

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

Version 4.0. This guidance document replaces the version of April 2014 and can be voluntarily applied from June, 2015, and must be applied from the dates given in the table on page 2

Changes to the previous version are highlighted in yellow

Editing log – Guidance Document on Work-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January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Registration of Plant Protection Products	DK + expert groups	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
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		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

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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 and re-authorisation 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 the procedure will be applied on a case by case basis. 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.

It should be noted however, that new product applications on-going at the time of adoption of the Regulation (EC) No 1107/2009, and re-registration for all existing products containing active substances **approved according to directive** 91/414/EEC should be assessed in accordance with the transitional measures in Article 80.5 of regulation (EC) No 1107/2009.

The document might be updated twice 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 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 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 3.3.1 and 3.3.2.

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 [Appendix IV](#).

The steering committee has telephone conferences approximately every second month and face-to-face meetings at least once a year. The steering group 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 group, minutes of the meetings as well as updating the list of applications with agreed ZRMS and timelines. The chair of the steering committee is also the primary contact point for the Central and Southern zones. The chair is also a member of the Inter-zonal steering committee, also the in-coming chair is part of the Inter-zonal steering committee.

3.2 Prerequisites for work-sharing

3.2.1 Re-registration for authorised products

The minimum requirement for voluntary co-operation on re-assessment is that the product has a valid authorisation and is intended to be kept on the market in at least 2 Member States. 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/plant/protection/resources/risk_envelope_gd_rev_14032_011_en.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.

3.2.2 New product authorisation submitted before 14 June 2011

Under the transitional measures of the **Regulation (EC) No 1107/2009** a decision on voluntary work-sharing on applications submitted before June 14th 2011 will be taken on a case by case basis depending on available resources and priorities set in each country. Formulations and GAPs should be **harmonised** as much as possible to reduce the workload.

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 applications of renewal of authorisation according to current EU guidance document on renewal of authorisation (SANTE/2010/13170).**

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 appointed zRMS within 3 months from the date of enter into force of the re-approval of the active substance. An application shall be sent to all concerned Member States in the zone.

3.3.3 Renewal of authorised products under transitional measures

This section relates to products that contains active substances that was approved or reapproved in relation to directive 91/414.

The latest deadline for submission of a full Annex III dossier should be 2 years prior to the final deadline specified in the inclusion Regulation, which should allow time for the full Annex III assessment by the zRMS and for the decision making in the cMS. Submissions could always be submitted before that deadline, e.g. where early re-

registration is sought by the applicants or where Member States have specific concerns about particular products or uses.

3.3.4 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. 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/plant/protection/resources/risk_envelope_gd_rev_14032_011_en.pdf

3.4 How is the zonal RMS appointed?

Whilst the applicants 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 Annex I consideration (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 and the resource availability in each country. The decision will be made by the zonal steering committee.

3.5 Communication with applicants

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 IV).

3.5.1 Renewal of authorised products

Applicants are encouraged to make early contact with the respective contact point listed in **Appendix IV: Contact points**. A notification in advance of the submission should be done to the proposed ZRMS and all concerned MS according to current EU guidance document on renewal of authorisation (SANTE/2010/13170). The decision on ZRMS will be communicated to the applicants. Subsequent communication during the evaluation of the core dossier should be between the applicant and the ZRMS.

EU Guidance document on Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 should be followed as well as the North zone guidance document. For issues related to specific national requirements the applicant should contact the respective country.

3.5.2 Renewal of authorised products under transitional measures

Following the compliance check (Step 1 of the re-registration process) all registration holders should submit a pre-notification using the form available on the Commission web site (see Appendix II).

The information should be submitted at the latest 6 months before the Step 2 submission deadline to all concerned MS. The decision on ZRMS will be communicated to the applicants. Subsequent communication during the evaluation of the core dossier should be between the applicant and the ZRMS. For issues related to specific national requirements the applicant should contact the respective country.

3.5.3 New product authorisation

Applicants are encouraged to make early contact with the respective contact point listed in **Appendix IV: Contact points**. A notification 6 months in advance of the submission should be done to the proposed ZRMS and all concerned MS.

For applications **for a new product authorisation** the EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed as well as the Northern zone guidance document.

3.6 Format for the application

Applicants are requested to submit documentation as specified below and a draft Registration Report, as detailed in **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, latest version)**.

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 requirements are as follows:

- (i) **Covering letter**, including brief summary of the application.
- (ii) Northern Zone **Application form** in English and/or in the language of the relevant MS. The form is available at each authority's website.

- (iii) **Completeness check** scheme

- (iv) **Labels**

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

To the ZRMS, all labels should be submitted.

- (v) **Draft Registration Report (dRR) in word format**

- Part A,
- Part B as a Northern zone core,
- Part C
- If applicable, national addenda.

To the ZRMS, Part A and other national addenda for all concerned MS should be submitted.

(vi) **GAP tables** – complete with all intended uses in the zone which also appoints which use is relevant for which country.

(vii) **Individual test and study reports** - in accordance with the requirements specified in regulation (EU) No 284/2013. Applicants are encouraged to submit the dossier in Caddy XML format. 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).

(ix) A **justification** if data protection is claimed. The justification shall confirm whether the study has been protected previously in a specific MS or at an EU level (or whether that protection has expired) as required in Article 59.3 of the Regulation.

For uses not considered for approval of active substance, an assessment against agreed 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.

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.

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.

Six weeks after receipt applicants will be informed about the completeness of their applications. For incomplete applications a 4 weeks period is given in general to complete the dossiers. Additional time may be given under certain circumstances. The total time to complete a dossier may not exceed 6 months. 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 should be resolved between the applicant and the ZRMS during the core assessment period. If additional information is requested from the applicant this should be submitted and evaluated without changing the timelines. If co-operation with the applicant fails, and the application is refused, the other competent authorities of the zone should be informed of the outcome at the earliest possible opportunity. Besides bilateral consultations among experts, other competent authorities should refrain from working on the national submission until such time as the ZRMS core assessment is completed.

3.8 **Renewal** of Products containing more than one active substance

Products containing more than one active substance will be assessed by the ZRMS if the ZRMS has this product on the market. In other cases products containing a mixture of active substances have to be evaluated on national level.

For renewals according to article 43 in regulation (EC) No 1107/2009 an application for renewal shall be submitted within 3 month after entering into force of the re approval of each active substance. However, if the active substances in the product have an approval within 12 months from each other exemptions are possible in accordance with EU Guidance document on Renewal of authorisation according to Article 43 of Regulation (EC) No 1107/2009 (SANTE/11509/2013).

3.9 Commenting procedures

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 III – Reporting table** and must be submitted before the agreed deadline (see timelines, 3.11) in order to be taken into consideration by the ZRMS. Bilateral discussions among experts during the evaluation are encouraged.

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

3.10 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. Nevertheless, national requirements, risk assessment schemes and risk mitigation measures and other restrictions or conditions are adapted to the national conditions and are implemented by each individual country. This means that an authorisation granted in one country not necessarily means that an authorisation also will be granted in another. For further details on risk mitigation options see **Appendix VI: List of mitigation options available in the Member States in the zone**

If it is concluded from the assessment of the worst case identified in the 'risk envelope' approach, that an unacceptable risk cannot be excluded, uses under certain conditions (e.g. reduced rate) or with applicable risk mitigation measures within the CMS will be evaluated to check if acceptable uses are identified.

3.11 Time lines

3.11.1 Re-registration for authorised products under transitional measures

Following the compliance check (Step I of the re-registration process) registration holders are requested to submit to all CMS the pre-notification form available at the Commission web site (see Appendix II):

Replies from each registration holder are collated into a table that contains the information requested for all products containing a specific substance.

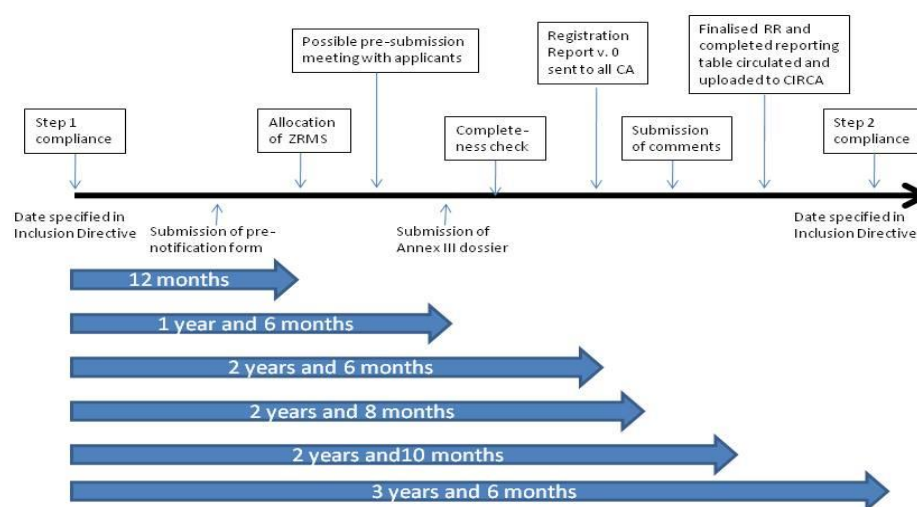
On the basis of the information received a decision by the Steering committee on the allocation of products should be taken at least four months in advance of the expiring date for submission of Annex III dossiers (i.e. see point 5.2.1 of the Guidance document on the procedures relating to plant protection products following inclusion of an existing active substance in the inclusion regulation).

The ZRMS should as soon as possible contact registration holders and discuss their applications. Pre-submission meetings are recommended to clarify questions related to, among others, the GAPs and the "risk envelope" approach. The evaluation of all products containing a specific substance should be organised by the ZRMS as an individual project, setting specific deadlines and allocating in advance the necessary resources for the fulfilment of the obligations.

A six week period is given for the ZRMS to check the completeness of the application. The Registration Reports (revision 0) should be submitted by the ZRMS to the competent authorities of the other Member States 12 months after submission of the application. A six to eight weeks consultation period is foreseen during which competent authorities of other Member States in the zone submit their comments.

Two months after the consultation period has expired, the ZRMS has updated the core evaluation and prepared a reporting table (see Appendix III) with all received comments including a remark on whether the comment has been accepted or not. A final version (revision 1) of the Registration Report is prepared with all changes that have been accepted. The registration report and the reporting table will be uploaded on Circabc. A notification, by e-mail, will be sent to all other MS in the zone with link to the document on CIRCABC. It is the aim that a final version of the RR and the reporting table is uploaded on CIRCABC for information of all Member States eight months before the Step 2 deadline.

SCHEME OF THE PROCESS FOR RE-AUTHORISATIONS



3.11.2 New product authorisations

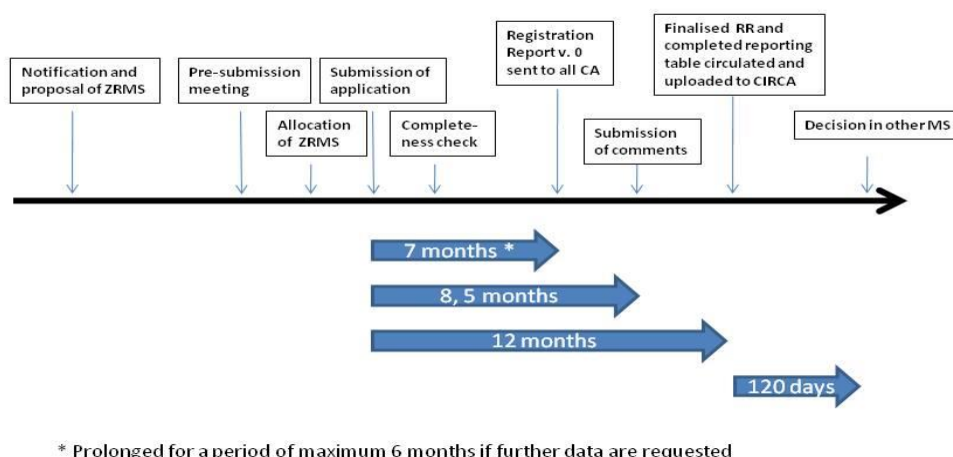
A decision on **who will act as ZRMS** will be taken based on **proposed ZRMS by the applicant as well as** available resources and priorities set in each country. If a ZRMS is appointed, the evaluation of the product and all its uses should be organised by the ZRMS as an individual project, setting 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.

RR (revision 0) should be submitted by the ZRMS to the competent authorities of the other Member States seven months after submission of a complete application. A six weeks consultation period is foreseen during which competent authorities of other Member States in the zone and the applicant submit their comments. In case further information/studies are required a maximum six month period is given to the applicant to complement the application.

After the consultation period has expired, the ZRMS prepares a reporting table (see [Appendix III](#)) with all received comments including a remark on whether the comment has been accepted or not. A new version (revision 1) of the Registration Report is prepared with all changes that have been accepted and is uploaded on Circabc together with the reporting table and a notification is sent to the MSs within the zone. The other **concerned** Member States should taking a decision within 120 days (**excluding clock-stop time, if any left**) of receipt of the assessment report and the copy of the certificate of registration in the ZRMS.

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



3.12 Inter-zonal uses

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

3.13 Applications for mutual recognitions

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

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.

3.14 Provisional authorisations

In principle, applications for provisional authorisations will be dealt with in the same way as applications for new authorisations

3.15 Withdrawal and amendment of authorisation based on zonal evaluations

The SANCO/2010/13170 (latest version) of **Guidance document on renewal, withdrawal and amendments under Regulation (EC) No 1107/2009** should be followed.

4 Assessment

Applicants are required to submit a full Annex III dossier as required in Directive 91/414/EEC and subsequently Regulation EC 1107/2009 in the format specified in **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 rev 1 02 October 2009 with later updates/revisions¹)**

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 V: Summary of national requirements for Annex III dossiers**, 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.

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, 2nd revision of the first edition, Rome, November 2010
http://whqlibdoc.who.int/publications/2006/9251048576_eng_update3.pdf

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.

- 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 11 July 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis.
- SANCO/825/2000, rev. 8.1 16/11/2010 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 July 2009 rev.3)
- 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://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/data-requirements-handbook-contents.htm>)
- EU Guidance document on the assessment of the equivalence of technical materials (SANCO/10597/2003, rev. 10.1 13 July 2012)
- Guidance document on significant and non-significant formulation changes SANCO 12638/2011, 20 November 2012²

The (draft) Registration Report (SANCO/6895/2009 rev 1 of 02 October 2009 or further revision) should be followed.

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

(http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm)

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.

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

² Not accepted in SE. Formulation changes will be assessed on a case by case basis.

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

4.1.2 Physical, chemical and technical properties of the plant protection

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.

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. For more information regarding the acceptance of commercial packaging if different from the packaging tested in shelf life study please refer to Chemicals Regulation Directorate DATA REQUIREMENTS HANDBOOK.

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 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. If new methods are submitted a reason as to why these are needed should be provided.

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
- 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/EEC³

Specific national requirements are listed for each country within the Northern zone in [Appendix V: Summary of national requirements for Annex III dossiers](#) and [Appendix VI: List of mitigation options available in the Member States in the](#) zone.

³ SANCO/12638/2011 is not accepted in SE. Formulation changes will be assessed on a case by case basis.

4.2.1 Toxicological studies

The introductory section should include a short summary of the toxicology profile of the active substance(s) including the AOEL(s).

4.2.2 Acute Toxicity

A short summary of each study should be included. When the hazard assessment of 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.

4.2.3 Exposure

Assessments regarding exposure of operators, workers, bystanders are obligatory and assessment of resident exposure is obligatory from 1 January 2016. The exposure assessment shall cover the worst case conditions for all types of intended uses within the Northern zone.

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

For products containing more than one active substance, cumulative risk assessment of operator/worker/bystander/resident exposure should be conducted. Further refinement of the cumulative risk assessment is needed if the sum of the predicted exposure as % of the AOELs exceeds 100 %. 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.

If relevant data on safeners, synergists and adjuvants are available a risk assessment should be carried out. If the data are too limited to perform a risk assessment, Safety Data Sheets (SDS) are used in a hazard assessment only.

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.

4.2.3.1 *Operator Exposure (IIIA 7.3)*

The following exposure models are acceptable⁴:

- UK POEM
- German model (75th percentile)

⁴ See Appendix V for national requirements for Finland

- 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 calculations it should be assumed as a default that adults have a body weight of 60 kg. For outdoor application both the UK POEM and the German model should be included in the core dRR. As a higher tier, refinements using Northern Zone work rates could be accepted (ha/day, see Table 4.2.3.1-1).

Table 4.2.3.1-1. Northern Zone work rates accepted in higher tier refinement.

Crop	Area/day
Vegetables (tomato, cucumber, cauliflower)	10 ha
Fruit trees	5 ha
Berries	5 ha
Ornamentals, field, tractor mounted application	1 ha

Field studies

If modelling indicates unacceptable risk, or if there are no relevant application method available in the above mentioned models, field measurements could be conducted in order to obtain more accurate and specific exposure data.

For field studies to be accepted the study should:

- be performed according to OECD Guideline no 9 and follow GLP standards (OECD guideline No 6)
- be conducted with the highest dose rate in the NZ GAP table
- be conducted on the product applied for
- cover all other relevant product parameters (e.g. neck opening, container size etc.)
- include all outliers in the data set as they represent realistic use

The exposure should be derived as the 75th centile of the distribution of measurements in the sample, or as a higher value (further guidance on the interpretation of Field studies are found in the Scientific Opinion on Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents).

There should be a short summary describing the field study, specifying whether closed cabins with/without an air conditioning/air filtration system are used, personal protective equipment, equipment used for loading, the volume of the spray tank and spray boom width etc. It should be noted that user conditions of higher tier exposure studies might affect the user conditions stipulated in the national product authorization.

4.2.3.2 *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 4.2.3.2-1. 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 1 st tier	Work rate ha/day	0.1ha		0.1ha		0.1ha	
	Exposure duration	2h			2h		1h
Low target 2 nd tier ^a	Work rate ha/day	0.01ha ^b		0.01ha			
	Exposure duration	0.5h ^b			0.5h ^b		0.5h ^b
High target 1 st tier	Work rate ha/day		1 ha ^b	0.1ha			
High target 2 nd 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

4.2.3.3 Bystander & Resident Exposure

The following exposure calculations and input parameters are acceptable:

- EUROPOEM II Bystander Exposure to Pesticides³ or comparable calculations (such as the principles described in Martin et al.⁶)
- Exposed body surface: 2 m² for adults and 0.66 m² for children

³Bystander exposure to Pesticides – Report of the Bystander working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002

⁴ 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.

- Duration of exposure: 60 min but refinements can be done in higher tier assessment (bystander), 2h (residents)
- Body weight: 60 kg (adult) and 10 kg (children)

For an application for the use of a PPP on grassland, lawn, turf etc. an assessment of re-entry/waiting periods has to be submitted in the core assessment. However, acceptability of a re-entry/waiting period will be decided on by each MS.

4.2.3.4 Worker Exposure

The following exposure calculations and input parameters are acceptable:

- EURO POEM II Worker Re-entry Model⁷
- Work duration: 6-8 hours depending on activity
- Work duration for crop inspection (cereals): 2 hours
- Body weight: 60 kg (adult)

If data on the amount of dislodgeable residues under the proposed conditions of use are not available, default assumptions shall be used. At first tier the estimation shall be made using available data with the assumption that the worker is not using any PPE. Further refinement using PPE is needed if the predicted exposure of the AOELs exceeds 100%.

4.2.4 Dermal Absorption

A short summary of each study should be included. If the dermal absorption study is performed on another product, a scientifically based bridging statement should be included in the dossier and/or dRR. The bridging statement should include a comparison of the composition of the two products (the criteria for when two formulations can be considered similar are listed in the Guidance on Dermal Absorption (2012)) and also take into consideration a possible difference in the dilution rates.

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 8 or 10.

⁷ Post-Application Exposure of Workers to Pesticides in Agriculture – Report of the Re-entry Working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002

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 rev1 from 2 October 2009, with later updates/revisions).

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

- The “Lundehrn guidelines”:
- SANCO/7028/VI/95 rev.3. 22 July 1997. Appendix A – Metabolism and distribution in plants
- SANCO/7029/VI/95 rev. 5. 22 July 1997. Appendix B – General recommendations for the design, preparation and realization of residue trials
- SANCO/7524/VI/95 rev. 2. 22 July 1997. Appendix C – Testing of plant protection products in rotational crops
- SANCO/7525/VI/95 rev. 9. 01 March 2011. Appendix D – Comparability, extrapolation, group tolerance and data requirements
- SANCO/7035/VI/95 rev. 5. 22 July 1997. Appendix E – Processing studies
- SANCO/7030/VI/95 rev. 3. 22 July 1997. Appendix F – Metabolism and distribution in domestic animals
- SANCO/7031/VI/95 rev. 4. 22 July 1996. Appendix G – Livestock feeding studies
- SANCO/7032/VI/95 rev. 5. 22 July 1997. Appendix H – Storage stability of residue samples
- SANCO/7039/VI/95 EN. 22 July 1997. Appendix I – Calculation of maximum residue levels and safety intervals
- 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
- MANUAL Part E EPCO Working Documents - Technical Advice No E 4, revision 4 (September 2005)

OECD GUIDELINE FOR THE TESTING OF CHEMICALS Magnitude of the Pesticide Residues in Processed Commodities, OECD/OCDE 508 Adopted: 3 October 2008

Specific national requirements are specified for each country in [Appendix V: Summary of national requirements for Annex III dossiers](#).

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). 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. An example of other methods used along with PRIMo is the German VELs model. 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. Meanwhile probabilistic approaches have gained more and more interest and can be used in addition, where desired, in order to build up more experience on such methods for the future.

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 V: Summary of national requirements for Annex III dossiers](#).

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. 9. 01 March 2011. Appendix D, 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. 9. 01 March 2011. Appendix D, Table 4) with exceptions.

4.4 Efficacy

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

Specific national requirements are specified for each country in **Appendix V: Summary of national requirements for Annex III dossiers.**

4.5 Environmental Fate and Behaviour

Disclaimer: *This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases specific national guidance must be consulted additionally. Specific national requirements are presented in **Appendix V: Summary of national requirements for Annex III dossiers.***

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/EEC⁸.
- Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (version 1.1, Date 18 December 2014): Based on the official guidance document of FOCUS Degradation Kinetics in the context of 91/414/EEC and Regulation (EC) No 1107/2009, SANCO/10058/2005 version 2.0 (final). June 2006.
- Generic Guidance for Surface Water Scenarios (version 1.3, Date December 2014): 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 1.2. December 2012.
- 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, Date May 2014): Based on the reports of the FOCUS Groundwater Scenarios workgroup (finalised in 2000), the FOCUS Ground Water Work Group (as

⁸ Note that this guidance is though not accepted by DK (see Appendix VI). For the assessment of groundwater exposure in DK, all metabolites are considered relevant unless they are inherently non-relevant (see guidance).

noted in 2014) and the FOCUS Work Group on Degradation Kinetics (finalised in 2009) as modified by EFSA DegT50 guidance (as noted in 2014).

Please note that the following member states in the Northern Zone do not accept non-equilibrium sorption in the modelling approach; EE, FI, LT, NO, SE.

- EFSA Journal 2014;12(5):3662. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT50 values of active substances of plant protection products and transformation products of these active substances in soil⁹.
- 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).

For the time being the following has been agreed:

- For non-professional use (home gardens), substantial differences exist between the Member States (see Appendix V). Exposure estimations are case-by-case decisions.
- Protected crops are presently assessed as closed systems until a guidance document from EFSA is available.
- The interpretation of the acceptability/representativeness of a field study for the specific agricultural landscape and protection goals should be done for each country since climatic and soil conditions vary and field data might not be valid/representative for all Member States.

4.5.1 Soil

Only PEC_{ini} ¹⁰, $PEC_{21\text{ dayTWA}}$, PEC_{max} ¹¹ 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 $DT_{50\text{field}}$ (non-normalized) should be applied. If no representative field data are available a worst case $DT_{50\text{lab}}$ (normalized) should be used.

If field studies are used it must be scientifically justified that these are representative for the conditions in the Northern zone as a whole (among others, with regard to soil type, pH and climate). Field studies must comply with the CTB checklist¹² for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil.

For PEC_{ini} 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

⁹ Please note the new interception values.

¹⁰ PEC_{ini} : PEC_{soil} after last application calculated for a single season

¹¹ PEC_{max} : Maximum PEC_{soil} derived in calculations for a single season and for all applications

¹² Cornelese & Pol (2006). Manual for the Authorisation of Pesticides. Chapter 6. Version 1.0; 14 April 2006. Appendix 3 Field studies on degradation rate.

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.

FI: See specific national requirement in Appendix V.

Finnish PEC_{soil}-calculator:

The Finnish PEC_{soil}-calculator provides the accumulated level of the active substance in a 5 cm soil horizon. If required and justified by common tilling practice in the crop concerned, the incorporation of the active substance into 20 cm soil may be considered as a refinement option (see above). An acceptable estimate of the refined PEC_{plateau} for tilled soil is 0.25 x PEC_{plateau} (5 cm, baseline/lower part of curve) and adding the final year application(s) of chemical to the top 5 cm soil.

The Finnish PEC_{soil}-calculator considers only SFO degradation kinetics. For substances with non-SFO degradation pattern, other appropriate models should be used. In this case, PEC_{plateau} shall be calculated as follows:

- For the calculation of the baseline plateau PEC_{soil} representative DT₅₀field (worst case, non-normalized) or worst case DT₅₀lab normalized to 6°C¹³ shall be used together with a soil depth of 20 cm if tilling is applicable, otherwise 5 cm.
- For the last year of the PEC_{plateau}-calculations though, the same parameters as for the calculations of PEC_{ini} shall be applied, i.e. a worst case DT₅₀field (non-normalized) or DT₅₀lab normalized to 10°C¹⁴ and a soil depth of 5 cm.

The Finnish PEC_{soil}-calculator is available at <http://www.tukes.fi/pecsoilcalculator>. 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.

A Nordic PEC_{soil}-calculator is currently being developed. Until release, the Finnish PEC_{soil}-calculator should be used.

National cut-off criteria:

DK: For approval, DT₅₀ must be < 6 months. Please consult the Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off: <http://eng.mst.dk/topics/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 DT₅₀lab (**normalised**) in soil of more than 100 days will not be authorised for outdoor use.

SE: For authorisation of non-professional use, see Appendix V.

4.5.2 Ground water

¹³ Mean temperature for a whole year, winter included, applicable for PEC_{plateau} calculation which takes the whole year into account.

¹⁴ Mean for a season, winter not included, applicable for PEC_{ini} and PEC_{TWA} that only concerns one season.

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted. Only substance specific parameters can be changed.

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 for.

Simulations have to be conducted for all crops included in the GAP. When a crop is not included in the list 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, worst case data representative for the concerned member states should be applied in the groundwater simulations.

Data requirements may be revised after finalization of the Nordic-Baltic groundwater scenario project.

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			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 ₂ O): minimum 4, maximum 8.2, & median 6.7.
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

Table 4.5.2-2 National requirements for PECgw simulations

Country	Country specific approach	Country specific approach needed:
FI:	PEARL 4.4.4 OR PELMO 5.5.3 Hamburg & Jokioinen. Simulations shall cover the earliest and latest possible treatment period applied for, as well as additional treatment periods in between if the time interval between the first and the last treatment period is more than 40 days. However, when creating input data for modelling, the given time interval between the starting dates of the treatment periods in the simulations shall not exceed 30 days. If only a single simulation is required, the starting date of the simulated treatment period has to be chosen to represent a worst case situation considering contamination of groundwater.	
DK:	PELMO 5.5.3 Hamburg OR MACRO 4.4.2/5.5.3⁸ Karup and Langvad. As input the following shall be used: 80th percentile for the degradation (not geomean DT₅₀), 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	- if it is clear from PELMO 5.5.3 Hamburg (using standard input values) that there is a risk of leaching (> 0.001 µg/L) for the uses applied for. All metabolites need to be covered by the assessment. Only 1 year out of 20 may exceed 0.1 µg/l

Country	Country specific approach	Country specific approach needed:																				
	years as output (not 80th percentile). Further guidance available at www.mst.dk																					
SE:	MACRO 5.5.4¹⁵ Önnestad, Krusenbergl and Näsbygård For the Swedish scenario Näsbygård several simulations with different starting dates are required if the $K_{OC} < 500$ L/kg and the $DT_{50soil} < 50$ days (modeling endpoint). These simulations shall cover the earliest and latest possible treatment period applied for, as well as additional treatment periods in between if the time interval between the first and the last treatment period is more than 40 days. However, when creating input data for modelling, the given time interval between the starting dates of the treatment periods in the simulations shall not exceed 30 days. If only a single simulation is required, the starting date of the simulated treatment period has to be chosen to represent a worst case situation considering contamination of groundwater.	- if risk for leaching to groundwater is an area of concern pointed out in the EU review report - if the $K_{oc} > 100$ L/kg, unless a PELMO 5.5.3 simulation (Hamburg scenario) gives a $PEC_{gw} < 0.01$ µg/L for the active substance and toxicological relevant metabolites or < 1.0 µg/l for non-relevant metabolites - if the $K_{oc} \leq 100$ L/kg and PELMO 5.5.3 OR PEARL 4.4.4 simulation (Hamburg scenario) gives a $PEC_{gw} > 0.01$ µg/L for the active substance and toxicological relevant metabolites or > 1.0 µg/l for non-relevant metabolites The conditions apply independently of each other. <table border="1"> <thead> <tr> <th rowspan="2"></th><th colspan="2">National approach needed:</th></tr> <tr> <th>$K_{oc} > 100$ L/kg</th><th>$K_{oc} < 100$ L/kg</th></tr> </thead> <tbody> <tr> <td>risk for leaching to groundwater is an area of concern pointed out in the EU review report</td><td>yes</td><td>yes</td></tr> <tr> <td>PELMO 5.5.3 (Hamburg) $PEC_{gw} > 0.01$ µg/L</td><td>yes</td><td>yes</td></tr> <tr> <td>PELMO 5.5.3 (Hamburg) $PEC_{gw} < 0.01$ µg/L</td><td>no</td><td>no</td></tr> <tr> <td>PEARL 4.4.4 (Hamburg) $PEC_{gw} > 0.01$ µg/L</td><td>yes^a</td><td>yes</td></tr> <tr> <td>PEARL 4.4.4 (Hamburg) $PEC_{gw} < 0.01$ µg/L</td><td>yes^a</td><td>no</td></tr> </tbody> </table> ^a Simulations conducted with PEARL are not accepted any longer for chemicals with a $K_{oc} > 100$ L/kg Metabolites: Please be aware that if MACRO-simulations are triggered for the parent substance, according to the above table, it means that all (relevant and		National approach needed:		$K_{oc} > 100$ L/kg	$K_{oc} < 100$ L/kg	risk for leaching to groundwater is an area of concern pointed out in the EU review report	yes	yes	PELMO 5.5.3 (Hamburg) $PEC_{gw} > 0.01$ µg/L	yes	yes	PELMO 5.5.3 (Hamburg) $PEC_{gw} < 0.01$ µg/L	no	no	PEARL 4.4.4 (Hamburg) $PEC_{gw} > 0.01$ µg/L	yes ^a	yes	PEARL 4.4.4 (Hamburg) $PEC_{gw} < 0.01$ µg/L	yes ^a	no
	National approach needed:																					
	$K_{oc} > 100$ L/kg	$K_{oc} < 100$ L/kg																				
risk for leaching to groundwater is an area of concern pointed out in the EU review report	yes	yes																				
PELMO 5.5.3 (Hamburg) $PEC_{gw} > 0.01$ µg/L	yes	yes																				
PELMO 5.5.3 (Hamburg) $PEC_{gw} < 0.01$ µg/L	no	no																				
PEARL 4.4.4 (Hamburg) $PEC_{gw} > 0.01$ µg/L	yes ^a	yes																				
PEARL 4.4.4 (Hamburg) $PEC_{gw} < 0.01$ µg/L	yes ^a	no																				

¹⁵ Please note that when using the stand-alone tool that allows the user to generate m2t-files (M2T.EXE) from MACRO output files (e.g. MACRO001.bin) the file name of the MACRO output file has to be modified so that it is written in lower case. Usually, the MACRO output file names created by the MACRO model are written in upper case.

Country	Country specific approach	Country specific approach needed:																				
		non-relevant) metabolites have to be simulated with MACRO. Non-relevant metabolites cannot be excluded.																				
NO:	If a product is applied in Sweden with the same GAP, modelling as required by Sweden is sufficient for Norway as well. If not applied in Sweden or only applied in Norway, modelling with MACRO 5.5.4 and the Norwegian scenarios Heia and Rustad is required. Relevant files and background information is available at www.mattilsynet.no or on request.	- if risk for leakage to groundwater is an area of concern pointed out in the EU review report - if the Koc > 100 L/kg, unless a PELMO 5.5.3 simulation (Hamburg scenario) gives a PECgw < 0.01 µg/L for the active substance and toxicological relevant metabolites or < 1.0 µg/l for non-relevant metabolites - if the Koc ≤ 100 L/kg and PELMO 5.5.3 OR PEARL 4.4.4 simulation (Hamburg scenario) gives a PECgw > 0.01 µg/L for the active substance and toxicological relevant metabolites or > 1.0 µg/l for non-relevant metabolites The conditions apply independently of each other. <table border="1"> <thead> <tr> <th rowspan="2"></th><th colspan="2">National approach needed:</th></tr> <tr> <th>Koc > 100 L/kg</th><th>Koc < 100 L/kg</th></tr> </thead> <tbody> <tr> <td>risk for leaching to groundwater is an area of concern pointed out in the EU review report</td><td>yes</td><td>yes</td></tr> <tr> <td>PELMO 5.5.3 (Hamburg) PECgw > 0.01 µg/L</td><td>yes</td><td>yes</td></tr> <tr> <td>PELMO 5.5.3 (Hamburg) PECgw < 0.01 µg/L</td><td>no</td><td>no</td></tr> <tr> <td>PEARL 4.4.4 (Hamburg) PECgw > 0.01 µg/L</td><td>yes^a</td><td>yes</td></tr> <tr> <td>PEARL 4.4.4 (Hamburg) PECgw < 0.01 µg/L</td><td>yes^a</td><td>no</td></tr> </tbody> </table> ^a Simulations conducted with PEARL are not accepted any longer for chemicals with a Koc > 100 L/kg Metabolites: Please be aware that if MACRO-simulations are triggered for the parent substance, according to the above table, it means that all (relevant and non-relevant) metabolites have to be simulated with MACRO. Non-relevant metabolites cannot be excluded.		National approach needed:		Koc > 100 L/kg	Koc < 100 L/kg	risk for leaching to groundwater is an area of concern pointed out in the EU review report	yes	yes	PELMO 5.5.3 (Hamburg) PECgw > 0.01 µg/L	yes	yes	PELMO 5.5.3 (Hamburg) PECgw < 0.01 µg/L	no	no	PEARL 4.4.4 (Hamburg) PECgw > 0.01 µg/L	yes ^a	yes	PEARL 4.4.4 (Hamburg) PECgw < 0.01 µg/L	yes ^a	no
	National approach needed:																					
	Koc > 100 L/kg	Koc < 100 L/kg																				
risk for leaching to groundwater is an area of concern pointed out in the EU review report	yes	yes																				
PELMO 5.5.3 (Hamburg) PECgw > 0.01 µg/L	yes	yes																				
PELMO 5.5.3 (Hamburg) PECgw < 0.01 µg/L	no	no																				
PEARL 4.4.4 (Hamburg) PECgw > 0.01 µg/L	yes ^a	yes																				
PEARL 4.4.4 (Hamburg) PECgw < 0.01 µg/L	yes ^a	no																				
LV:	PEARL 4.4.4 OR PELMO 5.5.3 Hamburg & Jokioinen.																					

Country	Country specific approach	Country specific approach needed:
LT:	PEARL 4.4.4 OR PELMO 5.5.3 Hamburg for active substance and metabolites. As input the following shall be used: 80th percentile for the degradation (not geomean DT₅₀), 20th percentile for K_{foc} (not mean) and 80th percentile of output. If a product is applied in Denmark with the same GAP, modelling as required by Denmark is sufficient for Lithuania as well.	- if risk for leakage to groundwater is an area of concern identified in the review report.
EE	PEARL 4.4.4 OR PELMO 5.5.3 Hamburg & Jokioinen.	

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 th /95 th percentile)		
	Compound	PECgw	model & scenario

Modelling endpoints in accordance with the FOCUS degradation kinetics report (SANCO 10058/2005 v2.0) should be used. All input values used for the simulations have to be reported. When using field DT₅₀ values as model input, an evaluation of the representativeness and of the appropriateness of the data for modelling purposes according to the CTB criteria¹⁶ and to chapter 9 in FOCUS degradation kinetics (Sanco/10058/2005, version 2.0, June 2006) must be performed.

¹⁶ Cornelese & Pol (2006). Manual for the Authorisation of Pesticides. Chapter 6. Version 1.0; 14 April 2006. Appendix 3 Field studies on degradation rate.

If one or both of the limit values (0.1 µg/L for each individual substance¹⁷ and 0.5 µg/L for the sum of substances¹⁸) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. lysimeter studies, field studies, and/or monitoring data) 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. The PEC_{gw} of metabolites must not exceed 10 µg/L. Metabolites for which the PEC_{gw} exceed 10 µg/L are not covered by the “non-relevance-approach” in the guidance document on the assessment of the relevance of metabolites in groundwater¹⁹. This is the official policy in the following Northern zone member states; EE, FI, LT, LV, 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			2-3	4	1/3*	
Sugar beets	3			2-3	4	-	
Winter cereals	1			2-3	1	1	
Beans	4			2-3	4	6**	
Cabbage	1			2-3		1	
Carrots	1			2-3		1	
Linseed	1			2-3		-	
Maize	1			2-3	3	-	
Spring OSR	4			2-3	2-3	6	
Winter OSR	4			2-3	2-3	6	
Onions	1			2-3		4	
Peas	4			2-3	4	4	
Spring cereals	1			2-3	1	1	
Strawberries				2-3		5	

* In early potatoes crop rotation may not necessarily be applied.

** Harvested as seed.

4.5.3 Surface water

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted.

¹⁷ Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.

¹⁸ Sum of substances in a sample refer to all active substances + metabolites stated as relevant. In DK though, all metabolites are defined as relevant.

¹⁹ 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.

PEC_{sw} is to be calculated with the FOCUS STEP3 scenarios D1-D6 and R1-R4 in accordance with the country specific requirements (Table 4.5.3-1). Simulations have to be conducted for all crops included in the GAP. When a crop is not included in the list of relevant scenarios, the user should select a crop resembling the intended crop based on expert judgement.

S Step 2 PEC calculations are sufficient for parents and metabolites IF the resulting ETR²⁰- threshold values for aquatic ecotoxicology are exceeded by a factor of 10.

For DT₅₀ in soil, sediment and water, modelling endpoints in accordance with the FOCUS degradation kinetics report (SANCO 10058/2005 v2.0) should be used. If K_{oc} and/or DT₅₀ are pH dependent, worst case data representative for the concerned member states should be applied in the simulations (see Table 4.5.2-1). 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	D2	D3	D4	D5	D6	R1	R2	R3	R4
Denmark			X	X						
Estonia	X		X	X			X			
Sweden	X			X			X			
Norway	X	X	X	X	X	X	X	X	X	X
Lithuania	X		X	X			X			
Latvia	X		X	X			X			
Finland	X			X			X			

²⁰ Exposure–toxicity ratio

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	FVOB	FVOB	FVOB	FVOB	FVOB		
3								
5								
10	FVOB							
15						FVB		
20	FVOB					O		
25								
30	VOB			OB	OB	FVOB		
35		OB						
40			O					
45								
50	O		O					
Runoff vegetative buffer zone (m)								
	-	10	10	-	10	10	10	
Drift reducing nozzles *								
	-	-	Yes ^A	-	-	-	Yes ^B	

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 VI

** See further information in Appendix VI

A: 50%, 75%, 90 %

B: Arable crops & vegetable: 50, 75 or 90%

Orchards: 25, 50, 75, 90 or 99%

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

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

S = single application, M =multiple applications

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.

4.5.4 Monitoring data

Available monitoring data from the zone 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.

SE: See specific policy in Appendix V.

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.

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 V: Summary of national requirements for Annex III dossiers.***
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.

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 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, 23 January, 2013.

In principle, the guidance given in PPR opinions can 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 are 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 this 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).

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 ~~also~~ 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)

As a general rule, products that have a restriction of use due to their ecotoxicological profile, should not be authorised for non-professional use. When evaluating products for non-professional use/home gardens, toxicity to bees and persistence are especially taken into account. Products that are very toxic to bees/pollinating insects (LD50 <1.0 µg/bee) will not be authorised for outdoor use.

4.6.3 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 assessments²¹ 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

²¹ In EFSA's 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 use the lowest endpoint and take account of additional toxicity data by an ad-hoc assessment.

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.

When refinements of the risk assessment are necessary, the revised Northern Zone higher tier guidance document (available at the Danish EPA webpage regarding Pesticides; <http://mst.dk/82462.aspx>) describing relevant scenarios to be used in a refined risk assessment should be used together with the associated spreadsheet.

4.6.4 Aquatic ecosystems

In the core ecotox assessment a table containing all relevant FOCUS PEC SW and PEC SED (see section 4.5.3) and corresponding TERs should be included²². 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 VII. It is important to present all calculations made in the risk assessment in a transparent way, also those calculations not included in the example tables.

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. TER 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 is relevant for each Member state.

Refinement by using PEC_{TWA}

It is not accepted to use PEC_{TWA} in **acute** risk assessments for aquatic organisms. For the long term risk assessment, it is acceptable to follow the EFSA AGD²³.

Refinement by using exposure profiles in higher tier studies (Chapter 9.1 and parts of chapter 9.2 in EFSA AGD)

In chapter 9.1 of the EFSA AGD it is described 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. 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–

²² Remember, that a extra safety margin of 10 is required on top of the TER-trigger, if TER calculations are based on FOCUSsw Step 2 PEC values (see 4.5.3)

²³ PEC_{TWA} can be used in risk assessments of algae if the criteria for TWA are fulfilled.

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 considered to cover for all sensitive life stages or all species in field, since the effect of e.g. a pulse 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.

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

Valid toxicity data from additional species, exceeding data requirements (EU/284/2013) can be used to refine the aquatic risk assessment. There are two possible options to refine the toxicity endpoint used in the risk assessment, that depends on the amount of additional data. 1.) the use of geometric mean) 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).

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	Median HC5
Algae		X	X
Aquatic plants		X	X
Invertebrates	Acute	X	X
	Long-term		X
Fish	Acute	X	X
	Long-term		

The use of geometric mean refers to section 8.3 in the revised EFSA AGD. However, use of geometric mean for long-term invertebrate²⁴ and fish endpoint are not accepted. The reason is that further research on whether the measurement errors in the NOECs roughly follows a normal distribution is needed before the use of a geometric mean or similar can be recommended, as is stated in the EFSA guidance document for Birds and mammals (EFSA Journal 2009; 7(12):1438). If use of geometric mean leads to a more critical acute endpoint, this endpoint shall be used in the aquatic risk assessment. However, derivation of a less critical acute endpoint shall always be assisted by a weight of evidence (WoE) approach, using all available information.

For the WoE approach, the most sensitive species tested would need to be systematically associated to an AF_{other} , i.e. to 10^{25} for acute. Therefore an overall $AF > 10$ for acute should be applied to derive the RACs to account for the non-reduced AF_{other} (=10) and as well for partly but not fully reduced $AF_{spec, remaining} (>1)$ (i.e. since the

²⁴ Different from EFSA AGD.

²⁵ 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 (Assessment factor (AF): $AF_{overall} = AF_{spec} \times AF_{other}$).

geometric mean is applicable when the number of toxicity data is > 2 and < 5 for aquatic vertebrates and >2 and <8 for invertebrates and primary producers (see SSD section²⁶), there remain still some uncertainties on species sensitivity distribution leading to an $AF_{spec} < 10$ but >1). The following advice is given:

- (i) When the most sensitive species tested is lower than the geomean by a factor 100 for acute, the RAC_{WoE} should be used, i.e. lowest species tested divided by an overall $AF > 10$, i.e. $AF_{overall} = 10 (AF_{other}) \times AF_{spec, remaining}$. As a default value for the $AF_{spec, remaining}$ a value of 2 at minimum is proposed, leading to a **default $AF_{overall}$ of 20²⁷**.
- (ii) When the most sensitive species tested is lower than the geometric mean by a factor comprised between 10 and 100 for acute, **compare $RAC_{geometric\ mean}$ (e.g. $geomean / 100$) to the RAC_{WoE}** (lowest species tested divided by an overall $AF > 60$ ²⁸) and **use the lowest RAC** for risk assessment.
- (iii) When the most sensitive species tested is lower than the geometric mean by a factor comprised between 1 and 10 for acute, divide the geometric mean with the standard AF of 100 to derive a $RAC_{geometric\ mean}$.

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 already 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 assessment factor (AF) as proposed in the EFSA AGD. The RAC base 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 (see Denmark in Appendix V for further details).

4.6.5 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.

²⁶ Different from EFSA AGD

²⁷ Sweden and Norway will not accept an $AF_{species} = 2$, when the most sensitive species tested is lower than the geomean by a factor 100. Instead it is suggested to apply the same assessment factor on datasets where the ratio is between 10 and 100 ($AF_{species} = 6$) and on datasets where the ratio is more than 100 (see ii).

²⁸ The overall AF would be > 10 as it consists of a AF_{other} of 10 x $AF_{spec, remaining}$. As a default value for the $AF_{spec, remaining}$ a value of 6 at minimum is proposed for pragmatic reason (as it should be between 2 and 10 it seems a pragmatic approach to take 6). This is leading to a default $AF_{overall}$ of 60. This value of 6 at minimum accounts for the fact that there are more uncertainties on the species sensitivity remaining in (ii) since the lowest value tested is not as low as in (i).

The interpretation of the acceptability/representativeness of the field study 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 VI: List of mitigation options available in the Member States in the zone](#).

4.6.6 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 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 VI: 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.

4.6.7 Earthworms and other soil organisms

In the core assessment a first tier risk assessment using laboratory data should be presented. The endpoint (LC50 and NOEC) used in the risk assessment of earthworms (and other soil organisms) should be divided by a factor of 2 when the log K_{ow} is greater than 2, unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of log K_{ow}. 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 could 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 (standard values given in FOCUS Surface Water) is acceptable for the core assessment. At present use of $PEC_{pore\ water}$ in the soil risk assessment is not accepted.

National requirement (Denmark): Specific requirements for persistent substances²⁹; 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 V: Summary of national requirements for Annex III](#)).

4.6.8 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. 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 * MAF¹ * basic drift value¹

¹ the correct number of applications according to the GAP.

If required, non-spray in field buffer zones of 5, 10, 15 and 20 m could be used as risk mitigation measure.

See [Appendix VI: 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.

4.6.9 Assessment of the relevance of metabolites

The metabolites deemed relevant for ecotoxicological risk assessment in the NZ are given in the fate section (see core dRR, Part B section 5). Metabolites recorded in food items (see core dRR, Part B section 3) that might be eaten by birds or mammals should also be addressed in the risk assessment. The risk assessment is in principle similar to the assessment for the a.s., if not covered by the a.s. risk assessment. The relevant EU GD should be followed, if nothing else is stated in this GD.

4.6.10 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.

²⁹ 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 now 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.

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 end point 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 activity

Please use the pre-notification form available at:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/form_to_notify_intended_zonal_applications.doc

6 Appendix II: Form to notify zones of intended re-authorisation activity

Please use the pre-notification form available at:

http://ec.europa.eu/food/plant/pesticides/approval_active_substances/docs/form_to_notify_intended_zonal_applications.doc

7 Appendix III – Reporting table

Active substance:

Trade name/Formulation type:

Rapporteur:

cMS:

Send for comments:

Deadline:

dRR point	Country	Comment	Reply rapporteur	Accepted Yes/No

8 Appendix IV: Contact points

Pre-notifications and applications should be submitted to:

Country	e-mail	Postal Address
Denmark	pesticider@mst.dk	Pesticider & Genteknologi Miljøstyrelsen Strandgade 29 DK - 1401 København K Denmark
Estonia	Jan-Roland.Raukas@pma.agri.ee with copy to Rain.Reiman@pma.agri.ee	Estonian Agricultural Board Plant Protection Department Teaduse 2 Saku 75501, Estonia
Finland	ppp@tukes.fi	Finnish Safety and Chemicals Agency P.O.Box 66 (Opastinsilta 12 B) FI-00521 Helsinki, Finland
Iceland	ust@ust.is	The Environment Agency of Iceland Sudurlandsbraut 24 108 Reykjavík, Iceland
Latvia	zonal@vaad.gov.lv	State Plant Protection Service Plant Protection Department Lielvarde iela 36/38, 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 ³⁰	postmottak@mattilsynet.no with copy to tor.erik.jorgensen@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

³⁰ 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: Strandgade 29, 1401 Copenhagen K, Denmark Tel: + 45 72544578 E-mail: vm@mst.dk
Estonia	Title: Chief specialist of Plant Protection Department Name: Rain Reiman Authority: Estonian Agricultural Board Address: Teaduse 2, Saku 75501 Estonia Tel: +372 6712 653 (direct) (ext. 612 for teleconference) E-mail: rain.reiman@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: Heini.Paloheimo@tukes.fi
Iceland	Title: Advisor Name: Bjorn Gunnlaugsson Authority: Environment Agency of Iceland Address: Sudurlandsbraut 24, 108 Reykjavik Tel (direct): 00354 5912082 E-mail: bjorngunn@ust.is
Latvia	Title: Director of Plant Protection Department Name: Vents Ezers Authority: State Plant Protection Service Address: Lielvārdes 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: tefor@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

9 Appendix V: Summary of national requirements for Annex III dossiers

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	- The Danish EPA use the German model with the geometric mean when calculating the operator exposure. - Usually the AOEL determined in EU is appropriate, however if there are critical effects and when applying extra assessment factors to the NOAEL of that effect the AOEL is lower than the one in the DAR, then the lower one is used. The extra assessment factors are 3 for reprotoxicity/teratogenicity and 5-10 for carcinogenicity. - The reduction factor for gloves while mixing and loading is 90 % and 60 % while spraying. The reduction factor for full body safety equipment is 50 %.		Yes Danish/English	Danish: http://mst.dk/virksomhed-myndighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English: http://eng.mst.dk/topics/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
	Non-professional users will use handheld spray equipment and have no PPE to protect them. DK does not accept the EU definition of non-relevance of metabolites. From 26. November 2015 Plant Protection Products authorised in Denmark are divided into two groups for professional users and non-professional users, respectively The products are split as follows: Group 1) For professional users: Products which can only be purchased and used by professional users who possess a valid spraying certificate/permit. Group 2) For non-professional users: Products which can be purchased and used by everyone, including garden owners without a spraying certificate or spraying permit. Products in group 1 can from 26. November 2015 only be sold to professional users.	Therefore PECgw calculations demonstration limit values < 0.1 ug/L are needed for all metabolites that are not inherently non-relevant (see guidance under fate)		

Denmark				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
	The Danish Statutory Order on pesticides states that very toxic and toxic pesticides which are classified with acute toxicity in categories 1, 2, or 3 (Directives 67/548/EC³¹ and 1999/45/EC³²) or as specific target organ toxic in category 1 (Regulation no. 1272/2008³³), 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, except for professional control of rats, water voles and moles. These products cannot be sold to, or used by, non-professionals. The criteria PPP's must meet in order to be sold to and used by non-professionals because they are deemed sufficiently safe to use without requirements for			

³¹ Directive 67/548/EC of The European Parliament and of the Council of 27 June 1967 concerning the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances as amended

³² Directive 1999/45/EC of The European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations as amended

³³ 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
	special training are outlined in Annex 17 of the Framework for Risk Assessment of Plant Protection Products.			
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	DT50 soil < 6 months – otherwise no approval The following requirements should be included in the core assessment: Makro Danish scen. or PELMO Hamburg + specific input and output values All metabolites that are not inherently non-relevant needs to be covered by the assessment.	Yes Danish/English	Danish: http://mst.dk/virksomhed-myndighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English: http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/
Ecotoxicology	General Birds and Mammals Higher tier guidance on risk assessment for birds and mammals Aquatic organisms Specific aquatic risk assessment	Geometric mean approach not accepted Danish refinement options for: FS, PD, PT, RUD, DT50 and interception Specific assessment principles for mesocosm studies	Danish/English	Danish: http://mst.dk/virksomhed-myndighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/ English: http://eng.mst.dk/topics/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
	Soil organisms Specific requirements for persistent substances	Field effect studies for substances with DT50 soil between 3 and 6 months		

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			
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		<u>Exposure assessment:</u> National work rate / day for barley is 40 ha. The operator exposure assessment is done mainly by using EUROPOEM I, but when needed, UK POEM and German model can be exploited. Dutch model is applied to greenhouse uses. 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	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
		- Fatal or toxic if swallowed, in contact with skin or if inhaled - Skin corrosive - Causes serious eye damage or is irritating to eyes - Causes respiratory or skin sensitisation - Carcinogenic, toxic to reproduction, mutagenic or fulfils criteria for specific target organ toxicity - Product is presenting an aspiration hazard - Waiting period exceeds 7 days - The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL.		
Residues	NO			
Efficacy	Dossier must cover Finnish conditions			
Fate and behaviour	NO	PECsoil should be calculated by using the Finnish PECsoil calculator. The worst case laboratory DT50 value should be used primarily as an input value, but a worst case field DT50 value can be used on case by case basis if the DT50 value has been normalized to 20 °C and to field capacity.	Fate and behaviour	NO
Ecotoxicology	NO			

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 R23–R28; R40;R45;R49;R46; R68;R60; R61; R62; R63; R41; R64; R48; R33 -or if classified with CLP equivalents as indicated in the National Regulation No.509 from point 11.2.1 to 11.2.10. - if operator risk during use of PPP or after it when not using individual personal equipment exceeds allowable value PPP can not be authorised for non-professional use; - if PPP is classified with R65 it can only be authorised for non-professional use if its packaging/opening has construction safe for children; - if PPP is classified as Harmful, Highly flammable or Extremely flammable it can only be authorised for non-professional use if its packaging has clearly palpable danger symbol.	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
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	Operator exposure: in Tier 2 refinement the German model with the geometric mean is acceptable. Non-professional use: Plant protection products in “common practice” may not be authorised for use by non-professional users which have any of the following characteristics:		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
	1. Product is acutely very toxic or toxic (T+, R26-28, R39 or T, R23-25, R39); 2. Product is corrosive and cause burns or severe burns (C, R34 or R35); 3. Product is carcinogenic, toxic to reproduction or mutagenic and is classified in categories 1,2 or 3; 4. Product may cause harm to breastfed babies (R64); 5. Product is danger of serious damage to health by prolonged exposure (T, R48 or Xn, R48); 6. If the extent of operator exposure (without personal protective equipment) in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.			
Residues	No			
Efficacy	No			
Fate and behaviour	Yes	See core text in chapter 4.5.2	No	
Ecotoxicology	No			

Norway				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
Phys. Chem. properties and anal. method	No	<u>The following plant protection products may not be authorised for use by non-professional users:</u> - Products that are explosive (E) or oxidizing (O).	Yes, in Norwegian	
Toxicology	No	<u>The directions for approval of non-professional use:</u> Important issues are: - use of substitutional principle - evaluation regarding storage of the plant protection product - evaluation regarding personal protection equipment for non professional users lacking skills in handling plant protection products. <u>The following plant protection products may not be authorised for use by non-professional users:</u> - Products that are acute very toxic (T+), toxic (T) or corrosive (C). - Labelled with one of the following DSD-sentences or the corresponding risk phrases according to Regulation (EC) No 1272/2008 (CLP): - R40: Limited evidence of a carcinogenic effect.	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
		- R41: Risk of serious damage to eyes. - R42: May cause sensitisation by inhalation - R48: Danger of serious damage to health by prolonged exposure. - R62: Possible risk of impaired fertility. - R63: Possible risk of harm to the unborn child. - R68: Possible risk of irreversible effects 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. <u>Concentrate</u>: Plant protection products with irritating characteristics may be approved. Products labelled as harmful to health may be approved if there are no better alternatives (health). These products will not be approved if there is extensive need for personal protection equipment. <u>Powder soluble in water</u>: 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 for Agricultural and Environmental Research is responsible for the evaluations and trials.
Fate and behaviour	No	<u>Directions for approval of non-professional use</u>: When evaluating such products persistence is especially important. Products that have a mean half-life in soil		

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
		of more than 100 days will not be authorised for outdoor use.		
Ecotoxicology	No	<u>Directions for approval of non-professional use:</u> 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 to bees/pollinating insects (LD50 <1.0 µg/bee) will not be authorised for outdoor use.		

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
Products which may be used by non-professional users	Plant protection products are not suitable to be placed in class 3 (non-professional 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			Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +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
	- Are acutely toxic requiring risk phrases H300, H301, H310, H311, H330 or H331 according to the Regulation (EC) No 1272/2008 (CLP), highly corrosive requiring the risk phrase H314, carcinogenic, toxic to reproduction or mutagenic requiring the risk phrases H350, H351, H360, H361, H362, H340 or H341 (categories 1A, 1B or 2 according to CLP) - Products which cause severe damage to eyes and require the risk phrase H318 - Products requiring the risk phrase H304 which do not have childproof packaging - Causing allergy requiring risk phrase H317 unless it can be shown that exposure is negligible - Acutely harmful by inhalation, in contact with the skin or if swallowed requiring risk phrases H302, H312 or H332 - Danger of serious damage to health by prolonged exposure requiring risk phrase H372 or H373 - May cause harm to breastfed babies requiring risk phrase H362 - If the calculation of user exposure (without protective clothing) in or after application in "normal" use exceeds the AOEL (Acceptable Operator Exposure Level) - They are formulated as concentrates and require dilution before use (unless low-risk substances are concerned) - They 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) - Products which are particularly harmful to pollinating insects - 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. Keml generally recommends that class 3 products (non-professional use products) are sold as ready-to-use solutions in packs of 10 kg or 10 L or less.			
Phys. Chem. properties and anal. method	NO			
Toxicology	NO			
Residues	NO			
Efficacy	NO			

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
Fate and behaviour	YES	See core text in chapter 4.5.2		
Ecotoxicology	NO			

10 Appendix VI: 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	- limits on spraying methods authorized - requirements on special permits for spraying personnel - requirements on special packaging (dimensions, design, possibly water-soluble packaging) - treatment periods and periods of retainment - waiting periods for re-entry into treated areas - specific requirements on the use of protective equipment	
Residues	- PHI	
Fate		
Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications	
Ecotox		
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	Not accepted
Bees	Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise	
Birds and mammals	Restriction in timing – only fall application, dose and frequency restrictions, collection of spills	
Soil organisms	Restrictions of use, dose and frequency	
Non-target plants	Buffer zones to protected areas	Not accepted

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 °C.
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 km² 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.	Not an option.
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.	Not an option.
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		
Operator exposure	- requirements on special certification or background for professional users - restrictions of the daily work rate (time duration and/or treated area) - prescription the application of extra adequate personal protective equipment	
Worker exposure	- waiting periods for re-entry into treated areas - prescription the application of adequate personal protective equipment	
Residues	- when PPP is used in forestry and for berries, mushrooms PHI is established more then 1 day, the treated are must be noted with warning symbols - 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: use only after sunset to sunrise. Restrictions of use on flowering weeds: no use on flowering weeds/destroy weeds before flowering. Cover	

Lithuania	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, ...? %)
	bee hives during spraying time for a (indicate time). Regulation of use PPP: to inform beekeepers that have bees in radius of 1km	
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 organisms	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	Risk-mitigation options in Norway include buffer zones to mitigate spray drift: up to 30 meters (we do not make use of drift reducing nozzles or other mitigation measures for spray drift or run off as we currently lack both knowledge of the efficiency of different measures under Norwegian conditions and the means to control such measures).	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%, ...? %)
Surface water	See also text in chapter 4.5 Sweden does not use fixed buffer zones. Instead the use of buffer zones are regulated in the regulation SNFS 97:2, 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 modify the size of the Buffer Zone 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 fruit cultivation. Consequently, if a risk assessment identify a need for a buffer zone of between 1 and 15 m in field crops or 1 to 20 m in fruit cultivation, 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. Spray-free buffer zone (determined using "Hjälpredan") is to be used as first option for off-field risk mitigation. If the risk assessment indicates that (fixed) 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" you can find at: http://sakertvaxtskydd.se/sv/Bibliotek/Mitigating-spray-drift-in-Sweden1/	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 plants	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%
Surface water	See text in chapter 4.5	
Non target arthropods	Spray drift buffer zones could be used to reduce off-field risks. In Sweden, wind adjusted spray drift buffer zones are used. In order for the operator to determine the wind adjusted spray drift buffer zones a tool called Hjälpredan (the Helper) have been produced. When the Hjälpredan is used it equals FOCUS spray drift buffer zones up to 15 m (arable crops) and 20 m (orchards). Therefore, Keml does not grant authorization for products which need (FOCUS) spray drift buffer zones greater than 15 for arable crops and 20 m for orchards. If necessary, drift reducing	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%

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	equipment could be used in combination with spray drift buffer zones to further reduce the risk (if the efficacy is maintained)..	
Non target plants	Spray drift buffer zones alone or in combination with drift reducing equipment could be used to reduce the risk (see point “Non target arthropods” above).	Arable crops: 50, 75 or 90% 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).	

11 Appendix VII: Template for Aquatic Risk Assessment including mitigation measures

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

Intended use	Winter cereals				
Application regime (single or multipel)	Single application				
Active substance	Substance X				
Organism	Fish (<i>O. mykiss</i>)				
Reproductive endpoint [µg/L]	8 µg/L				
Assessment factor	10				
Country	FOCUS Step 4			RAC _{SW}	Is PEC _{SW} max > RAC _{SW} ? Yes/No
	Worst-case scenario (ditch, stream or pond)	PEC _{SW} max (µg/L)	Risk mitigation measure		
Sweden	R1				
	D1				
	D4				
Denmark	D3				
	D4				
Finland	R1				
	D1				
	D4				
Estonia	R1				
	D1				
	D3				
	D4				
Lithuania	R1				
	D1				

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	D3				
	D4				
Latvia	R1				
	D1				
	D3				
	D4				
Norway	R1				
	R2				
	R3				
	R4				
	D1				
	D2				
	D3				
	D4				
	D5				
	D6				

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

Intended use		Winter cereals						
Application regime (single or multiple)		Single application						
Active substances		Substance X and Substance Y						
Organisms		Fish (<i>O. mykiss</i>) and aquatic invertebrates (<i>D. magna</i>)						
Reproductive endpoints for <i>O. mykiss</i> [$\mu\text{g/L}$]¹		8 μg Substance X/L and 6 μg Substance Y/L or $\text{NOEC}_{\text{mix-CA}}$						
Reproductive endpoints for <i>D. magna</i> [$\mu\text{g/L}$]¹		6 μg Substance X /L and 4 μg Substance Y /L or $\text{NOEC}_{\text{mix-CA}}$						
Assessment factor used in the RAC calculation to derive RQ_{mix}²								
Assessment factor used in the RQ_{mix} or $\text{ETR}_{\text{mix-CA}}$ calculation³								
Country	Worst-case combination scenario ⁴	Substance	FOCUS step	$\text{PEC}_{\text{sw}} \text{ max}$ ($\mu\text{g/L}$)	Mitigation measure	PEC_{mix} ⁵	$\text{ETR}_{\text{mix-ca}}$ or RQ_{mix}	Is risk acceptable?
Fish								
Sweden	R1 stream	Substance X	Step 4		10 m VFS			Yes/No
		Substance Y	Step 3		--			
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 ETR_{mix}-ca calculation the assessment factor should be according to the ETR trigger value. If the risk assessment is based on RQ_{mix}, 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 RQ_{mix} and ETR_{mix} that shall be presented in the table (not the scenarios with the highest PEC_{sw} values for each active substance).
