

**GUIDANCE DOCUMENT  
ON WORK-SHARING IN THE NORTHERN ZONE IN THE AUTHORISA-  
TION OF PLANT PROTECTION PRODUCTS**

Version 6.0. This guidance document replaces the version of April 2016 and can be voluntarily applied from May 2017. The document must be applied from the dates given in the table starting on page 2.

Changes to the previous version are highlighted in yellow.

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

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January 2011	0.0	Draft Guidance Document on Work-Sharing in the Northern Zone in the Registration of Plant Protection Products	DK + expert groups	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

		4.5 Environmental fate and behaviour	expert group	1 November 2017
		4.6 Ecotoxicology	expert group	1 November 2017

**The correct reference for the NZ work sharing GD:**

Northern zone, 2017. Guidance document on work-sharing in the Northern zone in the authorization of plant protection products. Version 6, May 2017.

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## 1 Legal Status

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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

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

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

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

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

## 3 Procedures

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In summary, the procedure is as follows:

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

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

The ZRMS will then finalize the assessment with the comments received taken into account and make it available via CIRCABC. The Member States within the zone will be notified via e-mail. The cMS will then complete their national assessments based on the ZRMS core assessment taking into consideration national requirements, risk assessment schemes and national options for risk mitigation when relevant.

The procedures for new applications and re-registrations are described in more details in the Chapters 3.3, 3.5 and 3.8.

### 3.1 Zonal steering committee

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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 III: Contact points](#).

The steering committee has telephone conferences approximately every second month and face-to-face meetings at least once a year. The steering committee is normally chaired by one country for one year on a rotational basis. Chairs are responsible for drafting the agendas of the meeting of the steering committee, minutes of the meetings as well as to coordinate updating the list of applications with agreed ZRMS and timelines. The chair of the steering committee is also the primary contact point for the Central- and Southern zones. The chair and incoming-chair are members of the Inter-zonal committee.

Incoming chairs year 2017 – 2023:

Year	Country*
2017	Denmark
2018	Finland
2019	Latvia
2020	Lithuania
2021	Estonia
2022	Sweden
2023	Norway

\*Iceland is excluded.

### 3.2 Prerequisites for work-sharing

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#### 3.2.1 Re-registration for authorised products

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Formulations and GAP should be harmonised as much as possible in the Member States where re-registration is to be applied. This will allow a ‘risk envelope’ approach to the assessment, whereby only the worst case exposure scenarios for each area of the risk assessment are evaluated, with other ‘less risky’ scenarios being deemed acceptable. Different formulations may be covered by the same risk assessment if bridging studies and scientific justifications are available. Guidance on the ‘risk envelope’ approach is available at the EU level as detailed in

[http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_doss\\_risk-env\\_20110314.pdf](http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf)

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

### 3.3 Submission of application

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#### 3.3.1 Pre-submission notifications

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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 (SAN-TE/2010/13170 [\(or later version\)](#)). Applicants should use the latest version of the pre-notification form (SANCO/12544/2014).

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

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An application for renewal of authorisation shall be submitted to the appointed ZRMS within 3 months from the date of enters into force of the re-approval of the active substance. An application shall be sent to all concerned Member States in the zone.

#### 3.3.3 New products authorisation

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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/sites/food/files/plant/docs/pesticides\\_ppp\\_app-proc\\_guide\\_doss\\_risk-env\\_20110314.pdf](http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_risk-env_20110314.pdf)

### 3.4 How is the zonal RMS appointed?

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

- the identity of the original RMS for the [evaluation of the active substance](#) (noting that in the Northern zone it will only in few cases be possible to allocate the work to the original RMS)
- the relevance/importance of the products in each country
- the resource availability in each country.

The decision will be made by the zonal steering committee.

### 3.5 Communication with applicants

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

### 3.5.1 Renewal of authorised products

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Applicants are encouraged to make early contact with the respective contact point listed in [Appendix III: 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 (SAN-TE/2010/13170 [\(or later version\)](#)). 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 Northern zone guidance document. For issues related to specific national requirements [\(specified in Appendix IV\)](#) the applicant should contact the respective country.

### 3.5.2 New product authorisation

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Applicants are encouraged to make early contact with the respective contact point listed in [Appendix III: 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

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Applicants are requested to submit documentation as specified below and a draft Registration Report. [The template for the draft registration report is to be found on the Commissions webpage: \[http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\\_ppp\\\_app-proc\\\_guide\\\_doss\\\_reg-report-draft.zip\]\(http://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\_ppp\_app-proc\_guide\_doss\_reg-report-draft.zip\)](#) (this guidance is not required for AIR II substances).

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

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

### 3.6.1 General requirements are as follows:

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The application and documentation must include the following:

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

#### Documentation on CD

The application and documentation should meet the following criteria:

- Should be submitted on CD with 3 copies of each CD
- Preferably submission in Caddy.xml format
- When possible, using a maximum of 100 letters in the file directory (including the file name)

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

See [Appendix VII](#) for a recommended structure for the documentation.

- Northern Zone **Application form** in English and/or in the language of the relevant MS. The form is available at each authority's website.
- **Completeness check** scheme
- **Labels**
  - National labels in national languages
  - Master label in English containing a description of the use in the whole zone.

All labels should be submitted to the ZRMS.

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

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

Dossier content:

- Assessment based on adopted active substance endpoints.
  - Assessments based on guidance in place at dossier submission.
  - The sections of the dRR must be targeted and transparent.
  - Only information and data relevant for the concerned countries/Northern Zone should be presented.
- **GAP tables** – complete with all intended uses in the zone, which also appoints which use is relevant for which country. The GAP should cover the Northern Zone for zonal applications and the EU-countries for inter-zonal applications.
  - **Active substance dossier** (if not previously submitted) (incl. study reports) - in accordance with the requirements specified in regulation (EU) No 283/2013 (or (EU) No 545/2011 for AIRII substances).
  - **Individual test and study reports.** Further guidance on which data requirements that are applicable in a certain case can be found in EU Guidance document on the interpretation of the transitional measures for the data requirements for chemical active substances and plant protection products according to regulation (EU) no 283/2013 and regulation (EU) no 284/2013 (SANCO/11509 /2013–rev. 3).
  - **Justification** for new data submitted.

- 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 **using established** endpoints and by the application of the Uniform Principles is required. Where different or additional endpoints are proposed, these must be supported by appropriate data/information.

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

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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.

Within approximately 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 according to article 43

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#### 3.8.1 Updates and harmonization of the use of the products in connection with the renewals

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According to the EU guidance document regarding renewals of product authorisations pursuant to article 43, only already authorised uses in the individual Member States (MS) and amendments, resulting from changes in the evaluation of the active substance should be assessed for applications for renewal in accordance with article 43.

The Northern Zone will consider GAP changes in connection with the renewals if the following conditions are fulfilled:

1. Changes in uses fall within the Risk Envelope
2. Changes are covered by the efficacy and MRL data previously evaluated in the context of national authorizations
3. Minor formulation changes as defined in the EU guidance document for Minor Changes (NB Sweden do not accept this guidance document, please contact Swedish chemicals Agency for guidance).

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

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

### 3.8.2 Other issues to consider

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Changes in technical guidance documents and their implication for art. 43 renewals. Such as:

- Dermal absorption<sup>1</sup> and operator exposure guidance has recently changed – new assessments needed even though a.s. endpoints have not changed.
- Fate endpoints from LoEP for a.s. should be used – many will have changed due to new guidance – new PEC calculations will be needed.
- Aquatic guidance for higher tiers has recently changed.

Mutual recognition is not possible under art. 43. Authorisations that previously have been authorised through mutual recognition must be submitted as zonal applications for renewal.

### 3.8.3 Expiry dates

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If the active substance is prolonged on EU-level, then the products can be prolonged until the same date, plus 1 year (according to article 32). SE, LV, EE and FI will require a letter of intent from the applicant and will charge a fee. LT will require a letter of intent from the applicant, but will not charge a fee. NO and DK prolongs the authorisations automatically and does not charge a fee.

In case no application for renewal of an authorisation will be submitted, the product will expire at the date it has been extended to. Ordinary periods of grace for retail sale and use can be granted, according to Art. 46. If amendments of the product are such that the product will be considered as a new product, the old product will expire as explained above.

## 3.9 Renewal of Products containing more than one active substance

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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. In principle,

<sup>1</sup> It is our experience that a dermal absorption study with the product often needs to be performed, as the default values are more "conservative" in the current guidance.

products containing more than one active substance must be renewed for each active substance in accordance with Regulation 1107/2009. In accordance with the EU Guidance Document:

- If the second active substance expires within 12 months, the product renewal can be postponed until the deadline for the second a.s.
- Only one dossier needs to be submitted at the deadline of the second a.s.

If the product contains active substances that are not being renewed, the renewal will primarily be a re-evaluation of the active substance that is renewed. Thus, there should not be new/modified endpoints for the other active substances, new groundwater modelling etc. But on the other hand, there must be an up-to-date risk assessment following the guidance at the time of submission. For example, a cumulative risk assessment must be performed for endpoints where there are no product studies. This could mean that new PEC values are needed, if the PEC values have not previously been calculated in accordance with the Northern Zone Guidance Document.

### 3.10 Category 4 data

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

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

This justification should be sent to the appointed ZRMS together with the pre-notification. Before submission of the application there has to be an agreement between the ZRMS and the applicant if the data is considered as CAT 4 data, and when the data should be submitted. If no agreement has been reached, the CAT 4 data is per default not accepted. It is not possible to refer data gaps in the application to CAT 4 data after the submission of the application.

CAT 4 data will be discussed and decided upon by the Northern zone steering committee and the ZRMS informs the applicant of the decision.

Before the date of application for renewal (according to the renewal regulation), the applicant submit a formal application for renewal and should include.

- Cover letter
- List of CAT 4 studies to be submitted with the full dossier
- Indication of the time when the Cat. 4 studies will be finalised
- Indication of when the full dossier will be submitted (no later than 3 months after the final CAT 4 study is finalised)

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

### 3.11 Commenting procedures

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Concerned Member States of the zone should peer review the assessment made by the ZRMS focusing on areas having an impact on decision making, areas of concern pointed out in the inclusion regulation, and on new studies submitted to address data gaps identified in the review report or to cover data requirements for uses that have not been evaluated before. Comments should be submitted using the form in [Appendix II: Reporting table](#) and must be submitted before the agreed deadline (see timelines, 3.12) in order to be taken into consideration by the ZRMS. Bilateral discussions among experts during the evaluation are encouraged.

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

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

### 3.12 Decision making

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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 V: 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.

### 3.13 Timelines

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#### 3.13.1 Application for renewal of products (article 43)

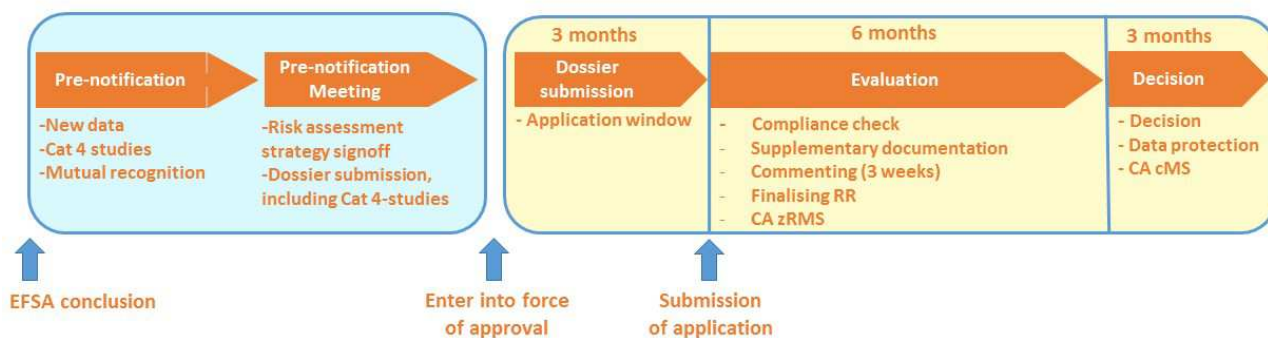
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Within 2 months following the publication of the EFSA conclusion, the authorisation holders must submit:

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

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

### SCHEME OF THE PROCESS FOR RE-AUTHORISATIONS



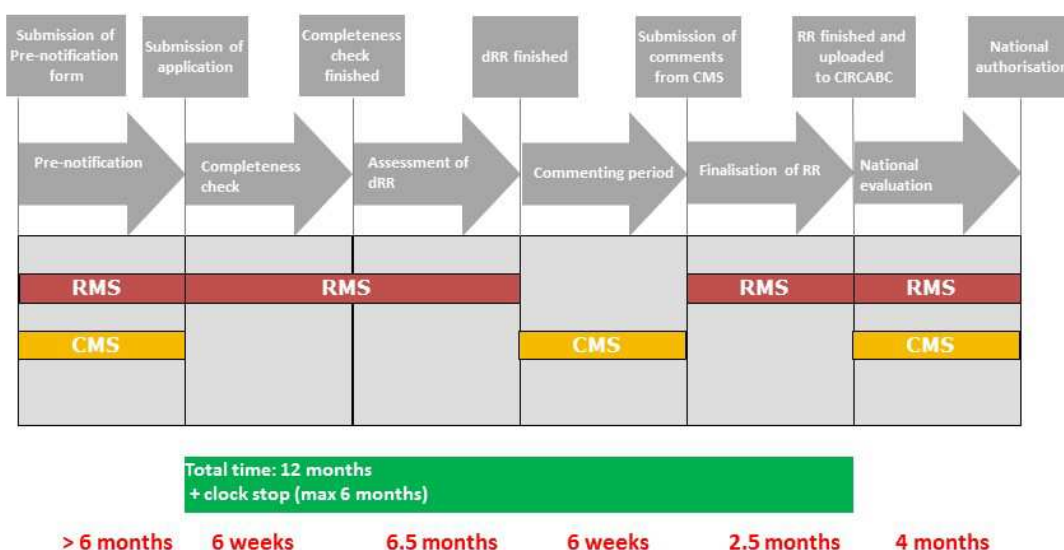
#### 3.13.2 New product authorisations

A decision on who will act as ZRMS will be taken based on proposed ZRMS by the applicant as well as available resources and priorities set in each 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 complete the application.

After the consultation period has expired, the ZRMS prepares a reporting table (see [Appendix II:](#)) with all received comments and the ZRMS response to the 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



### 3.14 Inter-zonal uses

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

### 3.15 Applications for mutual recognitions

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

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

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

### 3.16 Provisional authorisations

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

### 3.17 Withdrawal and amendment of authorisation based on zonal evaluations

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

## 4 Assessment

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Applicants are required to submit a full dossier according to the data requirements for products that is valid for the application (regulation 284/2013). In the format specified in the format of the draft registration Report – version 2015<sup>2</sup>.

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

- I. Applicants are required to prepare dossiers reflecting all intended uses in Northern zone.
- II. National data requirements concerning the specific problems in a country, as indicated in [Appendix IV: Summary of national requirements](#), have to be respected and data submitted for evaluation in the national addenda.
- III. An assessment should be conducted by applicants for the identification of worst case use(s)/scenarios following the risk envelope approach according to SANCO/11244/2011. Uses with similar characteristics

<sup>2</sup> 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.



can be assessed group-wise and that the risk assessment for different use groups can be simplified by focusing on the group with worst-case characteristics as a representative for other use groups.

Insofar, the concept requires:

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

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

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

Duplication of vertebrate studies shall not be accepted by MS according to Article 62 (2). Additionally, if other means exist (e.g. calculations) vertebrate studies shall not be accepted, even if they are generated for authorisation in a regulatory jurisdiction outside the EU.

#### 4.1 Identity, physical chemical properties and analytical methods

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

- Manual on development and use of FAO and WHO specifications for pesticides. First edition - third revision, Rome, March 2016.  
<http://apps.who.int/iris/bitstream/10665/246192/1/WHO-HTM-NTD-WHOPES-2016.4-eng.pdf?ua=1>
- The International Code of Conduct on Pesticide Management, FAO Rome and WHO Geneva 2014.  
<http://www.fao.org/agriculture/crops/thematic-sitemap/theme/pests/code/en/> / (March, 2015)
- United nations recommendations on the transport of dangerous goods (UN RTDG) manual of tests and criteria  
[http://www.unece.org/fileadmin/DAM/trans/danger/publi/manual/Rev4/English/01E\\_intro.pdf](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<sup>th</sup> July 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis.
- SANCO/825/2000, rev. 8.1, 16<sup>th</sup> of November 2010, Guidance document on pesticide residue analytical methods.
- Guidance document on the finalization of the reference specification for technical active substances after peer review (SANCO 6075/2009, rev.3, July 2009).
- Guidance document on Pesticide Residue analytical methods (Series on Pesticides, No.39, Series on Testing and Assessment; No.72; OECD 2007).
- Chemicals Regulation Directorate DATA REQUIREMENTS HANDBOOK  
<http://webarchive.nationalarchives.gov.uk/20151023155227/http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook>. A new EU guidance document based on this document is under development.

- EU Guidance document on the assessment of the equivalence of technical materials (SANCO 10597/2003, rev. 10.1, 13<sup>th</sup> of July 2012).
- Guidance document on significant and non-significant formulation changes SANCO 12638/2011, 20<sup>th</sup> November 2012<sup>3</sup>

Some of the guidance documents listed above are available on the EU Commission website [http://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/guidance\\_documents\\_en](http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)

#### 4.1.1 Identity of the plant protection product

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

The identity and content of safeners, synergists and co-formulants shall be given. For co-formulants, which are mixtures, the detailed complete composition shall be provided. If the applicant does not have access to proprietary data of the co-formulants, then the applicant must contact the supplier and ask them to submit the data directly to the competent authority. The competent authorities will treat this information as strictly confidential. The trade name, where available, shall also be provided in part C of the dRR.

Suggested alternative co-formulants (e.g. from different suppliers), if any, shall be included in the application. They must be identical<sup>4</sup> and detailed composition for each alternative co-formulant must be submitted to MS for equivalence assessment. If the applicant wants to add an alternative co-formulant at a later time, an application must be submitted for the alternative co-formulant to be assessed by the competent authorities and an updated Part C must be provided.

With regard to formulation changes, it is up to the MS in question to decide whether a formulation change is significant or non-significant. MS assessment will be performed by comparing the new formulation to the formulation for which a complete risk assessment was performed.

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

#### 4.1.2 Physical, chemical and technical properties of the plant protection product

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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.

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<sup>3</sup> Not accepted in SE and NO. Formulation changes will be assessed on a case-by-case basis.

<sup>4</sup> Only very small insignificant differences can be accepted.

An adjuvant can have a great influence on the physical and chemical properties of the formulation, especially technical characteristics. If the formulation is claimed to be used with an adjuvant then the physical-chemical properties are requested for the product mixed with the adjuvant in question.

Storage stability test at elevated temperature is always required independent of whether a 2-year storage stability test at ambient temperatures is available. The 2 year shelf life study should be carried out in the same material as the commercial packaging, and the final results of the study must be available before the authorisation is granted. Where appropriate, data on the content of relevant impurities, before and after storage, shall be provided. If theoretically a relevant impurity could be formed during storage, then its content should be determined before and after storage (accelerated and shelf-life studies). If it could not be formed during storage, then determination of its content is not required before and after storage. In cases where the relevant impurity cannot be formed upon storage, then a justification for not submitting data on the content of the relevant impurity in the formulated product shall be provided. However, a validated analytical method for the determination of the relevant impurity in the formulation is required.

If tank mixing is recommended on the label the physical compatibility should be demonstrated, by ASTM E1518-05 method or equivalent, and reported. Alternatively, the acceptability of tank mixing may be based on evidence from a relevant field study evaluated in efficacy section of the dRR (see also section 4.4 of this guidance). Known non-compatibility shall be reported.

#### 4.1.3 Methods of analysis

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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.

Study summaries shall be provided for all analytical methods and study reports of the methods relevant for the application shall be provided. This is applicable to the methods for:

- the analysis of the formulation;
- residue determination in food/feed of plant and animal origin;
- residue determination in the environmental matrices and body fluids and tissues.

If the method has previously been 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.

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

## 4.2 Toxicology

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

- SANCO/10328/2004-rev 8 (24.01.2012). Guidance Document on the Evaluation of New Active Substance Data Post Approval

- SANCO/221/2000 –rev.10, 25 February 2003. Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC
- EFSA Panel on Plant Protection Products and their Residues (PPR), 2012. Guidance on Dermal Absorption, EFSA Journal 2012; 10(4):2665
- SANCO/12638/2011. Guidance document on significant and non-significant changes of the chemical composition of authorised plant protection products under Regulation (EC) NO 1107/2009 of the EU Parliament and Council on placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC<sup>5</sup>
- EFSA (European Food Safety Authority), 2014. Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA Journal 2014; 12(10):3874, 55 pp., doi: 10.2903/j.efsa.2014.3874. (referred to as EFSA OPEX GD). The implementation schedule and applicability of this Guidance should follow SANTE-10832-2015 revised version 1.7, 27 January 2017.

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

#### 4.2.1 Acute Toxicity

If the PPP applied for has been considered in the EU peer review process of the active compounds it is not necessary to include a study summary in the dRR for evaluation. However, study summaries must be submitted if the toxicological classification (for any of the acute toxicity endpoints that are included in the data requirements) for the PPP was not according to CLP (Reg. 1272/2008). Likewise, if the study was evaluated according to previous data requirements that do not apply anymore.

Until ongoing discussions in the EU and the NZ are finalised acute inhalation toxicity should always be addressed if the product in any state is to be sprayed.

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

The replacement of a study with an alternative approach under the CLP Regulation requires, according to the data requirements, that the specific toxicity of all components should be provided or reliably predicted. This must be demonstrated by the applicant.

#### 4.2.2 Exposure Assessment

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

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

For products containing more than one active substance, cumulative risk assessment of operator/worker/bystander/resident exposure should be conducted. In the first tier, combined exposure is

<sup>5</sup> SANCO/12638/2011 is not accepted in SE. Formulation changes will be assessed on a case by case basis.

calculated as the sum of the component exposures (as % of the AOELs) without regard to the mode of action or mechanism/target of toxicity. Further refinement of the cumulative risk assessment is needed if the sum of the predicted exposure as % of the AOELs exceeds 100 % (i.e. exceeds 1 of the Hazard Index). Such refinements should be justified taking into consideration:

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

According to Regulation (EC) No 1107/2009 safeners, synergists, and adjuvants<sup>6</sup> shall be included in the risk assessment. Until detailed rules and the date of application are established, a hazard assessment using the Safety Data Sheets (SDS) should be performed.

Member States do not have the resources to evaluate new models. Applicants are therefore advised to use the models that are specified in this guidance document. Also the Applicants are encouraged to share new models and results from field studies with EFSA/COM in order to facilitate the development and harmonisation of exposure models.

Relevant approaches developed by EFSA should be applied when available.

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

#### 4.2.2.1 Operator Exposure

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The following exposure models are acceptable:

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

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

With regard to EFSA Guidance Exposure Calculator:

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

Initially, the assessment shall be made with the assumption that the operator is not using any PPE. However, regular workwear (as defined in the EFSA OPEX GD) is assumed. See Table 4.2.2.5-1 for an overview of the tiered approach, use of PPE and other risk mitigation measures applicable in the NZ.

Acute risk assessment for operator exposure is possible only when the AAOEL values for active substances are derived by EFSA and MS during the peer review, unless guidance on setting an AAOEL has been adopted by the Standing Committee on Plants, Animals, Food and Feed (SCPAFF).

#### 4.2.2.2 Non-professional user

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The following exposure models are acceptable:

- UK POEM

<sup>6</sup> See Appendix IV for national requirements for Norway on adjuvants.

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

The assessment of products for home & garden use should consider the type of formulation, condition/location of use, method of application, type and size of container. The choice of exposure model should be justified in the dRR and will be evaluated on a case by case basis. A product applied both upward and downward outdoor should be assessed according to both the German and UK POEM model. Relevant tiered approach to exposure evaluation should follow table 4.2.3.2-1. The use of personal protective equipment to reduce exposure to an allowable level is not acceptable for non-professionals because of the risk of inappropriate handling due to lack of knowledge in this group. It should be noted that user conditions of higher tier exposure assessments might affect the user conditions stipulated in the national product authorization.

**Table 4.2.2-1. Models and input values for a tiered exposure assessment of home & garden users**

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

<sup>a</sup> FI will assess 2<sup>nd</sup> tier on a case by case basis

<sup>b</sup> default value

<sup>c</sup> default work rate is ~0.01 ha/day

#### 4.2.2.3 Worker Exposure

The following exposure calculations and input parameters are acceptable:

- EFSA GD Exposure Calculator (latest version) to both outdoor and indoor scenarios
- Seed Tropex model - sowing

#### Dissipation of the active substance on the foliage

A default dissipation half-life of 30 days should be used for organic substances only if no DT<sub>50</sub> value or half-life data representative of the supported use(s) are reported.

### Dislodgeable foliar residues (DFR)

If data on the amount of dislodgeable foliar residues (DFR) under the proposed conditions of use are not available, default assumption (3 µg a.s./cm<sup>2</sup> of foliage/kg a.s. applied/ha;) shall be used.

Experimental data on DFR can be included, if **all of the following is fulfilled:**

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

Data from a DFR study could provide a basis for the selection of protective measure as re-entry/waiting period (in hours or days). However, acceptability of a re-entry/waiting period for particular PPP is decided on by each MS<sup>7</sup>.

### Transfer coefficient (TC)

At first, the assessment shall be made using available data with the assumption that the worker is not using any PPE: normal work clothing/workwear (coveralls or long sleeved jacket and trousers) is assumed. Further refinement using gloves (PPE) is needed if the predicted exposure exceeds the AOEL. Each MS decides on appropriateness of using gloves as a refinement of exposure assessment (see Table 4.2.2.5-1).

#### 4.2.2.4 Bystander & Resident Exposure

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

- **as a Tier I EFSA GD Exposure Calculator** (latest version) for resident. For PPPs with no potential acute systemic toxicity the longer term risk assessment for bystander is covered by the risk assessment for resident. If the estimated resident exposure (all pathways (mean)<sup>8</sup>) exceeds the AOEL no higher tier risk refinements are available, unless increasing of buffer zones and the use of drift-reducing nozzles could be considered. These risk mitigation measures may be accepted by some MS.
- When no safe use can be identified for resident (and for bystander simultaneously) EUROPOEM II Bystander Exposure to Pesticides<sup>9</sup> for bystander and German Guidance (Martin et al.<sup>10</sup>) for resident may be considered by some MS<sup>11</sup> using 60 min duration of exposure for EUROPOEM II and the other values as suggested for the respective model.

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

A risk assessment for recreational residence is necessary for an application of a PPP on golf course, turf, other sports lawns or amenity turf/grassland areas where member of the public are likely to have ac-

<sup>7</sup> See Appendix IV for National requirements and Appendix V for mitigation options available in the member states in the zone.

<sup>8</sup> **All pathways may not always be relevant**

<sup>9</sup> Bystander exposure to Pesticides – Report of the Bystander working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002

<sup>10</sup> 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.

<sup>11</sup> These models are not accepted in Denmark

cess<sup>12,13</sup>. Additionally, for an application of a PPP on golf course, turf, lawns, grassland etc. an assessment of re-entry/waiting periods has to be submitted in the core dRR. However, acceptability of a re-entry/waiting period will be decided on by each MS.

#### 4.2.2.5 Risk mitigation measures

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

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

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

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<sup>12</sup> See Appendix IV for restrictions in Norway for the use of PPPs on areas accessible for the public.

<sup>13</sup> In the EFSA GD Exposure Calculator choose golf course, turf and other sports lawns to assess the risk of recreational residence.



Table 4.2.2.5-1: NZ approach of choosing PPE and other risk mitigating measures in the EFSA calculator.

	DK	NO	SE	FI	LT	LV	EE	Harmonized
<b>Operator</b>								
Tiered approach Workwear (mix/load+appl) + 1. No PPE 2. Gloves mix/load 3. Gloves mix/load + appl	Y	Y	Y	Y	Y	Y	Y	Y
RPE	Y	Y	Y	Y	Y	Y	Y	Y
Head covered	Y	Y	Y	Y	Y	Y	Y	Y
Closed cab	Y	N	Y	N	Y	Y	Y	N
Other measures (DRE=drift reducing equipment)	Y (DRE expected from medio 2017)	N	Y	Y	N	Y**	N	N
<b>Residents/ bystanders</b>								
Buffer strip	Y	N	Y	N	Y*	Y	Y	N
Drift reducing equipment	Y (expected from medio 2017)	N	Y	Y	N	Y	N	N
Both buffer strip + drift red.	Y (expected from medio 2017)	N	Y	N	N	Y**	N	N
<b>Workers</b>								
<b>Greenhouse</b>								
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear + 1. No PPE 2. Gloves	Y	Y	Y	Y	Y	Y	Y	Y
Re-entry period	Y	Y	Y	CbC***	Y	Y	Y	N
<b>Field use</b>								
Workwear	Y	Y	Y	Y	Y	Y	Y	Y
Tiered approach. Workwear + 1. No PPE 2. Gloves	N****	Y	N****	Y	Y	Y	Y	N
Re-entry period	CbC***	Y	N	CbC***	Y	N	Y	N

\*Under discussion, not yet based on legislation, may be partly accepted, \*\*Experience is needed before changing legislation, \*\*\*Case by case \*\*\*\* Gloves will be accepted case by case.

### 4.2.3 Dermal Absorption

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

If the dermal absorption study is performed on another similar product, a scientifically based bridging statement should be included in the dRR. The bridging statement should include a comparison of the composition of the two products and also take into consideration a possible difference in the dilution rates. The

criteria for when two formulations can be considered similar are listed in the latest Guidance on Dermal Absorption.

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

**New dermal absorption studies should preferably be conducted using human skin in vitro.**

#### 4.2.4 Assessment of the relevance of metabolites in groundwater

A metabolite is considered to be of concern when the concentration is above 0.1 µg/L. In some cases the Northern Zone FOCUS scenarios may predict higher concentrations of groundwater metabolites than the EU FOCUS scenarios. An assessment of the relevance of metabolites of concern in groundwater should be included in the core assessment if the metabolite has not been assessed during the EU evaluation.

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

### 4.3 Residues

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

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

The following guidance documents should be used for the core assessment for the northern zone in accordance with Commission Communication in the framework of the implementation of Commission regulation (EU) No 283/203 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ, C95/1):

- OECD (2009). Guidance Document on Overview of Residue Chemistry Studies (as revised in 2009). Environment, Health and Safety Publications. Series on Testing and Assessment No. 64 and Series on Pesticides No. 32
- OECD (2011) Guidance Document on Crop Field Trials (Series on Testing and Assessment No. 164 and Series on Pesticides No. 66)
- OECD (2008). Guidance document on magnitude of pesticide residues in processed commodities. Environment, Health and Safety Publications. Series on Testing and Assessment No. 96.
- OECD (2009). Guidance Document on the Definition of Residues. Environment, Health and Safety Publications. Series on Testing and Assessment No. 63 and Series on Pesticides No. 31
- SANCO/7525/VI/95 rev. 10.1 December 2015. Appendix D – Comparability, extrapolation, group tolerance and data requirements
- SANCO/7039/VI/95 EN. 22 July 1997. Appendix I – Calculation of maximum residue levels and safety intervals
- OECD MRL calculator (2011)
- SANCO/11187/2013 rev. 3. 31 January 2013. Appendix J – Nature of pesticide residues in fish

- SANCO/3029/99 EU, rev.4, 11 July 2000- Residues: Guidance for generating and reporting methods of analysis in support of pre-registration data requirements
- SANCO/825/00 EU, rev. 8.1, November 2010, Guidance document on pesticide residue analytical methods (post-registration monitoring and control)
- OECD (2007). Guidance Document on Pesticide Residue Analytical Methods. Environment, Health and Safety Publications. Series on Testing and Assessment No. 7 and Series on Pesticides No. 39
- OECD TEST GUIDELINES No. 501, 502, 503, 504, 506, 507, 508, 509

Specific national requirements are specified for each country in [Appendix IV: Summary of national requirements](#).

#### 4.3.1 Stability of residues

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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

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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)

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Supervised field trials from Northern residue zone, defined in guidance document SANCO/7525/VI/95, should be used. Insert at least a brief summary of residue trials for all uses (e.g. summary schemes) including,

- Report No. and Location including Postal Code
- Commodity/Variety
- Date of 1. Sowing or Planting, 2. Flowering, 3. Harvest
- Application rate per treatment (g as/hl & water l/ha & g as/ha)
- Method of treatment
- Dates of treatment(s) or no of treatment(s) and last date
- Spray interval (days)
- Growth stage at last treatment or date
- Portion analyzed
- Residues (mg/kg)
- PHI (days)
- Remarks

Include also a statement of the validity of the analytical methods used and explain extrapolation between crops (according to the guidance document SANCO/7525/VI/95 rev. 10.1, 01 December 2015). Indicate if the methods include analysis of all substances included in the residue definition for both monitoring and risk assessment.

#### 4.3.4 Livestock feeding studies

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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

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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

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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

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

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

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

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

A chronic dietary exposure should be evaluated by calculation of the theoretical maximum daily intake (TMDI) using EFSA model (PRIMo rev 2.0) using all existing MRL values. If these calculations result in an ADI exceedance, refinements should be done using supervised trial median residue (STMR) values from the supervised residue trials. Further refinements could sometimes be relevant.

A short term intake calculation should also be performed using the EFSA model (PRIMo rev 2.0 or later) based on the MRL values for the crops included in the application. If the calculations result in an ARfD exceedance, refinements could be done using highest residues (HR) from the supervised residue trials. When estimating the short term dietary exposure STMR values should not be used.

In case new national data are to be employed for the NESTI and NEDI assessments, such national requirements shall be specified for each country in [Appendix IV: Summary of national requirements](#) .

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

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The rules for comparability, extrapolation, group tolerance and data requirements for pesticides residues in food and raw agricultural commodities, described in guidance document SANCO/7525/VI/95 rev. 10.1, 01 December 2015., should be used.

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

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

The extrapolation rules apply also for establishing of the non-residue situation (guidance document SANCO/7525/VI/95 rev. 10.1, 01 December 2015).

#### 4.3.9 Residue issues related to renewal of products (article 43)

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

### 4.4 Efficacy

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The guidance for the efficacy section is available at

<http://agro.au.dk/en/public-sector-consultancy/guidance-on-requirements-for-efficacy-data/>

Specific national requirements are specified for each country in [Appendix IV: Summary of national requirements](#).

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

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1. Applicants are strongly encouraged to submit a BAD. Trial reports should be submitted and if a BAD is not submitted, the applicant is obliged to provide information on the origin of the data summarized in the various tables/figures of the dRR. The dRR should be a concise summary of the BAD and if a BAD is not submitted a concise summary of the supporting data. A dRR with all sections must be submitted.
2. The applicants can ask for label extension but only for uses already authorized in at least one of the countries in the Northern zone.
3. The applicants are required to provide an overview of the current authorizations in the Northern zone either as a table inserted in the dRR or by providing the current GAP tables (in English) for each of the concerned countries in the zone. Labels in local language are not sufficient documentation.
4. The countries in the Northern zone belong to two EPPO zones (Maritime and North-East) and if the applicant applies for authorization in both zones, efficacy data from both zones should be submitted. However, as mentioned in the EPPO Standard P1/241 Guidance on Comparable Climate *'data from other zones may in any case be considered acceptable if the actual prevailing*

*conditions are comparable*'. It is up to the applicant to justify that data from one EPPO zone is acceptable for registration in the other EPPO zone. Data from other zones than the Maritime and the North-East zone should not be included in the dRR.

5. Dose extrapolation of +/- 10% are accepted without further justification. Other extrapolations should be justified in the dRR. Concerning extrapolation between pest species and crops, the applicant should consult the Guidance on requirements for efficacy data for zonal evaluation of a plant protection product in the Northern Zone.
6. If the active ingredient is candidate for substitution, the starting point for Comparative Assessment (CA) is efficacy. CA is a national issue and not a zonal issue and the data/justification for maintaining the product on the market should be included in the National Addenda, and not in the core assessment.

#### 4.5 Environmental Fate and Behaviour

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##### **Disclaimer:**

1. *This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases specific national guidance must be consulted additionally. Specific national requirements are presented in [Appendix IV: Summary of national requirements](#).*
2. EU-guidance documents should be followed from the implementation date of the specific guidance document. Any deviations from the EU-guidance that is stated in the NZ guidance document should be followed from the implementation date of the NZ guidance document.

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

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

- SANCO/221/2000 rev.10 (final). 25 February 2003. Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC<sup>14</sup>.
- Generic Guidance for Estimating Persistence and Degradation Kinetics from Environmental Fate Studies in Pesticides in EU Registration (version 1.1, 18 December 2014): Based on the official guidance document of FOCUS Degradation Kinetics in the context of 91/414/EEC and Regulation (EC) No 1107/2009, SANCO/10058/2005 version 2.0 (final). June 2006.
- Generic Guidance for Surface Water Scenarios (version 1.4, May 2015): Based on official guidance document of FOCUS Surface Water Scenarios in the context of 91/414/EEC and Regulation (EC) No 1107/2009, SANCO/4802/2001 rev.2 (final), version 1.4, May 2015.
- SANCO/321/2000 rev.2. November 2000. FOCUS groundwater scenarios in the EU review of active substances.
- Generic Guidance for Tier 1 FOCUS Ground Water Assessments (version 2.2, May 2014): Based on the reports of the FOCUS Groundwater Scenarios workgroup (finalised in 2000), the FOCUS Ground Water Work Group (as noted in 2014) and the FOCUS Work Group on Degradation Kinetics (finalised in 2009) as modified by EFSA DegT<sub>50</sub> 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, LV, NO, SE.*

<sup>14</sup> Note that this guidance is not accepted by DK (see Appendix IV). For the assessment of groundwater exposure in DK, please see the Danish national guidance document.

- EFSA Journal 2014; 12(5):3662. EFSA Guidance Document for evaluating laboratory and field dissipation studies to obtain DegT<sub>50</sub> values of active substances of plant protection products and transformation products of these active substances in soil<sup>15</sup>.
- Guidance document on clustering and ranking of emissions of plant protection products and transformation products of these active substances from protected crops (greenhouses and crops grown under cover) to relevant environmental compartments, SANCO/12184/2014 rev. 5 (27 January 2015).
- Guidance document on the preparation and submission of dossiers for plant protection products according to the “risk envelope approach”, SANCO/11244/2011 rev. 5 (14 March 2011).

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

- For **non-professional use** (home gardens), substantial differences exist between the Member States (see Appendix IV). Exposure estimations are case-by-case decisions.
- The interpretation of the acceptability/representativeness of a field study for the specific agricultural landscape and protection goals should be done for each country since climatic and soil conditions vary and **field data** might not be valid/representative for all Member States.
- The **risk envelope** approach is acceptable for calculation of PEC<sub>soil</sub>. PEC<sub>gw</sub> and PEC<sub>sw</sub> modelling is more complex. The risk envelope approach may only be used in cases where the worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised should be modelled.
- For **granulates**, the interception shall be set to 0 % for PEC calculations for all crops.

#### 4.5.1 Soil

Only PEC<sub>max (1st season)</sub><sup>16</sup>, PEC<sub>21 dayTWA</sub>, PEC<sub>acc</sub><sup>17</sup> and PEC<sub>plateau</sub> should be reported and used in risk assessments. In some MS of the Northern Zone, other PEC<sub>TWA</sub> 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<sub>50</sub>field (non-normalized) should be applied. If no representative field data are available a worst case DT<sub>50</sub>lab (normalized) should be used.

**FI:** See specific national requirement in [Appendix IV](#).

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 follow the [EFSA GD \(2014\) on DegT<sub>50</sub>](#) for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil.

PEC<sub>soil</sub> for metabolites should be calculated as parent compounds with a dose corrected for molecular weight and maximum observed % AR.

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

<sup>15</sup> This guidance should be used for all a.s. which have been evaluated at the EU level after this guidance entered into force. It may be used for other a.s. if this is the only way of demonstrating safe use. That means, recalculation of existing LoEP data on DT<sub>50</sub> and Koc according to the guidance will not be required. Please note the new interception values, which should be used for all submissions.

<sup>16</sup> PEC<sub>max (1st season)</sub>: maximum PEC<sub>soil</sub> in the first season taking into account all applications = PEC<sub>ini</sub> in the Finnish PEC<sub>soil</sub> calculator.

<sup>17</sup> PEC<sub>acc</sub>: the highest concentration during a period of 20 years including all applications from the last year

The Nordic PECsoil calculator (tool and user manual available at <http://www.kemi.se/en/directly-to/pesticides/application-guide/plant-protection-products/application-forms-and-guidance-documents-for-plant-protection-products>) shall be used for the Northern Zone core assessment. In the core assessment, a screen shot of the user interface showing all results and inputs for the parent and all metabolites shall be presented. Only the results from the Finnish temperature scenario, which is pre-implemented into the PECsoil calculator, are accepted.

The Finnish PECsoil-calculator (available at <http://www.tukes.fi/pecsoilcalculator>) can still be used, but it is recommended to use the new Nordic PEC calculator.

#### **Nordic PEC<sub>soil</sub>-calculator:**

The Nordic PEC<sub>soil</sub> calculator permits to use SFO or DFOP kinetics for the worst-case DT<sub>50</sub>. If the worst-case DT<sub>50</sub> is derived with FOMC-kinetics, a pseudo-SFO degradation rate may be applied. PEC<sub>plateau</sub> can be calculated for applications every year, every 2<sup>nd</sup> or every 3<sup>rd</sup> year. Please see table 4.5.2-4 for possible crop rotations periods in years for each member state. The calculator permits for adjustment of the mixing depth (5-20 cm) according to tilling practice for the crop. The last year mixing depth must however always be set to 5 cm.

#### **National cut-off criteria:**

**DK:** For approval, DT<sub>50</sub> for both the active substance and some metabolites must be < 180 days. Please consult the latest version of Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off: <http://eng.mst.dk/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 DT<sub>50lab</sub> (normalised) in soil of more than 100 days will not be authorised for outdoor use.

### 4.5.2 Ground water

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted. Only substance specific parameters can be changed. The latest FOCUS models available at the time of submission have to be used in PEC calculations.

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

The risk envelope approach may only be used in cases where the worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised should be modelled. When a crop is not parameterised in any of the relevant scenario(s), the user should select a crop resembling the intended crop based on expert judgement. The choice of crop should be justified. In addition to the summary in the dRR, the modelling report with representative files should always be provided in document K. Other output files shall be made available when requested from the regulatory authority.

If K<sub>oc</sub> and/or DT<sub>50</sub> are pH dependent, the data representative for the pH range of soils in the concerned member states (see Table 4.5.2-1) should be used for calculation of appropriate input values for the groundwater simulations<sup>18</sup>. In cases where both acidic and alkaline conditions are relevant for a MS, please

<sup>18</sup> Latvian requirement: the PEC gw for both acidic and alkaline conditions should be presented initially; if acidic soils do not represent the worst case leaching conditions (parent and/or metabolites), the whole data set (acidic and alkaline merged) can be used.



consider that the worst case-conditions for metabolites can be different from the worst case conditions for parent compounds or precursors.

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

Country	Soils pH		Further comments
	Acidic (<7)	Alkaline (>7)	
Denmark	yes		Most Danish agricultural soils have pH < 7, only a few have pH >7
Estonia	yes		Most Estonian agricultural soils have pH of 4.5 – 7, only a few have pH >7
Sweden	yes	yes	Wide range of pH. Swedish arable land: minimum 4.2 and maximum 8.7
Norway	Yes		Most Norwegian agricultural soils have a pH of 5 – 7.
Lithuania	yes	yes	Arable land pH (H <sub>2</sub> O): minimum 4 and maximum 8.2.
Latvia	yes		Most Latvian agricultural soils have a pH of 4.5 - 7
Finland	yes		Finnish agricultural soils have pH 5 – 7. Risk assessment for acidic soils should be provided

Modelling endpoints in accordance with the FOCUS degradation kinetics report should be used. All input values used for the simulations have to be reported. Field DT<sub>50</sub> values used as model input need to follow EFSA GD on DegT<sub>50</sub> (2014).

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

Table 4.5.2-2 National requirements for PECgw simulations. The newest model version should always be used, unless otherwise specified.

MS	Tier I - PELMO	Tier II – simulations with MACRO <sup>19</sup>			
		Triggered when	The following scenarios shall be used	Comment to MACRO assessment	Evaluation of MACRO results
SE and NO	FOCUS PELMO: Hamburg	<p>a.s./relevant metabolites/non-assessed metabolites<sup>20</sup> &gt; 0.001 µg/L</p> <p>Non-relevant metabolites evaluated up to step 5 in EU assessment &gt; 0.1 µg/L</p> <p>Non-relevant metabolites evaluated up to step 4 in EU assessment &gt; 0.0075 µg/L</p> <p>Risk of leaching to GW is listed as an area of concern in the EU review report</p>	<p>Krusenberg</p> <p>Önnestad</p> <p>Näsbygård<sup>21</sup></p> <p>Rustad<sup>22</sup></p>	<p>If MACRO-simulations are triggered for the parent substance, all (relevant and non-relevant) metabolites have to be simulated with MACRO. Non-relevant metabolites cannot be excluded.</p>	<p>a.s./relevant metabolites &lt; 0.1 µg/L → ok</p> <p>Non-relevant metabolites evaluated up to step 5 in EU assessment &lt; 10 µg/L → ok</p> <p>Non-relevant metabolites evaluated up to step 4 in EU assessment &lt; 0.75 µg/L → ok</p> <p>Non-relevant metabolites evaluated up to step 4 in EU assessment ≥ 0.75 µg/L and &lt; 10 µg/L → Step 5 of relevance assessment needed</p>
MS	Tier I - PELMO	Tier II - simulations with MACRO 4.4.2 or 5.5.3 (Karup and Langvad) or PELMO (Hamburg) with specified input/output			
		Triggered when	MS specific comment		Evaluation of MACRO/PELMO results
DK	FOCUS PELMO: Hamburg	a.s./any metabolite > 0.001 µg/L	<p>As input the following shall be used: 80<sup>th</sup> percentile for the degradation (not geomean DT<sub>50</sub>), 20<sup>th</sup> percentile for K<sub>loc</sub> and 80<sup>th</sup> percentile for 1/n (not arithmetic mean) and number of years that exceed 0.1 µg/L out of 20 years as output (not 80<sup>th</sup> percentile). All metabolites need to be covered by the assessment. Further guidance available at <a href="http://www.mst.dk">www.mst.dk</a></p>		<p>a.s./all metabolites &lt; 0.1 µg/L → ok</p> <p>Only 1 year out of 20 may exceed 0.1 µg/L. In some cases, and after evaluation by DEPA (see the Danish national guidance) some metabolites may be accepted at concentrations up to 0.75 µg/L.</p>
MS	Tier I – PEARL or PELMO	Tier II – simulations with PEARL or PELMO (Hamburg)			
		Triggered when	MS specific comment		Evaluation of PEARL/PELMO results
LT	FOCUS PEARL or PELMO: Hamburg	Risk of leaching to groundwater is listed as an area of concern in the EU review report	<p>As input the following shall be used: 80<sup>th</sup> percentile for the degradation (not geomean DT<sub>50</sub>), 20<sup>th</sup> percentile for K<sub>loc</sub> (not mean) and 80<sup>th</sup> percentile of output. If a product is applied in DK with the same GAP, modelling as required by DK is sufficient for LT as well.</p>		<p>a.s./relevant metabolites &lt; 0.1 µg/L → ok</p> <p>Non-relevant metabolites evaluated up to</p>

<sup>19</sup> Information about the different versions of the MACRO model and their bugs is available at: <http://esdac.jrc.ec.europa.eu/projects/macro>.

<sup>20</sup> Metabolites which have not been assessed as being relevant or non-relevant at EU-level since the PECgw of the metabolites was < 0.1 µg/L in the EU-assessment.

<sup>21</sup> For Näsbygård, several simulations with different application dates are required if the K<sub>oc</sub> < 500 L/kg and the DT<sub>50,soil</sub> < 50 days (modelling endpoint). The simulations shall cover the earliest and latest possible treatment period applied for in relation to the GAP BBCH window. The treatment period is defined by the maximum number of applications (≥ 1) and the minimum number of days between each application. If the time between the first and the last treatment period is more than 40 days, at least one additional treatment period “in between” shall be simulated. The time between the starting dates of the treatment periods in each simulation must not exceed 30 days. In those cases only a single simulation is required, the starting date of the simulated treatment period has to be chosen to represent a worst case situation regarding contamination of groundwater.

<sup>22</sup> Rustad is only required for Norway. Relevant files and background information is available at [www.mattilsynet.no](http://www.mattilsynet.no) or on request.

MS	Tier I – PEARL or PELMO	step 5 in EU assessment < 10 µg/L → ok
FI <sup>23</sup>	FOCUS PEARL or PELMO: Hamburg and Jokioinen	Non-relevant metabolites evaluated up to step 4 in EU assessment < 0.75 µg/L → ok
LV		
EE		Non-relevant metabolites evaluated up to step 4 in EU assessment ≥ 0.75 µg/L and < 10 µg/L → Step 5 of relevance assessment needed

<sup>23</sup> See the criteria for the restriction on the use of the product on the classified ground water areas in Appendix V.

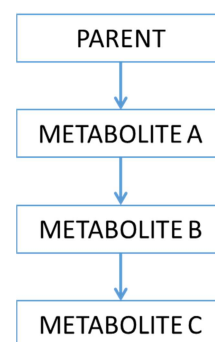
### General guidance on simulating PECgw for metabolites in MACRO:

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

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

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

A. PARENT → METABOLITE A	
Applied dose	Dose parent x (1-i)
Conversion factor	$ff_{met A} \times (Mw_{met A} / Mw_{par})$
Use results from	Parent and metabolite A
B. METABOLITE A → METABOLITE B	
Applied dose	Dose parent x (1-i) x $ff_{met A} \times (Mw_{met A} / Mw_{par})$
Conversion factor	$ff_{met B} \times (Mw_{met B} / Mw_{met A})$
Use results from	Only metabolite B
C. METABOLITE B → METABOLITE C	
Applied dose	Dose parent x (1-i) x $ff_{met A} \times ff_{met B} \times (Mw_{met B} / Mw_{par})$
Conversion factor	$ff_{met C} \times (Mw_{met C} / Mw_{met B})$
Use results from	Only metabolite C



$ff$  = formation fraction,  $Mw$  = molecular weight,  $met$  = metabolite,  $par$  = parent,  $i$  = plant interception

*If no reliable true degradation or formation fraction data are available:*

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

Applied dose: dose parent x (1-interception) x max observed x ( $Mw_{met} / Mw_{par}$ )

### Presentation of results from PECgw model simulations:

The documentation must be well structured and transparent in order to demonstrate which models and scenarios that have been used for each country. An example of a summary table is given in Table 4.5.2-3.

**Table 4.5.2-3 Example of summary table for the PECgw results**

Country	PECgw (80 <sup>th</sup> /95 <sup>th</sup> percentile)		
	Compound	PECgw	model & scenario

If one or both of the limit values (0.1 µg/L for each individual substance<sup>24</sup> and 0.5 µg/L for the sum of substances<sup>25</sup>) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. lysimeter studies, field studies, and/or monitoring data<sup>26</sup>) convincingly demonstrate that unacceptable leaching will not occur in a Northern Zone context. When evaluating such studies, consideration must be given to whether soil properties, climate conditions and application (crops, vegetation cover, application method, formulation of the product, dose and time of application) correspond to Northern Zone conditions. Metabolites for which the PEC<sub>gw</sub> exceeds 10 µg/L are not covered by the “non-relevance-approach” in the guidance document on the assessment of the relevance of metabolites in groundwater<sup>27</sup>. This is the official policy in the following Northern zone member states; EE, FI, LT, LV, NO, SE.

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

**Table 4.5.2-4 Possible crop rotation period in years (for cells left blank an argumentation is required)**

Crop	Country						
	Denmark	Estonia	Finland	Latvia	Lithuania	Norway	Sweden
Potatoes	4		1/3***	2-3	4	1/3*	
Sugar beets	3		1	2-3	4	-	
Winter cereals	1		1	2-3	1	1	
Beans	4		3	2-3	4	6**	
Cabbage	1		1/3*	2-3		1	
Carrots	1		1/3*	2-3		1	
Linseed	1		1	2-3		-	
Maize	1		-	2-3	3	-	
Spring OSR	4		4	2-3	2-3	6	
Winter OSR	4		4	2-3	2-3	6	
Onions	1		1/5*	2-3		4	
Peas	4		5	2-3	4	4	
Spring cereals	1		1	2-3	1	1	
Strawberries			1	2-3		5	

1: every year. 2: every second year. 3: every third year etc.

\* In early potatoes, cabbage, carrot and onion crop rotation may not necessarily be applied.

\*\* Harvested as seed.

\*\*\* 3 years crop rotation is for seed potato

### 4.5.3 Surface water

No adjustments of the standard parameters and scenario conditions of the FOCUS models are accepted. The latest FOCUS models available at the time of submission have to be used in PEC calculations.

PEC<sub>sw</sub> is to be calculated with the FOCUS STEP3 scenarios D1, D3-D6 and R1-R4 in accordance with the country specific requirements (Table 4.5.3-1). The risk envelope approach may only be used in cases where the worst case exposure is identifiable and scientifically justified. Note that all crops that are parameterised

<sup>24</sup> Individual substance refers to active substances and to metabolites stated as relevant. In DK though, all metabolites are defined as relevant.

<sup>25</sup> Sum of substances in a sample refer to all active substances + metabolites stated as relevant. In DK though, all metabolites are defined as relevant.

<sup>26</sup> Note that monitoring data for higher tier groundwater assessments is only accepted by Denmark (The Danish Pesticide Leaching Assessment Programme, PLAP).

<sup>27</sup> 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.

should be modelled. When a crop is not parameterised in any of the relevant scenarios, the user should select a crop resembling the intended crop based on expert judgement.

For calculations at Step 1 and 2 the latest version (version 3.2) should be used<sup>28</sup>.

For DT<sub>50</sub> in soil, sediment and water, modelling endpoints in accordance with the recent version FOCUS degradation kinetics report should be used. If K<sub>oc</sub> and/or DT<sub>50</sub> are pH dependent, data representative for the concerned member states should be applied in the simulations (see Table 4.5.2-1 and text in chapter 4.5.2 - Groundwater). FOCUS default values should be applied where appropriate. All input values used for the simulations have to be reported, including the application window chosen for the step 3 & 4 simulations.

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

**Table 4.5.3-1 Member State specific requirements for FOCUS scenarios considered in the assessment of surface water and sediment exposure**

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

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

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

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

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

<sup>28</sup> If older versions of Step 1 and 2 is used Step 2 PEC calculations are sufficient for parents and metabolites IF the resulting Exposure-toxicity ratio threshold values for aquatic ecotoxicology are exceeded by a factor of 10.

**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*
<b>Width of non-spray buffer zones to mitigate drift (m)</b>							
2	FVOB						
3							
5		FVOB	FVOB	FVOB	FVOB	FVOB	
10	FVOB						
15							FVB
20	FVOB						O
25							
30	VOB		OB				
35		OB		OB	OB		
40			O				
45							
50	O		O				
<b>Runoff vegetative buffer zone (m)**</b>							
	-	10	10	10	10	10	
<b>Drift reducing nozzles (%) *</b>							
25	-	-	-	-	-	-	O
50	-	-	Yes	-	-	-	FVOB
75	-	-	Yes	-	-	-	FVOB
90	-	-	Yes	-	-	-	FVOB
99	-	-	-	-	-	-	O

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

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

\*\*Calculation shall be performed with the SWAN tool, applying the reduction factors for a 10-12 m buffer strip, as outlined in table 7 p. 33 in FOCUS Landscape and mitigation<sup>29</sup>

The documentation must be well structured and transparent in order to demonstrate which scenarios and mitigation measures are relevant for each country. It should be clear which PEC<sub>sw</sub> 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 PEC<sub>sw</sub> [µg/L] and PEC<sub>sed</sub> [µg/kg] which are to be used in the risk assessment**

Country	Comp.	Appl.	Step 2		Step 3		Step 4			
			PEC <sub>sw</sub>	PEC <sub>sed</sub>	Scenario	PEC <sub>sw</sub>	PEC <sub>sed</sub>	Mitigation measure	PEC <sub>sw</sub>	PEC <sub>sed</sub>
		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.

<sup>29</sup> C. Brown et al. 2007, Landscape and Mitigation factors in aquatic ecological risk assessment. Volume 1, Extended Summary and Recommendations (SANCO/10422/2005, version 2.0, September 2007)

#### 4.5.4 Monitoring data

Available monitoring data from the zone (see Table 4.5.4-1) concerning fate and behaviour of the active substance and relevant metabolites, degradation and reaction products should be reported. The data might, in some Member States, be used in support of the groundwater and surface water modelling. Note that monitoring data is not accepted as a higher tier refinement by member states other than by Denmark. Please read the Danish Framework for the Assessment of Plant Protection Products for more details. Monitoring data indicating higher environmental exposure than the predicted modelled values could for some MSs lead to restrictions in the use of plant protection products at national level.

**Table 4.5.4-1 Monitoring programmes in the Northern zone.**

Member state	Monitoring programme
Denmark	The Danish Pesticide Leaching Assessment Programme ( <a href="#">PLAP</a> )
Estonia	-
Sweden	Växtskyddsmedel i miljön, Swedish University of Agricultural Sciences (SLU) <a href="http://www.slu.se/">http://www.slu.se/</a>
Norway	The Norwegian Agricultural Environmental Monitoring Programme ( <a href="#">JOVA</a> ), Norwegian Institute of Bioeconomy Research ( <a href="#">NIBIO</a> )
Lithuania	-
Latvia	-
Finland	-

SE: See specific policy in Appendix IV.

#### 4.5.5 Assessment of the relevance of metabolites in groundwater

A metabolite is considered to be of concern when the concentration is above 0.1 µg/L. In some cases the Northern Zone FOCUS scenarios may predict higher concentrations of groundwater metabolites than the EU FOCUS scenarios. An assessment of the relevance of metabolites of concern in groundwater should be included in the core assessment if the metabolite has not been assessed during the EU evaluation.

The assessment of the relevance should cover all the requirements in the GD (SANCO/221/2000 – rev.10) on the relevance of metabolites in groundwater. The full relevance assessment is to be presented in the core dRR, Part B section 8 or 10. Denmark generally considers all metabolites as relevant, but in some cases, and after evaluation by DEPA (see the Danish national guidance), some metabolites may be accepted at concentrations up to 0.75 µg/L.

#### 4.6 Ecotoxicology

##### Disclaimers:

1. This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. Specific national requirements are presented in [Appendix IV: Summary of national requirements](#).
2. The present guidance for the environmental risk assessment regarding applications for approval of plant protection products in the Northern Zone highlights parts which MS in Northern Zone disagrees with in EU and EFSA Guidance Documents mentioned below. Please note, other parts of EU and EFSA Guidance Documents not mentioned here may still be considered unacceptable in the Northern Zone.

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. **The most recent version.**

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

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

#### 4.6.1 Mixture toxicity

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

Further details on how mixture toxicity should be assessed are found e.g. in the Aquatic Guidance Document (EFSA Journal 2013; 11(7): 3290) and in the guidance document for birds and mammals in appendix B of Guidance of EFSA Risk assessment for birds and mammals (EFSA Journal 2009; 7(12) 1438). **It should be noted that mixture toxicity should always be considered also for long-term risk assessment for birds and mammals. The active substances can jointly contribute to the same adverse effects on non-target species or to different adverse effects which together cause higher toxicity.**

#### 4.6.2 Non-professional use/Home gardens

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

##### *National requirements (Norway)*

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

#### 4.6.3 Risk assessment for uses in protected structures

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

ronmental fate exposure assessment will advise on the need for a risk assessment for aquatic organisms and soil dwelling organisms.

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

#### 4.6.4 Birds and mammals

The risk assessments for birds and mammals should be presented in the core assessment. The EFSA guidance document for birds and mammals (EFSA Journal 2009; 7(12) 1438) should be used for the screening and tier 1 assessments<sup>30</sup> with a few amendments. If a product will be used in late growth stages of maize (BBCH  $\geq 30$ ), the bird species willow warbler has to be added to the package of species presented in the EFSA guidance document. The reason for this is that this species is frequently detected in late growth stages of maize in the Northern Zone and it is not covered by the species presented in the EFSA guidance document. A shortcut value (SV) of 52.2 shall be used for assessment of acute risk and SV = 20.3 for assessment of long-term risk for willow warbler.

It should be noted that mixture toxicity should always be considered also for long-term risk assessment. Different mode of action of the active substances is not a valid reason for not assessing combination effects.

When refinements of the risk assessment are necessary, the 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.

#### 4.6.5 Aquatic ecosystems

In the core assessment, a first tier risk assessment in accordance with Guidance on tiered risk assessment for plant protection products for aquatic organisms in edge-of-field surface waters, EFSA Journal 2013; 11(7): 3290 (abbreviated as EFSA AGD in this NZ GD) should be presented. The terminology use in the EFSA AGD is accepted in aquatic ecotox section of this NZ GD, e.g. Regulatory acceptable concentration (RAC). A table containing all relevant FOCUS PEC SW and PEC SED (see section 4.5.3) and corresponding TERs should be included<sup>31</sup>. The risk assessment tables shall contain all country specific scenarios and relevant mitigation measures for the countries in which authorization is applied for. Examples of how the aquatic step 4 risk assessment and the aquatic mixture toxicity risk assessment should be presented are given in **Appendix VI**. It is important to present all calculations made in the risk assessment in a transparent way, also those calculations not included in the example tables.

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

##### *Refinement of the exposure by different risk mitigation options*

For the core assessment, risk mitigation by spray drift buffer zones are accepted (see Member State specific buffer zones in section 4.5.3). Other nationally specific mitigation options (run-off reduction and spray drift

<sup>30</sup> 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 uses the lowest endpoint and takes account of additional toxicity data by an ad-hoc assessment.

<sup>31</sup> 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)

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 are relevant for each Member state.

#### *Refinement by using $PEC_{TWA}$*

It is not accepted to use  $PEC_{TWA}$  in **acute** risk assessments for aquatic organisms. For the long term risk assessment, it is acceptable to follow the EFSA AGD<sup>32</sup> regarding use of  $PEC_{TWA}$ . In addition to fulfilling the conditions of the decision scheme regarding use of  $PEC_{sw,twa}$  in the EFSA AGD, it has to be clearly demonstrated, that the boundary conditions of reciprocity and latency of effects are fulfilled for the relevant twa period.

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

Chapter 9.1 of the EFSA AGD describes how time-variable exposures (e.g. pulse durations and/or intervals between pulses) derived from the FOCUS modelling could be used to refine the aquatic risk assessment. The refinement described in Chapter 9.1 in EFSA AGD is, however, not accepted for refined risk assessments in the Northern Zone. Based on the many site- and time-variable parameters affecting the shapes of the FOCUS peaks, it is not considered scientifically justified to mimic the exposure profiles from FOCUS modelling in higher tier studies at the resolution described in chapter 9.1 of EFSA AGD. Some of these variable parameters affecting the exposure profiles are described in the EFSA AGD, e.g.; physical–chemical properties of the PPP, the application regime in the crop, the relative importance of different entry routes (e.g. drift, surface runoff, 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 all sensitive life stages or all species in the field, since the effect of e.g. a pulsed exposure is highly species specific and dependent on sensitive life stages and/or different life strategies. Consequently, in the Northern Zone, time-variable exposures derived from the FOCUS modelling cannot be used to refine the aquatic risk assessment as described in chapter 9.1 and parts of chapter 9.2 of the EFSA AGD.

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

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

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

<sup>32</sup>  $PEC_{twa}$  can be used in risk assessments of algae if the criteria for TWA are fulfilled.

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

Aquatic organism	Acute/Long-term	Geometric mean	N <sub>GM</sub> *	Median HC5	N <sub>HC5</sub>
Algae		X	3-7	X	8+
Aquatic plants		X	3-7	X	8+
Invertebrates	Acute	X	3-7	X	8+
	Long-term	X	3-7	X	8+
Fish	Acute	X	3-4	X	5+
	Long-term				

\* Geometric mean = GM.

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

A geometric mean approach shall always be assisted by a Weight of Evidence (WoE) approach. Guidance on how a WoE approach is performed is given for the acute risk assessment (below). Many of the concerns identified in relation to derivation of acute RAC based on geometric mean or WoE is also relevant for the long-term situation and need to be addressed by the applicant. However, until enough experience is gained in deriving long-term RAC based on geometric mean or WoE, such long-term RACs will be assessed on a case-by-case basis, applying expert judgement. Expert judgement will be applied for derivation of RAC based on geometric mean or WoE for algae and macrophytes.

The theory behind the WoE approach is that the lower the endpoint of the most sensitive test species, the more of the species variability is considered to have been addressed and therefore the AF can be reduced. The overall AF (AF<sub>overall</sub>) applied to acute and long-term endpoints can be related to variation in species sensitivity (AF<sub>spec</sub>) and other uncertainties (AF<sub>other</sub>). The latter includes e.g. inter-laboratory variation and lab to field extrapolation.

For acute AF it seems reasonable to maintain as a default approach the assumption from the former aquatic GD (EC, 2002) that the AF<sub>spec</sub> and AF<sub>other</sub> have an equal weight, i.e. AF<sub>spec</sub> = 10 and AF<sub>other</sub> = 10 for acute toxicity AF: AF<sub>overall</sub> = AF<sub>spec</sub> × AF<sub>other</sub>.

For the acute assessment:

- (i) When the most sensitive species tested is more sensitive than the derived geometric mean value by a factor 100 for acute endpoints, the RAC<sub>WoE</sub> should be used: The most sensitive endpoint divided by an overall AF >10, i.e. AF<sub>overall</sub> = 10 (AF<sub>other</sub>) × AF<sub>spec</sub>. As a default value for the AF<sub>spec</sub> a value of 2 at minimum is proposed, leading to a **default AF<sub>overall</sub> of 20**<sup>33</sup>. I.e. acute RAC<sub>WoE</sub> = most sensitive endpoint<sub>acute</sub> / 20. Compare RAC<sub>geometric mean</sub> (geomean/100) with the RAC<sub>WoE</sub> (most sensitive endpoint/20) and use the lowest RAC for the risk assessment.
- (ii) When the most sensitive species tested is more sensitive than the derived geometric mean value by a factor between 10 and 100 for acute endpoints, the RAC<sub>WoE</sub> should be used: AF<sub>overall</sub> =

<sup>33</sup> Sweden and Norway will not accept an AF<sub>species</sub> = 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<sub>species</sub> = 6) and on datasets where the ratio is more than 100 (see ii).

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

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

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

#### *Refinement with mesocosms*

Mesocosm studies (including “old” mesocosms for which a LoEP value is available and used in the risk assessment) should always be reported and evaluated according to the EFSA AGD and presented in the core dossier. Minimal detectable differences (MDD) should be reported together with the NOEC table for each investigated endpoint in time and used as recommended in the EFSA AGD. Only the RAC derived on basis of the Ecological Threshold Option (ETO) from mesocosms can be used in the core risk assessment, with an AF as proposed in the EFSA AGD. The RAC based on Ecological Recovery Option (ERO) is only accepted by Denmark, but only if the recovery period is maximum 4 weeks and an AF of 5 is used (see Denmark in Appendix IV for further details).

#### 4.6.6 Bees

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

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

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

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

#### 4.6.7 Non target arthropods

In the core assessment, first tier in-field and off-field risk assessments using HQ (ESCORT 2; standard lab glass plate studies) should be presented. If necessary, higher tier laboratory studies should be presented and evaluated against the 50 % trigger value for negative effects. The evaluation of field studies and the higher tier risk assessment should also be presented in the core assessment according to the guidance document of the Dutch Platform for the Assessment of Higher Tier Studies (de Jong, Bakker, Brown, Jilesen, Posthuma-Doodeman, Smit, van der Steen, van Eekelen; <http://www.rivm.nl/bibliotheek/rapporten/601712006.pdf>).

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

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

#### 4.6.8 Earthworms and other soil organisms

In the core assessment, a first tier risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002 rev 2 final) should be presented. The endpoints (LC50 and NOEC/EC10) used in the risk assessment of earthworms (and other soil organisms) should be divided by a factor of 2 when the log Kow is greater than 2, unless it can be demonstrated by soil sorption data or other evidence that the toxicity is independent of organic carbon content in soil. Hence, the endpoint must be divided by a factor of 2 even if the toxicity tests are performed with soil containing less organic matter than 10%.

If required, also a higher tier risk assessment based on higher tier field studies should be presented and evaluated in the core assessment. The field studies should be evaluated following the guidance given in part 2 of the document by de Jong *et al.* (A guidance document of the Dutch platform for the assessment of higher tier studies, Guidance for summarizing earthworm field studies, RIVM 2006). Old field studies should always be reevaluated according to this guidance. The interpretation of the acceptability/representativeness of the field study for the specific agricultural landscape and protection goals should be done for each Member state. If field studies from other zones are used in the risk assessment, it must be shown that the exposure profile is representative for the Northern zone conditions. If a new field study is performed it is recommended that the concentration of the active substance in the soil is measured and presented. The evaluation should also include recovery times for the organisms and information on how many % of the organisms that are affected. For the core assessment initial effect less than 50 % (according to RIVM 2006) and recovery within a growing season for representative field studies are required.

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

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

National requirement (Denmark): Specific requirements for persistent substances<sup>34</sup>; Field effect studies for substances with DT50 soil between 3 and 6 months (further details can be found in the Danish Framework for Risk Assessment of Plant Protection Products, see [Appendix IV: Summary of national requirements](#)).

<sup>34</sup> 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

#### 4.6.9 Non target plants

In the core assessment, a risk assessment in accordance with the terrestrial guidance document (SAN-CO/10329/2002 rev 2 final) should be presented<sup>35</sup>. If a probabilistic risk assessment is used, endpoints from at least 10 species are required. Unacceptable effects must be excluded for all species tested. Hence, the HC5 must not exceed the EC50 of the most sensitive species in the SSD. If so, a deterministic risk assessment should be used instead.

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

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

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

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

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

#### 4.6.10 Assessment of the relevance of metabolites

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

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

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

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

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risk of spreading in the environment and effects on organisms (standard ecotoxicological endpoints may not capture the full effects of prolonged exposure). Persistent substances can also cause effects on and lead to residues in subsequent crops. This also applies to the metabolites of an active substance.

<sup>35</sup> Finland and Estonia do not accept an assessment factor of 1 in probabilistic risk assessment of non-target plants. An assessment factor of 3 is required in the probabilistic risk assessment in national addendum for Finland and an assessment factor of 2 is required in the probabilistic risk assessment in national addendum for Estonia.

## 5 Appendix I: Form to notify zones of intended authorisation or re-authorisation activity

Please use the pre-notification form in the latest version of the guidance document **Template to notify intended zonal applications under Article 33 and Article 43 of Regulation (EC) No 1107/2009** (SAN-CO/12544/2014).



## 6 Appendix II: Reporting table

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Active substance:

Trade name/Formulation type:

Rapporteur:

cMS:

Send for comments:

Deadline:

dRR point	Country	Comment	Reply rapporteur	Accepted Yes/No

## 7 Appendix III: Contact points

Pre-notifications and applications should be submitted to:

Country	e-mail	Postal Address
Denmark	<a href="mailto:pesticider@mst.dk">pesticider@mst.dk</a>	Pesticider & Biocider Miljøstyrelsen Strandgade 29 DK - 1401 København K Denmark
Estonia	<a href="mailto:Rain.Reiman@pma.agri.ee">Rain.Reiman@pma.agri.ee</a>	Estonian Agricultural Board Plant Protection Department Teaduse 2 Saku 75501, Estonia
Finland	<a href="mailto:ppp_zonal@tukes.fi">ppp_zonal@tukes.fi</a>	Finnish Safety and Chemicals Agency P.O.Box 66 (Opastinsilta 12 B) FI-00521 Helsinki, Finland
Iceland	<a href="mailto:ust@ust.is">ust@ust.is</a>	The Environment Agency of Iceland Sudurlandsbraut 24 108 Reykjavík, Iceland
Latvia	<a href="mailto:zonal@vaad.gov.lv">zonal@vaad.gov.lv</a>	State Plant Protection Service Plant Protection Department Lielvārdes iela 36/38, Riga, LV-1006
Lithuania	<a href="mailto:info@vatzum.lt">info@vatzum.lt</a> with copy to <a href="mailto:kristina.valioniene@vatzum.lt">kristina.valioniene@vatzum.lt</a> .	State Plant Service under Ministry of Agriculture Ozo str.4A LT-08200 Vilnius, Lithuania.
Norway <sup>36</sup>	<a href="mailto:postmottak@mattilsynet.no">postmottak@mattilsynet.no</a> with copy to <a href="mailto:pesticider@mattilsynet.no">pesticider@mattilsynet.no</a>	Norwegian Food Safety Authority, National Registration Department, Felles post- mottak, P.O.Box 383, N-2381 Brumunddal, Norway
Sweden	<a href="mailto:kemi@kemi.se">kemi@kemi.se</a>	Kemikalieinspektionen P.O Box 2 SE-172 13 Sundbyberg, Sweden

<sup>36</sup> 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	<p><b>Title:</b> Coordinator for National Approvals  <b>Name:</b> Vibeke Møller  <b>Authority:</b> Danish EPA  <b>Address:</b> Strandgade 29, 1401 Copenhagen K, Denmark  <b>Tel:</b> + 45 72544578  <b>E-mail:</b> <a href="mailto:vm@mst.dk">vm@mst.dk</a></p>
Estonia	<p><b>Title:</b> Chief specialist of Plant Protection Department  <b>Name:</b> Rain Reiman  <b>Authority:</b> Estonian Agricultural Board  <b>Address:</b> Teaduse 2, Saku 75501 Estonia  <b>Tel:</b> +372 6712 653 (direct) (ext. 612 for teleconference)  <b>E-mail:</b> <a href="mailto:rain.reiman@pma.agri.ee">rain.reiman@pma.agri.ee</a></p>
Finland	<p><b>Title:</b> Senior Officer  <b>Name:</b> Heini Paloheimo  <b>Authority:</b> Finnish Safety and Chemicals Agency (Tukes)  <b>Address:</b> P.O. Box 66, FI-00521 Helsinki, Finland  <b>Tel:</b> +358 29 5052000  <b>E-mail:</b> <a href="mailto:ppp_zonal@tukes.fi">ppp_zonal@tukes.fi</a></p>
Iceland	<p><b>Title:</b> Advisor  <b>Name:</b> Bjorn Gunnlaugsson  <b>Authority:</b> Environment Agency of Iceland  <b>Address:</b> Sudurlandsbraut 24, 108 Reykjavik  <b>Tel (direct):</b> 00354 5912082  <b>E-mail:</b> <a href="mailto:bjorgunn@ust.is">bjorgunn@ust.is</a></p>
Latvia	<p><b>Title:</b> Director of Plant Protection Department  <b>Name:</b> Vents Ezers  <b>Authority:</b> State Plant Protection Service  <b>Address:</b> Lielvārdes iela 36/38, Riga, LV-1006  <b>Tel:</b> 00371 67550929  <b>E-mail:</b> <a href="mailto:vents.ezers@vaad.gov.lv">vents.ezers@vaad.gov.lv</a></p>
Lithuania	<p><b>Title:</b> : Head of Plant Protection products authorization division  <b>Name:</b> Kristina Valioniene  <b>Authority:</b> State Plant Service under Ministry of Agriculture  <b>Address:</b> Smelio str.8, LT-11324 Vilnius, Lithuania  <b>Tel:</b> +370 5 26 24 940  <b>E-mail:</b> <a href="mailto:kristina.valioniene@vatzum.lt">kristina.valioniene@vatzum.lt</a></p>
Norway	<p><b>Title:</b> Head of Department  <b>Name:</b> Tor Erik Jörgensen  <b>Authority:</b> Norwegian Food Safety Authority  <b>Address:</b> P.O.Box 3, N-1431 Ås  <b>Tel:</b> +47 22 77 91 26 or +47 95 04 12 83  <b>E-mail:</b> <a href="mailto:tejour@mattilsynet.no">tejour@mattilsynet.no</a></p>
Sweden	<p><b>Title:</b> Regulatory Coordinator  <b>Name:</b> Camilla Thorin  <b>Authority:</b> Swedish Chemicals Agency  <b>Address:</b> P.O. Box 2, SE-172 13 Sundbyberg, Sweden  <b>Tel:</b> +46 8 519 41 256  <b>E-mail:</b> <a href="mailto:camilla.thorin@kemi.se">camilla.thorin@kemi.se</a></p>

## 8 Appendix IV: Summary of national requirements

Denmark				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
Phys. Chem. properties and anal. method	NO			
Toxicology	Yes – for non-professional uses and for metabolites that potentially leach to groundwater.	<ul style="list-style-type: none"> <li>• DK does not accept EUROPOEM II or German Guidance (Martin et al) as second tier for bystander and resident risk assessment.</li> <li>• DK requires risk assessment for toddlers/small children for uses on recreational lawns in public areas but not for golf courses.</li> <li>• DK does not accept the use of re-entry times as a refinement for risk assessment of recreational residence.</li> <li>• DK does not accept the EU definition of non-relevance of metabolites. Denmark generally considers all metabolites as relevant, but in some cases, and after evaluation by DEPA (see the Danish national guidance), some metabolites may be accepted at concentrations up to 0.75 µg/L.</li> <li>• Pesticides that are classified acute toxic</li> </ul>	Yes Danish/English	<p>Danish: <a href="http://mst.dk/virksomhed-myndighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/">http://mst.dk/virksomhed-myndighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingsrammer-for-miljoe-og-sundhed/</a></p> <p>English: <a href="http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/">http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/</a></p>

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
		<p>in categories 1, 2, or 3 or with specific target organ toxicity SE in category 1 according to CLP (Regulation no. 1272/2008<sup>37</sup>), may not be used in private gardens, public areas and similar areas which are accessible to the public, areas around residential buildings, childcare institutions and similar, or to treat vegetation on borders with public roads or private gardens. In addition, these products cannot be sold to or be used by non-professional users.</p> <ul style="list-style-type: none"> <li>• PPP's intended to be sold to and used by non-professional users have to fulfil the criteria outlined in Annex 14 of the Framework for Risk Assessment of Plant Protection Products (DEPA).</li> <li>• Products for non-professional users: Products which can be purchased and used by everyone, including garden owners without a spraying certificate or spraying permit.</li> <li>• Non-professional users are assumed to use handheld spray equipment and have no PPE to protect them.</li> </ul>		

<sup>37</sup> 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
Residues	Dossier must cover Danish conditions			
Efficacy	Dossier must cover Danish conditions. Bridging studies required for similar products.			
Fate and behaviour	Specific persistency assessment  Specific groundwater modelling – including all metabolites	DT <sub>50</sub> soil < 180 days for active substance and some metabolites – otherwise no approval. Please consult the Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off  The following requirements should be included in the core assessment: Makro Danish scen. or PELMO Hamburg + specific input and output values All metabolites that are not inherently non-relevant needs to be covered by the assessment.	Yes Danish/English	Danish: <a href="http://mst.dk/virksomhed-myn-dighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingrammer-for-miljoe-og-sundhed/">http://mst.dk/virksomhed-myn-dighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingrammer-for-miljoe-og-sundhed/</a>  English: <a href="http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/">http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/</a>
Ecotoxicology	<b>General</b>  <b>Birds and Mammals</b> Higher tier guidance on risk assessment for birds and mammals  <b>Aquatic organisms</b> Specific aquatic risk assessment	Danish refinement options for: FS, PD, PT, RUD, DT <sub>50</sub> and interception  Specific assessment principles for mesocosm studies	Danish/English	Danish: <a href="http://mst.dk/virksomhed-myn-dighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingrammer-for-miljoe-og-sundhed/">http://mst.dk/virksomhed-myn-dighed/bekaempelsesmidler/sproejtemidler/ansoeger/vurderingrammer-for-miljoe-og-sundhed/</a>  English: <a href="http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/">http://eng.mst.dk/topics/pesticides/applications-for-authorisation-after-14-june-2011/evaluation-framework/</a>

<b>Estonia</b>				
<b>Section</b>	<b>Supplementary data requirements for Annex III dossier Yes/NO</b>	<b>Goal(s) of Guidance document</b>	<b>Guidance Document available Yes/No and language of the document</b>	<b>Address or contact point to obtain GD</b>
Phys. Chem. properties and anal. method	NO			
Toxicology	NO			
Residues	NO			
Efficacy	NO			
Fate and behaviour	NO			
Ecotoxicology	No			

<b>Finland</b>				
<b>Section</b>	<b>Supplementary data requirements for Annex III dossier Yes/NO</b>	<b>Goal(s) of Guidance document</b>	<b>Guidance Document available Yes/No and language of the document</b>	<b>Address or contact point to obtain GD</b>
Phys. Chem. properties and anal. method	NO			
Toxicology		<p><u>Exposure assessment:</u> National work rate / day for barley is 40 ha.</p> <p>Dutch model is applied to greenhouse uses. In 2014 the <i>EFSA Guidance on the assessment of exposure of operators,</i></p>	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
		<p><i>workers, residents and bystanders in risk assessment for plant protection products</i> was published. Tukes has decided to implement this Guidance for all applications for plant protection products that are submitted from <b>1 January 2016</b>.</p> <p>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.</p> <p><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:</p> <ul style="list-style-type: none"> <li>- Product is explosive</li> <li>- Extremely flammable, highly flammable or flammable</li> <li>- Fatal or toxic if swallowed, in contact with skin or if inhaled</li> <li>- Skin corrosive</li> <li>- Causes serious eye damage or is irritating to eyes</li> <li>- Causes respiratory or skin sensitisa-</li> </ul>		



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
		<ul style="list-style-type: none"> <li>- tion</li> <li>- Carcinogenic, toxic to reproduction, mutagenic or fulfils criteria for specific target organ toxicity</li> <li>- Product is presenting an aspiration hazard</li> <li>- Waiting period exceeds 7 days</li> <li>- The operator exposure (without personal protective equipment except gloves) under the proposed conditions of use exceeds the AOEL.</li> </ul>		
Residues	NO			
Efficacy	Dossier must cover Finnish conditions			
Fate and behaviour	NO	<p>PECsoil should be calculated by using the Finnish PECsoil calculator.</p> <p>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.</p>	Fate and behaviour	<b>NO</b>
Ecotoxicology	NO	<p><b>Non-professional use:</b>            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:</p>		

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
		<ul style="list-style-type: none"> <li>- Products containing an active ingredient listed as candidate for substitution at the EU level</li> <li>- Products with several or far-reaching conditions for use. This may, for example, mean requirements for safety distances, restriction of use in the ground water areas, restriction of use in the consecutive years (if risk for the soil organisms occurs after use in consecutive years)</li> <li>- Products which are particularly harmful to pollinating insects</li> <li>- Products (granules) which are particularly harmful to birds and mammals.</li> </ul>		

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 fol-	Yes national regulation, Latvian	<a href="#">2012.gada 24.jūlija MK noteikumi Nr.509 „Noteikumi par augu aizsardzības līdzekļu laišanu tirgū saskaņā ar Regulu Nr.1107/2009”</a>

<b>Latvia</b>				
<b>Section</b>	<b>Supplementary data requirements for Annex III dossier Yes/NO</b>	<b>Goal(s) of Guidance document</b>	<b>Guidance Document available Yes/No and language of the document</b>	<b>Address or contact point to obtain GD</b>
		<p>lowing R23–R28; R40;R45;R49;R46; R68;R60; R61; R62; R63; R41; R64; R48; R33</p> <p>- or if classified with CLP equivalents as indicated in the National Regulation No.509 from point 11.2.1 to 11.2.10.</p> <p>- 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;</p> <p>- if PPP is classified with R65 it can only be authorised for non-professional use if its packaging/opening has construction safe for children;</p> <p>- 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.</p>		
Residues	NO			
Efficacy	No			
Fate and behaviour	<b>Yes</b>	See core text in chapter 4.5.2		
Ecotoxicology	<b>No</b>			

## 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	<p><b>Professional use:</b> When long term risk assessment for bystander &amp; resident using EFSA GD Exposure Calculator indicates no safe use, EUROPOEM II Bystander Exposure to Pesticides for bystander and German Guidance (Martin et al.) for resident may be considered using 60 min duration of exposure for EUROPOEM II and the other values as suggested for the respective model.</p> <p><b>Non-professional use:</b> - Plant protection products may not be authorised for non-professional use if those are classified for acute toxicity categories 1, 2 or 3; for skin corrosion; for carcinogenicity, germ cell mutagenicity and reproductive toxicity; for effects on or via lactation; for respiratory sensitisation and for specific target organ toxicity.</p> <p>- Re-entry periods after an application of a PPP on turf, lawns, grassland etc. may not be accepted for non-professional use.</p>		No	
Residues	No			

<b>Lithuania</b>				
<b>Section</b>	<b>Supplementary data requirements for Annex III dossier Yes/NO</b>	<b>Goal(s) of Guidance document</b>	<b>Guidance Document available Yes/No and language of the document</b>	<b>Address or contact point to obtain GD</b>
Efficacy	Dossier must cover Lithuanian conditions.			
Fate and behaviour	Yes  <b>Non-professional use:</b> Plant protection products may not be authorised if risk mitigation measures are required to protect groundwater from contamination.	See core text in chapter 4.5.2	No	
Ecotoxicology	No  <b>Non-professional use:</b> Plant protection products may not be authorized for non-professional use if those are systemic products with insecticidal properties and if buffer zone to protect aquatic organisms is large than 10 m or VFS buffer zone is required.			

<b>Norway</b>				
<b>Section</b>	<b>Supplementary data requirements for Annex III dossier Yes/NO</b>	<b>Goal(s) of Guidance document</b>	<b>Guidance Document available Yes/No and language of the document</b>	<b>Address or contact point to obtain GD</b>
Phys. Chem.	No	<u>The following plant protection products</u>	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
properties and anal. method		<u>may not be authorised for use by non-professional users:</u> - Products that are explosive (E) or oxidizing (O).		
Toxicology	No	<p><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.</p> <p><u>The following plant protection products may not be authorised for use by non-professional users:</u> Products that are acutely toxic category 1-2 (deadly) or category 3 (toxic); that are corrosive for the skin and eyes or can cause serious eye damage; that may cause allergy or asthma symptoms or breathing difficulties if inhaled; that may or possibly may give cancer, genotoxic effects or impair fertility or the unborn child (CMR-substances) or that cause or may cause damage to organs by single or repeated exposure.</p>	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
		<p>Thus plant protection products in Norway for non—professional use labelled with one or more of the following risk phrases according to Regulation (EC) No 1272/2008 (CLP), will not be approved:</p> <ul style="list-style-type: none"> <li>- H300 Fatal if swallowed.</li> <li>- H301 Toxic if swallowed.</li> <li>- H310 Fatal if in contact with skin.</li> <li>- H311 Toxic if in contact with skin.</li> <li>- H314 Causes severe skin burns and eye damage.</li> <li>- H218 Causes serious eye damage.</li> <li>- H330 Fatal if inhaled.</li> <li>- H331 Toxic if inhaled.</li> <li>- H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.</li> <li>- H340 May cause genetic defects.</li> <li>- H341 Suspected of causing genetic defects.</li> <li>- H350 May cause cancer.</li> <li>- H351 Suspected of causing cancer.</li> <li>- H360 May damage fertility or the unborn child.</li> <li>- H361 Suspected of damaging fertility or the unborn child.</li> <li>- H370 Causes damage to organs.</li> <li>- H371 May cause damage to organs.</li> <li>- H372 Cause damage to organs through prolonged or repeated exposure.</li> </ul>		

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
		<p>- H373 May cause damage to organs through prolonged or repeated exposure.</p> <p>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.</p> <p><u>The following products can be accepted for non-professional use:</u></p> <p><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 need for personal protection equipment.</p> <p><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.</p>		



Norway				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
		<u>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 of Bioeconomy Research is responsible for the efficacy evaluations.
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 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		

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
		µg/bee) will not be authorised for outdoor use.		
Overall	Yes	National requirements for approval of adjuvants (see <a href="https://www.mattilsynet.no/language/english/plants/plant_protection_products/Approval_plant_protection_products/adjuvants.22424">https://www.mattilsynet.no/language/english/plants/plant_protection_products/Approval_plant_protection_products/adjuvants.22424</a> ).		

Sweden				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
Monitoring		Monitoring data is not accepted as an option for higher tier assessments in Sweden. Hence, historical monitoring data does not override any unacceptable risks identified from modelling results. Likewise, conditions including future monitoring programs does not justify disregarding any unacceptable risks identified from modelling results.		
Products which may be used by non-professional users		Plant protection products are not suitable to be placed in authorisation 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 - Products that have the following classification according to Regulation (EC) No 1272/2008: Acutely toxic or acutely harmful (Acute tox. 1-4), requiring hazard statement		Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +46 8 519 41 100, <a href="mailto:kemi@kemi.se">kemi@kemi.se</a>

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
	<p>H300 Fatal if swallowed  H301 Toxic if swallowed  H310 Fatal in contact with skin  H311 Toxic in contact with skin  H330 Fatal if inhaled  H331 Toxic if inhaled  H302 Harmful if swallowed  H312 Harmful in contact with skin  H332 Harmful if inhaled  Highly corrosive (Skin corr 1a, 1B, 1C) requiring hazard statement  H314 Causes severe skin burns and eye damage  Severely damaging to eyes (Eye Dam 1), requiring hazard statement  H318 Causes serious eye damage  Respiratory sensitisation (Resp sens 1), requiring hazard statement  H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled  Causing skin allergy (Skin sens 1; unless it can be shown that exposure is negligible) requiring hazard statement  H317 May cause an allergic skin reaction  Mutagenic, carcinogenic or toxic to reproduction (Muta 1A, 1B, 2; Carc 1A, 1B, 2; Repr 1A, 1B, 2) requiring hazard statement  H340 May cause genetic defects  H341 Suspected of causing genetic defects  H350 May cause cancer  H351 Suspected of causing cancer  H360 May damage fertility or the unborn child  H361 Suspected of damaging fertility or the unborn child  H362 May cause harm to breast-fed children  Specific organ toxicity (STOT SE 1, 2; STOT RE 1, 2) requiring hazard statement  H370 Causes damage to organs  H371 May cause damage to organs  H372 Causes damage to organs</p>			

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
	<p>H373 May cause damage to organs Toxic by aspiration (Asp tox 1) requiring hazard statement H304 May be fatal if swallowed and enters airways; unless they have childproof packaging</p> <ul style="list-style-type: none"> <li>- If the calculation of user exposure (without protective clothing) in or after application in “normal” use exceeds the AOEL (Acceptable Operator Exposure Level)</li> <li>- The products are formulated as concentrates and require dilution before use (unless products with particularly low risk are concerned*)</li> <li>- The products are packed in containers or are to be spread using containers which pose a special risk of spillage and misuse (unless low-risk substances are concerned)</li> <li>- The environmental risk assessment shows no or only a small margin to unacceptable effects in “normal” use</li> </ul> <p>Pack size and concentration are taken into account in allocating to an authorisation class. Keml generally recommends that authorisation class 3 products (non-professional use products) are sold as ready-to-use solutions in packs of 10 kg or 10 L or less.</p> <p>*In accordance with KIFS 2016:3, products formulated as concentrates that require dilution prior to use can only be accepted if they are of particularly low risk. According to the Swedish Chemicals Agency, particularly low risk is defined as follows:</p> <ul style="list-style-type: none"> <li>- The toxicity of the active substance is considered too low for an ADI, AfRD or AOEL to be determined.</li> <li>- The product is not harmful to bees such that labelling as SPe 8 has been considered necessary according to Regulation (EU) no 547/2011: SPe 8 Dangerous to bees</li> <li>- The product does not fulfil the criteria for the following classification according to Regulation (EC) No 1272/2008: Classification for physical hazards Environmental hazards, except H412 Harmful to aquatic life with long lasting effects H413 May cause long lasting harmful effects to aquatic life</li> </ul>			

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
	Health hazards, except H315 Causes skin irritation H319 Causes serious eye irritation EUH208 'Contains ( <i>name of sensitising substance</i> ). May produce an allergic reaction'.			
Phys. Chem. properties and anal. method	NO			
Toxicology	NO			
Residues	NO			
Efficacy	NO			
Fate and behaviour	NO			
Ecotoxicology	NO			

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

Denmark	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, ...? %)
<b>Toxicology</b>		
Operator exposure  Worker exposure  Bystander and resident exposure	<ul style="list-style-type: none"> <li>- limits on spraying methods authorized</li> <li>- requirements on special permits for spraying personnel</li> <li>- requirements on special packaging (dimensions, design, possibly water-soluble packaging)</li> <li>- specification of treatment periods and periods of retainment</li> <li>- specific requirements concerning use of protective equipment</li> <li>- waiting periods for re-entry into treated areas</li> <li>- specific requirements concerning use of protective equipment</li> <li>- buffer zone for spraying</li> </ul> <p style="background-color: yellow;">See also Table 4.2.2.5-1 on the use of risk mitigation measures in the EFSA GD exposure calculator.</p>	
<b>Residues</b>	- PHI	
<b>Fate</b>		
Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications	
<b>Ecotoxicology</b>		
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

<b>Estonia</b>	<b>Mitigation options</b>	
<b>General</b>	<ul style="list-style-type: none"> <li>- 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.</li> <li>- It is prohibited to spray when the air temperature exceeds 25 °C.</li> </ul>	
<b>Toxicology</b>		
Operator exposure Worker exposure	<ul style="list-style-type: none"> <li>- waiting periods for re-entry into treated areas</li> <li>- specific requirements on the use of protective equipment</li> </ul>	
<b>Residues</b>	- PHI	
<b>Fate</b>	<ul style="list-style-type: none"> <li>- the same plant protection product on the same field in consecutive years</li> <li>- it is prohibited to spray a plant protection product in a water protection zone closer than 20 meters from the water boundary of the Baltic Sea, Lake Võrtsjärv, Lake Lämmijärv, Lake Peipus and Lake Pskov, 10 meters from the water boundary of other lakes, reservoirs, rivers, brooks, springs, main ditches and channels, and artificial recipients of land improvement systems, 1 meter from the water boundary of artificial recipients of land improvement systems with a catchment area of less than 10 km<sup>2</sup> unless a wider buffer zone is noted on the labelling of the packaging of the plant protection product.</li> </ul>	
<b>Ecotoxicology</b>	- Buffer zone	
Bees	<ul style="list-style-type: none"> <li>- 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.</li> </ul>	

	- 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.
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<b>Finland</b>	<b>Mitigation options</b>	Drift reduction equipment e.g. nozzles (if yes 50%, ...? %)
<b>Ecotoxicology</b>		
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).	
<b>Fate and behaviour</b>		-
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%, ...? %)
<b>Ecotoxicology</b>		
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%, ...? %)
<b>Toxicology</b>		
Bystander & resident exposure  Worker exposure	<ul style="list-style-type: none"> <li>- when long term risk assessment for bystander &amp; resident using EFSA GD Exposure Calculator indicates no safe use, buffer zone of 5 or 10 meters could be considered</li> <li>- re-entry periods after an application of a PPP on golf course, turf, lawns, grassland etc. could be considered</li> <li>- if the predicted worker exposure exceeds the AOEL using gloves as a refinement of exposure assessment could be considered</li> </ul>	Drift reducing nozzles are not accepted
<b>Residues</b>	<ul style="list-style-type: none"> <li>- PHI</li> <li>- 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</li> <li>- in some cases all livestock keeping out of treated areas for some period after treatment</li> </ul>	
<b>Fate</b>		
Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications.	
<b>Ecotoxicology</b>		
Surface water	<p>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.</p>	Drift reducing nozzles are not accepted
Non target arthropods	<p>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.</p>	-
Non target plants	Buffer zones: min – 5 m, calculating on every 5 meters. From currently registered PPP maximum buffer zone is 10 m.	-
Bees	<p>If product is toxic to bees label signify as “dangerous to bees” (safety phrase).  Restrictions of use during flowering and foraging activity including restrictions in time: plants should be sprayed after the flying time of bees between 21 and 4 o’clock. Restrictions of use on flowering weeds: no use on flowering weeds/destroy weeds before flowering. Cover bee hives during spraying time for a (indicate time). Regulation of</p>	

<b>Lithuania</b>	<b>Mitigation options</b>	<b>Drift reduction equipment e.g. nozzles (if yes 50%, ...? %)</b>
	use PPP: to inform beekeepers those have bees in radius of 2.5km not later than 48 hours before application.	
Birds and mammals	For pellets and seed treatments: fully insert in to the soil; remove off spills. Other uses: no use during breeding season.	
Soil 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).	

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

Sweden	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, ...? %)
Surface water	<p>In Sweden, adjusted buffer zones are used as a complement to fixed buffer zones to reduce spray drift. The use of buffer zones are regulated in regulation <b>NFS 2015:2</b>, where it is stated that the person who uses pesticides is obliged to establish spray-free buffer zones based on the current conditions on the site (e.g. temperature and wind). In order for the operator to determine adjusted spray-drift buffer zones, "Hjälpredan" ("the helper"= Buffer Zone Calculator) has been developed. The "Hjälpredan" enables pesticide users to decide the size of the buffer zone at the point in time when the pesticide is going to be applied by combining information on current weather conditions and their sprayer configuration.</p> <p>The use of "Hjälpredan" is equivalent to a (fixed) maximum FOCUS step 4 spray-free buffer zone of 15 m in field crops or 20 m in orchards. Consequently, if it is identified in the risk assessment that a FOCUS step 4 spray-free buffer zone up to 15 m in field crops or up to 20 m in orchards is needed, this will result in a condition of use saying that the label shall include a requirement to use "Hjälpredan" in order to calculate and keep proper spray-free buffer zones.</p> <p>"Hjälpredan" (i.e. spray-free buffer zone) is to be used as first option for off-field risk mitigation. If the risk assessment indicates that spray-free buffer zones wider than 15/20 m are necessary in order to maintain a low risk to non-target organisms, "Hjälpredan" is not sufficient. Additional risk management measures may then be needed to fulfil the requirement for authorisation, for example drift-reducing equipment. However, it has to be established that the use of drift reducing nozzles does not impair on the efficacy of the product.</p> <p>More information about the "Hjälpredan" is available at:</p> <p><a href="http://sakertvaxtskydd.se/sv/Bibliotek/Mitigating-spray-drift-in-Sweden1/">http://sakertvaxtskydd.se/sv/Bibliotek/Mitigating-spray-drift-in-Sweden1/</a></p> <p>The surface water mitigation measures that are accepted in Sweden are listed in Table 4.5.3-2.</p>	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%
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 re-	

	quirements 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).	
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## 10 Appendix VI: Template for Aquatic Risk Assessment including mitigation measures

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

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

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

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

<b>Intended use</b>		Winter cereals						
<b>Application regime (single or multiple)</b>		Single application						
<b>Active substances</b>		Substance X and Substance Y						
<b>Organisms</b>		Fish ( <i>O. mykiss</i> ) and aquatic invertebrates ( <i>D. magna</i> )						
<b>Reproductive endpoints for <i>O. mykiss</i> [<math>\mu\text{g/L}</math>]<sup>1</sup></b>		8 $\mu\text{g}$ Substance X/L and 6 $\mu\text{g}$ Substance Y/L or $\text{NOEC}_{\text{mix-CA}}$						
<b>Reproductive endpoints for <i>D. magna</i> [<math>\mu\text{g/L}</math>]<sup>1</sup></b>		6 $\mu\text{g}$ Substance X /L and 4 $\mu\text{g}$ SubstanceY /Lor $\text{NOEC}_{\text{mix-CA}}$						
<b>Assessment factor used in the RAC calculation to derive <math>\text{RQ}_{\text{mix}}</math><sup>2</sup></b>								
<b>Assessment factor used in the <math>\text{RQ}_{\text{mix}}</math> or <math>\text{ETR}_{\text{mix-CA}}</math> calculation<sup>3</sup></b>								
Country	Worst-case combination scenario <sup>4</sup>	Substance	FOCUS step	$\text{PEC}_{\text{SW}} \text{ max}$ ( $\mu\text{g/L}$ )	Mitigation measure	$\text{PEC}_{\text{mix}}^5$	$\text{ETR}_{\text{mix-ca}}$ or $\text{RQ}_{\text{mix}}$	Is risk acceptable?
<b>Fish</b>								
Sweden	D1 stream	Substance X	Step 3		--			Yes/No
		Substance Y	Step 2		--			
Denmark	D3 ditch	Substance X	Step 4		20 m non-spray buffer			
		Substance Y	Step 4		20 m non-spray buffer			
Finland	D4 stream	Substance X	Step 3		--			
		Substance Y	Step 2		--			
Estonia								



Lithuania								
Latvia								
Norway								
<b>Invertebrates</b>								
Sweden								
Denmark								
Finland								
Estonia								
Lithuania								
Latvia								
Norway								

<sup>1</sup> 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

<sup>2</sup> Assessment factor used in RAC calculation will only be relevant if the risk assessment is based on  $RQ_{\text{mix-CA}}$ .

<sup>3</sup> If the risk assessment is based on ETR<sub>mix-ca</sub> calculation the assessment factor should be according to the ETR trigger value. If the risk assessment is based on RQ<sub>mix</sub>, the assessment factor is set to 1.


































<sup>4</sup> 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<sub>mix</sub> and ETR<sub>mix</sub> that shall be presented in the table (not the scenarios with the highest PEC<sub>sw</sub> values for each active substance).

<sup>5</sup> PEC<sub>mix</sub> column will only be relevant if the risk assessment is based on ETR<sub>mix-ca</sub> calculation.




































## 11 Appendix VII: Recommended structure for the documentation

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

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

**Caddy.xml format (dRR format version 2015):**

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

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

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

**Folder structure (dRR format version 2015):**

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