, or other products with the same active substance more than (indicate time and frequency).	

Norway	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	The surface water mitigation measures that are accepted in Norway are listed in Table 4.5.3-2.	Not an option
Non target arthropods	N/A	Not an option
Non target plants	N/A	Not an option
Bees	To protect bees, mitigation options include restrictions of use during flowering and foraging activity. This also includes restrictions in day-time applications: No use between 0400 and 2300 if temperatures exceed 10°C, or no use between 0600 and 2200 if temperatures do not exceed 10°C.	Not an option
Birds and mammals	N/A	Not an option

Sweden	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology	Sweden accepts mitigation options as shown in **Table 4.2.2.5-1: 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		
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 are 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 4.5.3-2.	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. 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".	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
Non target	In-field spray-free buffer zones could be used to reduce off-field risks. If necessary, drift reducing equipment could	Arable crops: 50, 75 or 90%

plants	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”.	Orchards: 25, 50, 75, 90 or 99%
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 labeling requirements for plant protection products” could be used. Additionally, spray drift buffer zones could be used to reduce the risk for bees (see point “Non target arthropods” above).	

10 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	Winter cereals
Application regime (single or multipel)	Single application
Active substance	Substance X
Organism	Fish *(O. mykiss)*
Reproductive endpoint [µg/L]	8 µg/L
Assessment factor	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 **Application regime (single or multiple)**		Winter cereals Single application						
Active substances		Substance X and Substance Y						
Organisms **Reproductive endpoints for *O. mykiss* [µg/L][1]** **Reproductive endpoints for *D. magna* [µg/L][1]** **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]**		Fish ***(O. mykiss)*** and aquatic invertebrates (*D. magna*) 8 µg Substance X/L and 6 µg Substance Y/L or $NOEC_{mix-CA}$ 6 µg Substance X /L and 4 µg SubstanceY /Lor $NOEC_{mix-CA}$						
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.

11 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

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

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, 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[41] 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 or of the co-formulants with unknown acute inhalation toxicity. If the spray is classifiable based on this assumption, 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 set out conditions for use.

If the spray is not classifiable based on the worst case assumption, further information on acute inhalation toxicity will not be required. The classification of the product should then be based on information fulfilling the CLP regulation without the addition of PPP data requirements.

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

1) > 1000 times dilution of the product (assume ATE 0.005 mg/L).

2) If less than 1000 times dilution the acceptable amount of ingredients having 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 is reflecting the upper limit of cat. 4 classification and hence if above the dilution is not classifiable:

   Acceptable amounts [Aa] of ingredients with unknown and cat 1 classification:
   $$\text{Aa \%} < \frac{dilution\ x\ 0.005\ mg/l}{5\ mg/l} x 100\%.$$

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

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

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

   For instance if the product is diluted more than 100 times then an amount of 100% or less of the ingredients of unknown acute inhalation toxicity or with a classification of acute tox cat. 1 is acceptable.

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