April 2013

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

Version 2.0. This guidance document replaces the version of 1 July 2011 and can be voluntarily applied from April 1st, 2013, and must be applied from October 1st, 2013.

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January 2011	**0.0**	Draft Guidance Document on Work-Sharing in the Northern Zone in the Registration of Plant Protection Products	**DK + expert groups**	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

Content

1 Legal Status

This document does not intend to produce legally binding effects and by its nature does not prejudice any measure taken by a Member State/country within the implementation prerogatives under Annex II, III and VI of Council Directive 91/414/EEC or subsequently Regulation EC 1107/2009, nor any case law developed with regard to these provisions. This document also does not preclude the possibility that the European Court of Justice may give one or another provision direct effect in Member States.

2 Introduction

This document describes a procedure for the submission and assessment of applications for authorisation and re-authorisation of plant protection products following Annex I inclusion of an active substance under Directive 91/414/EEC or its approval under Regulation EC 1107/2009 in the Northern zone.

It has been agreed by the responsible competent authorities in Denmark, Estonia, Finland, Latvia, Lithuania, Norway and Sweden. It is intended that it should be used in the context of the work sharing framework for registration of plant protection products to reduce the workload for both applicants and authorities. Where the transitional measures of Regulation EC 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 authorizations the procedure will be applied on a case by case basis. For applications of new authorizations submitted after 14. June 2011 the provisions of the EU guidance document on zonal evaluation and mutual recognition under Regulation EC 1107/2009 applies.

It should be noted however, that new product applications on-going at the time of adoption of the new Regulation, and re-registration for all existing products containing active substances on Annex I to 91/414/EEC should be assessed in accordance with the transitional measures in Article 80.5 of regulation EC/1107/2009.

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

Since the preparation of dossiers may have started before the details in this guidance document was known to applicants flexibility will be applied, regarding what is put into the core part of the dossier and what should be in national addenda,. Therefore a period of 6 months will be given, until the latest version of this guidance has to be followed.

For the latest updates the transitional period will be 6 months after the release in April 2013, which means by October 2013 at the latest. However, this guidance can be voluntarily followed already after its publication.

Wherever possible, the procedures in this document have been aligned with those in the new Regulation, to allow a smooth transition between the two processes.

3 Procedures

In summary, the procedure is as follows:

The applicant submits the application to all countries where they wish to gain/maintain authorisation. One lead country in the zone– the zonal RMS (ZRMS) will complete the evaluation of a **core dossier** on behalf of the concerned member states (cMS) in the zone.

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

The ZRMS will then finalize the assessment and make it available via CIRCABC. The countries 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 more in detail in chapters 3.3.1 and 3.3.2.

3.1 Zonal steering committee

The zonal steering committee is formed from representatives of the competent authorities of each country in the zone. Contact points are listed in **8 Appendix** IV. According to **SANCO/13169/2010 rev. 7,** 1 February 2013 , the role of the steering group is to

- facilitate communication in work-sharing matters,
- co-ordinate work-sharing activities within and between zones,
- organise the allocation of work to ZRMS
- monitor the work and
- to discuss and solve any general issues relating to the efficiency of the system

The steering committee has regular conference calls approximately every second month and meetings once-twice a year. The steering group is normally chaired by one country for 1 year on a rotational basis. Chairs are responsible for drafting the agendas of the meeting of the steering group, minutes of the meetings as well as updating the list of applications with agreed ZRMS and timelines. The chair of the steering committee is also the primary contact point for the Central and Southern zones. The chair is also a member of the Inter-zonal steering committee.

3.2 Prerequisites for work-sharing

3.2.1 Re-registration for authorised products

The minimum requirement for voluntary co-operation on re-assessment is that the product has a valid authorisation and is intended to be kept on the market in at least 2 countries. Formulations and GAP should be harmonized as much as possible in the countries where re-registration is intended. This will allow a 'risk envelope' approach to the assessment, whereby only the worst case exposure scenarios for each area of the risk assessment are evaluated, with other 'less risky' scenarios being deemed acceptable. Different formulations may be covered by the same risk assessment if bridging studies and scientific justifications are available. Guidance on the 'risk envelope' approach is available at the EU level as detailed in
http://ec.europa.eu/food/plant/protection/resources/risk_envelope_gd_rev_14032011_en.pdf

To facilitate work sharing and the allocation of ZRMS the pre-notification form available at the Competent Authority's official websites
should be completed by the applicant.

3.2.2 New product authorisation

Under the transitional measures of the new Regulation a decision on voluntary work-sharing on applications submitted before June 14th 2011 will be taken on a case by case basis depending on available resources and priorities set in each country. The minimum requirement is that the product is intended to be used in at least 2 countries. Formulations and GAPs should be harmonized as much as possible to reduce the workload.

3.3 Submission of application

3.3.1 Pre-submission notifications

All applicants are requested to submit to a pre-notification at the latest 6 months before submission of the dossier (applies for new applications as well as re-registrations. The pre-notification must be submitted to all concerned MS using the form available at the Competent Authority's official websites should be used.

3.3.2. Re-registration for authorised products

The latest deadline for submission of a full Annex III dossier should be 2 years prior to the final deadline specified in the inclusion Regulation, which should allow time for the full Annex III assessment by the zRMS and for decision making in cMS. Submissions could always be submitted before that deadline, e.g. where early re-registration is sought by the applicants or where countries have specific concerns about particular products or uses.

3.3.3. New product authorisation

The applicant should submit an application to all countries 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 harmonize GAPs as much as possible. This will allow a 'risk envelope' approach to the assessment, whereby only the worst case exposure scenarios for

each area of the risk assessment are evaluated, with other 'less risky' scenarios being deemed acceptable.

Guidance on the 'risk envelope' approach is available at the EU level as detailed in http://ec.europa.eu/food/plant/protection/resources/risk_envelope_gd_rev_14032011_en.pdf

3.4 How is the zonal RMS appointed?

Whilst the applicants preference for choice of ZRMS may be taken into consideration, the decision on ZRMS allocation should take into account the identity of the original RMS for the Annex I consideration (noting that in the Northern zone it will only in few cases be possible to allocate the work to the original RMS), the relevance/importance of the products in each country and the resource availability in each country. The decision will be made by the zonal steering committee.

3.5 Communication with applicants

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

3.5.1 Re-registration for authorised products

Following the compliance check (Step 1 of the re-registration process) all registration holders should submit a pre-notification using the form available at the Competent Authority's official websites.

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

3.5.2 New product authorisation

Applicants are encouraged to make early contact with the respective contact point listed in **8 Appendix** IV: Contact points. A notification 6 months in advance of submission should be done to the proposed ZRMS.
Under the transitional measures of Regulation EC 1107/2009 the following applies:

Following agreement on a work-sharing project for an evaluation of an application in the Steering committee the timeframe for completion of the evaluation of data and submission of the Registration Report with milestones will be decided and the applicant will be informed by the designated ZRMS.

For applications submitted after 14. June 2011 the EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed as well as the North zone guidance document.

3.6 Format for the application

Applicants are requested to submit documentation as specified below and a draft Registration Report, as detailed in **Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009** (latest version)) .

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

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

3.6.1 General requirements are as follows:

(i) **Covering letter**, including brief summary of the application.

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

(iii) **Completeness check** scheme

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

To ZRMS all labels should be submitted.

(v) **Draft Registration Report (DRR) in word format**
- Part A,
- Part B (8 sections) as a Northern zone core,
- Part C
- If applicable, national addenda.

To zRMS Part A and other national addenda for all concerned MS should be submitted.

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

(vii) **Document K-III** – individual test and study reports in accordance with the requirements specified in Annex III. Applicants are encouraged to submit the dossier in Caddy XML format.

(ix) A **justification** if data protection is claimed. The justification shall confirm whether the study has been protected previously in a specific MS or at an EU level (or whether that protection has expired) as required in Article 59 3 of the Regulation.

For uses not considered for Annex I Inclusion, an assessment against Annex I agreed endpoints and by the application of the Uniform Principles is required. Where different or additional endpoints are proposed, these must be supported by appropriate data/information.

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

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

3.7 Evaluation of the dossier

For each application a completeness check is carried out using the completeness check form. 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 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.

Two months after receipt applicants will be informed about the completeness of their applications. For incomplete applications a 4 weeks period is given to complete dossiers. ZRMS should inform the other countries about incomplete dossiers and the new deadline for submitting complete dossiers All new data submitted to zRMS shall also be sent to cMS preferably in one complete sending including all requirements during the evaluation. Where at the end of the period given to complete the dossier the applicant has not submitted the missing elements, the ZRMS will inform the applicant that the application is inadmissible or that the evaluation will be continued with only those uses that can be supported.

For a dossier accepted as complete, subsequent areas of clarification should be resolved between the applicant and 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 Re-registration of Products containing more than one active substance

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

3.9 Commenting procedures

Concerned Member States of the zone should peer review the assessment made by the ZRMS focusing on areas having an impact on decision making, areas of concern pointed out in the inclusion regulation, and on new studies submitted to address data gaps identified in the review report or to cover data requirements for uses that have not been evaluated before. Comments should be submitted using the form in **7 Appendix III – Reporting**

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

It is voluntary for zRMS to ask for comments by the applicant in cases of an application for re-registration and new product registration under transitional measures. According to the EU-guidance on zonal evaluations and mutual recognition under regulation (EC) No 1107/2009 the applicant shall be given the opportunity to comment on factual issues in the core assessment.

3.10 Decision making

The risk assessments and registration reports prepared by one country can 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 **10 Appendix VI: List of mitigation options available in the countries in the** zone

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

3.11 Time lines

3.11.1 Re-registration for authorised products

Following the compliance check (Step I of the re-registration process) registration holders are requested to submit to all cMS the pre-notification form available at:
http://www.mst.dk/NR/rdonlyres/8B69BBC3-96CA-42C4-9485-920DD34FC840/0/Notificationformforzonalapplications2.doc

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

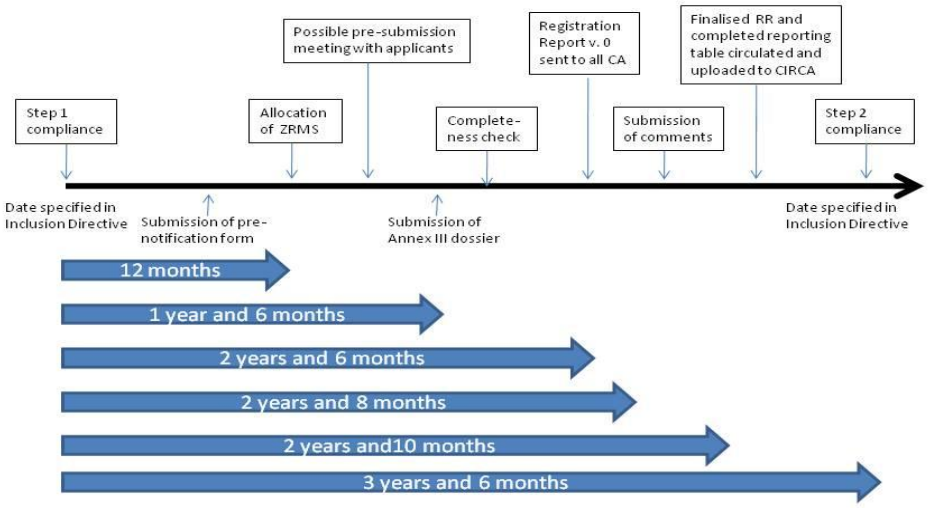
On the basis of the information above a decision by the Steering committee on the allocation of products should be taken at least four months in advance of the expiring date for submission of Annex III dossiers (i.e. see point 5.2.1 of the Guidance document on the procedures relating to plant protection products following inclusion of an existing active substance in Annex I of Council Directive 91/414/EEC).

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

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

Two months after the consultation period has expired ZRMS have updated the core evaluation and prepared a reporting table (see **7 Appendix** III) with all received comments including a remark on whether the comment has been accepted or not. A final version (revision 1) of the Registration Report is prepared with all changes that have been accepted and circulated together with the reporting table to competent authorities of the other countries. It is the aim that a final version of the Registration Report and the reporting table is uploaded on CIRCA for information of all countries eight months before the Step 2 deadline.

SCHEME OF THE PROCESS FOR RE-AUTHORISATIONS



3.11.2 New product authorisations

Under the transitional measures of Regulation EC 1107/2009 the following applies: Submission of an application to more than one country in the zone for an authorization of the same product with the same use will be taken up by the Steering committee. A decision on a work-sharing project will be taken based on 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 two months period is given for the ZRMS to check the completeness of the application.

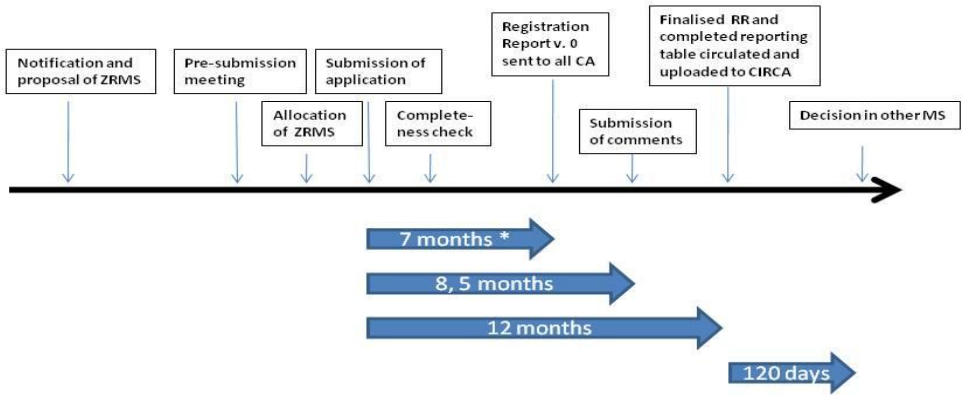
Registration Reports (revision 0) should be submitted by ZRMS to the competent authorities of the other countries seven months after submission of a complete application.

A six weeks consultation period is foreseen during which competent authorities of other countries in the zone and the applicant submit their comments. In case further information/studies are required a maximum six month period is given to the applicant to complement the application.

After the consultation period has expired the ZRMS prepares a reporting table (see **7 Appendix** III) with all received comments including a remark on whether the comment has been accepted or not. A new version (revision 1) of the Registration Report is prepared with all changes that have been accepted and circulated together with the reporting table to competent authorities of the other countries at the latest 12 months after the decision on ZRMS. The Registration Report and the reporting table are uploaded on CIRCA for information to all countries. The other countries with an application for the same authorization should aim at taking a decision within 120 days 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

For applications submitted after 14. June 2011 the EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed.



* Prolonged for a period of maximum 6 months if further data are requested

3.12 Inter-zonal uses

Under the transitional measures of Regulation EC 1107/2009 the following applies:
For uses where no emissions to the environment are expected (e.g. closed greenhouses, post-harvest treatment, empty store houses etc.) the applicant should highlight that **inter-zonal** work sharing may be possible when they notify the zones of their intended submission.

ZRMS in each zone may then coordinate work to ensure that duplication of work in each zone is minimised. Also for products with other uses parts of the evaluation could be used by other zones, e.g. data which are not related to the environmental and agricultural conditions.

For applications submitted after 14. June 2011 the EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed.

3.13 Applications for mutual recognitions

Under the transitional measures of Regulation EC 1107/2009 the following applies:
In principle applications for mutual recognition will be dealt with in the same way as applications for other new authorisations provided that all conditions for an application of mutual recognition are fulfilled.

For applications submitted after 14. June 2011 the EU Guidance document on zonal evaluation and mutual recognition under Regulation (EC) No 1107/2009 should be followed.

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

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

3.14 Provisional authorisations

In principle applications for provisional authorisations will be dealt with in the same way as applications for new authorisations under transitional measures of 1107/2009.

3.15 Withdrawal and amendment of authorization based on zonal evaluations

Under the transitional measures of Regulation EC 1107/2009 the following applies:
Amendments not requiring any evaluation of data (e.g. changes in the trade name, changes in the holder of the authorisation etc.) are handled by competent authorities in the respective country individually without any notifications to the others.

Amendments requiring an evaluation of data (e.g. extension of uses, new manufacturing sites, changes in the manufacturing process, new formulations etc.) should be submitted to the ZRMS only in those cases where a zonal evaluation already took place and the amendment is valid for more than one country within the zone. All countries for which the amendment is valid should also be informed by the authorization holder. In all other cases the application should be submitted to the respective country. The other countries will be informed in the regular zonal Steering Committee meetings.

For applications submitted after 14. June 2011 the EU Guidance document on renewal, withdrawal and amendments under Regulation (EC) No 1107/2009 should be followed.

4 Assessment

Applicants are required to submit a full Annex III dossier as required in Directive 91/414/EEC and subsequently Regulation EC 1107/2009 in the format specified in **Guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009 rev 1 02 October.2009**

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 (relevant to at least 2 countries)
II. National data requirements concerning the specific problems in a country, as indicated in **Appendix V: Summary of national requirements for Annex III dossiers**, have to be respected and data submitted for evaluation in the national addenda
III. An assessment should be conducted by applicants for the identification of worst case use(s)/scenarios. This is the most critical point for the success of the programme. Worst case uses might be different for the various sections of dossiers. It is very important that all worst case uses/scenarios are included in the dossier.

4.1 Identity, physical chemical properties and analytical methods

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

- Manual on development and use of FAO and WHO specifications for pesticides, 2nd revision of the first edition, Rome, November 2010 http://whqlibdoc.who.int/publications/2006/9251048576_eng_update3.pdf
- United nations recommendations on the transport of dangerous goods (UN RTDG) manual of tests and criteria http://www.unece.org/fileadmin/DAM/trans/danger/publi/manual/Rev4/English/01E_intro.pdf
- ECHA guidance on the application of the CLP criteria http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp
- SANCO/3030/1999, rev.4 11 July 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis.
- SANCO/825/2000, rev. 8.1 16/11/2010 Guidance document on pesticide residue analytical methods.
- Guidance document on the finalization of the reference specification for technical active substances after peer review (SANCO/6075 July 2009 rev.3)
- Guidance document on Pesticide Residue analytical methods (Series on Pesticides, No.39, Series on Testing and Assessment; No.72; OECD 2007).
- Chemicals Regulation Directorate DATA REQUIREMENTS HANDBOOK (http://www.pesticides.gov.uk/guidance/industries/pesticides/topics/pesticide-approvals/pesticides-registration/data-requirements-handbook/data-requirements-handbook-contents.htm)
- EU Guidance document on the assessment of the equivalence of technical materials (SANCO/10597/2003, rev. 10.1 13 July 2012)

- Guidance document on significant and non-significant formulation changes SANCO 12638/2011, 20 November 2012[1]

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

Some of the guidance documents listed above are available on the EU Commission website (http://ec.europa.eu/food/plant/pesticides/approval_active_substances/guideline_documents_en.htm)

4.1.1 Identity of the plant protection product (IIIA 1)

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

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

4.1.2 Physical, chemical and technical properties of the plant protection product (IIIA 2)

The dRR should be a standalone document and the result of individual tests and study reports shall be reported in the Phys-Chem properties table for transparency.

The 2 year shelf life study should be carried out in the same material as the commercial packaging. Where it is proposed that a liquid preparation is to be packaged in an intermediate bulk container or a container of size greater than 20 litres, results from a 20 litre container may be used to extrapolate to intermediate bulk containers.

If tank mixing is recommended on the label the physical compatibility should be demonstrated, by ASTM E1518-05 method or equivalent, and reported. Known non-compatibility shall be reported.

4.1.3 Methods of analysis (IIIA 5)

[1] Not accepted in SE. Formulation changes will be assessed on a case by case basis.

Study summaries shall be provided for all analytical methods and only methods relevant for the application shall be provided. 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.

4.2 Toxicology

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

- SANCO/10328/2004-rev 8 (24.01.2012). Guidance Document on the Evaluation of New Active Substance Data Post Approval
- SANCO/221/2000 –rev.10, 25 February 2003. Guidance Document on the Assessment of the Relevance of Metabolites in Groundwater of Substances Regulated Under Council Directive 91/414/EEC
- Guidance on Dermal Absorption, EFSA journal 2012; 10(4):2665

The (draft) Registration Report (SANCO/6895/2009 rev 1 02 October 2009) format should be followed.

Specific national requirements are listed for each country within the Northern zone in **9 Appendix V: Summary of national requirements for Annex III** dossiers and **10 Appendix VI: List of mitigation options available in the countries in the** zone.

4.2.1 Toxicological studies (IIIA 7)

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

4.2.2 Acute Toxicity (IIIA 7.1.1 – 7.1.6)

A short summary of each study should be included.

4.2.3 Exposure

Assessments regarding exposure of operators, workers, bystanders and/or 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. Further refinement of the cumulative risk assessment is needed if the sum of the predicted exposure as % of the AOELs exceeds 100 %. An EFSA opinion on grouping of pesticides for cumulative risk assessment on the basis of their toxicological properties is awaited in May 2013.

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

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

4.2.4 Operator Exposure (IIIA 7.3)

The following exposure models are acceptable:

- UK POEM
- German model (75th percentile)
- Dutch model (greenhouses)
- Seed Tropex model (seed treatment)

As a first tier the models should be used as they are with standard input parameters. As a higher tier, refinements using common Nordic-Baltic areas could be accepted (work rates/day, see section 4.2.9). For all calculations it should be assumed as a default that adults have a body weight of 60 kg.

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

For field studies to be accepted the study should:

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

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

There should be a short summary describing the field study, specifying whether closed cabins are used, personal protective equipment, equipment used for loading etc.

4.2.5 Bystander Exposure (IIIA 7.4)

The following exposure calculations and input parameters are acceptable:

- EUROPOEM II Bystander Exposure to Pesticides or comparable calculations
- Exposed body surface: 2 m^2 for adults and 0.66 m^2 for children
- Duration of exposure: 60 min but refinements can be done in higher tier assessment

- Body weight: 60 kg (adult)

4.2.6 Worker Exposure (IIIA 7.5)

The following exposure calculations and input parameters are acceptable:

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

4.2.7 Dermal Absorption (IIIA 7.6)

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

4.2.8 Assessment of the relevance of metabolites in groundwater

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. A metabolite is considered to be of concern when the concentration is above 0.1 µg/L.

4.2.9 Common Nordic-Baltic areas (work rate/day) used in tier 2 refinements of the core assessment.

Table 4.2.1. Common Nordic-Baltic work rate/day areas used in tier 2.

Crop	**Area**
Cereals, grasses	30 ha
Oil seed rape, potatoes, sugar beet	20 ha
Vegetables (tomato, cucumber, cauliflower)	10 ha
Fruit trees	5 ha
Berries	5 ha
Ornamentals, field, tractor mounted application, green house, hand held application outdoors	1 ha
Amateur hand held application outdoors	0.1 ha

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

4.3 Residues

The applicant should write a separate draft registration report (dRR) for the northern zone only instead of a core dRR for whole EU. The GAP and the residue data should reflect the intended use in the northern zone.
Headlines not mentioned in this guidance document should be dealt with in accordance with the guidance document on the presentation and evaluation of dossiers according to annex III of Directive 91/414/EEC in the format of a (draft) Registration Report (SANCO/6895/2009 rev1 from 2 October 2009).

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

- The "Lundehn guidelines":
- SANCO/7028/VI/95 rev.3. 22 July 1997. Appendix A – Metabolism and distribution in plants
- SANCO/7029/VI/95 rev. 5. 22 July 1997. Appendix B – General recommendations for the design, preparation and realization of residue trials
- SANCO/7524/VI/95 rev. 2. 22 July 1997. Appendix C – Testing of plant protection products in rotational crops
- SANCO/7525/VI/95 rev. 9. 01 March 2011. Appendix D – Comparability, extrapolation, group tolerance and data requirements
- SANCO/7035/VI/95 rev. 5. 22 July 1997. Appendix E – Processing studies
- SANCO/7030/VI/95 rev. 3. 22 July 1997. Appendix F – Metabolism and distribution in domestic animals
- SANCO/7031/VI/95 rev. 4. 22 July 1996. Appendix G – Livestock feeding studies
- SANCO/7032/VI/95 rev. 5. 22 July 1997. Appendix H – Storage stability of residue samples
- SANCO/7039/VI/95 EN. 22 July 1997. Appendix I – Calculation of maximum residue levels and safety intervals

Specific national requirements are specified for each country in **9 Appendix V: Summary of national requirements for Annex III** dossiers.

4.3.1 Stability of residues

Information on storage stability shall be included as well as the storage period between harvest and analysis in the residue trials. Alternatively, indicate whether the analyses have been performed within the period given for storage stability.

4.3.2 Studies on metabolism in plants or livestock

Insert brief summary of metabolism, distribution and expression of residue data in plants and livestock or cross reference to EU review. It shall be mentioned in which commodities and animals the metabolism studies are performed. Also unresolved problems/items from the EFSA conclusion report shall be mentioned as well as how they are solved, e.g. new studies.

Residue definitions currently in place for both monitoring and risk assessment shall be mentioned and a reference included. If there is a conversion factor from the residue definition for monitoring to risk assessment the factor shall be stated.

4.3.3 Residue trials (supervised field trials)

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

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

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

4.3.4 Livestock feeding studies

Insert brief summary of livestock feeding studies. If studies are not necessary (see guidance document SANCO/7031/VI/95) an explanation shall be given.

4.3.5 Studies on industrial processing and/or household preparation

Insert brief summary of studies on industrial processing and/or household preparation. If studies are not necessary (see guidance document SANCO/7035/VI/95) an explanation shall be given.

4.3.6 Studies for residues in representative succeeding crops

Insert brief summary of studies for residues in representative succeeding crops. If studies are not necessary (see guidance document SANCO/7524/VI/95) an explanation shall be given.

4.3.7 Estimation of Exposure Through Diet and Other Means

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

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

In addition that the evidence should be scientific, no guidelines exists as to how consumer safety should be assessed. Currently most widely used method is PRIMo, in which each MS can use dietary intakes based on their national diets. An example of other methods used along with PRIMo is the German VELS model. Deterministic methods have been proven useful to demonstrate the consumer safety for a use or uses of any given plant protection product and are currently the method of choice. Meanwhile probabilistic approaches have gained more and more interest and can be used in addition, where desired, in order to build up more experience on such methods for the future.

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

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

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

In case new national data are to be employed for the NESTI and NEDI assessments, such national requirements shall be specified for each country in **9 Appendix V: Summary of national requirements for Annex III** dossiers**.**

4.4 Efficacy

The guidance for the efficacy section is available at
http://agro.au.dk/forskning/myndighedsraadgivning/vejledning-vedr.-krav-til-effektivitetsdata/

Specific national requirements are specified for each country in **9 Appendix V: Summary of national requirements for Annex III** dossiers**.**

4.5 Environmental Fate and Behaviour

Disclaimer: *This guidance is for assembling a core assessment and does not fully cover the various national requirements for risk assessments. In some cases specific national guidance must be consulted additionally. Specific national requirements are presented in* **9 Appendix V: Summary of national requirements for Annex III** dossiers**.**

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

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

- SANCO/221/2000 rev.10 (final). 25 February 2003. Guidance document on the assessment of the relevance of metabolites in groundwater of substances regulated under council directive 91/414/EEC[3].
- SANCO/10058/2005 version 2.0 (final). June 2006. Guidance Document on Estimating Persistence and Degradation Kinetics from Environmental Fate Studies on Pesticides in EU Registration.
- SANCO/4802/2001 rev.2 (final), version 1.2. December 2012. Focus surface water scenarios in the EU evaluation process under 91/414/EEC.
- SANCO/321/2000 rev.2. November 2000. FOCUS groundwater scenarios in the EU review of active substances.

For the time being the following has been agreed:

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

4.5.1 Soil

For the core assessment PEC_{soil} should be calculated using the Nordic PEC-calculator. The Nordic PEC-calculator is estimated to be released in mid-2013. Until then the Finnish PEC-calculator should be used.

For substances with non-SFO degradation pattern, other appropriate models should be used.

In the latter case PEC_{ini} and PEC_{twa} shall be calculated using worst case DT_{50} field (non-normalized). If no representative field data are available a worst case DT_{50}lab normalized to 10˚C should be used.

$PEC_{plateau}$ shall be calculated as follows:

For the baseline plateau representative DT_{50}field (worst case, non-normalized) or worst case DT_{50}lab normalized to 6˚C shall be used together with a soil depth of 20 cm if tilling is applicable, otherwise
5 cm.

For the last year of the $PEC_{plateau}$-calculations though, the same parameters as for the calculations of PEC_{ini} shall be applied, i.e. a worst case DT_{50}field (non-normalized) or DT_{50}lab normalized to 10°C and a soil depth of 5 cm.

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

The Finnish PEC_{soil}-calculator provides the accumulated level of the active substance in a 5 cm soil horizon. If required and justified by common tilling practice in the crop concerned, the incorporation of the active substance into 20 cm soil may be considered as a refinement option. Examples of crops where this refinement cannot be used are no-tillage farming systems, orchards and golf courses.

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

An acceptable estimate of the refined $PEC_{plateau}$ for tilled soil is 0.25 x $PEC_{plateau}$ (5 cm, baseline/lower part of curve) and adding the final year application(s) of chemical to the top 5 cm soil. Hence it is assumed that no tilling is performed the final year.

In the Nordic PEC-calculator, to be released in mid-2013, $PEC_{plateau}$ and tilling considerations will be provided.

Only $PEC_{initial}$, $PEC_{21\ day\ TWA}$, PEC_{max} and $PEC_{plateau}$ should be reported and used in risk assessments. If other $PECT_{WA}$ are applied for the ecotoxicological risk assessment, these should additionally be reported. If field studies are used it must be justified that these are relevant to Northern zone member state conditions (among others, with regard to soil type, pH and climate). Field studies must comply with the CTB checklist[4] for assessing whether a field study on pesticide persistence in soil can be used to estimate transformation rates in soil.

National cut-off criteria:
DK: For approval, DT_{50} must be < 6 months. Please consult the Danish Framework for Assessment of Plant Protection Products for details about the persistence cut-off: http://www.mst.dk/Virksomhed_og_myndighed/Bekaempelsesmidler/Pesticider/Ansøger+efter+den+14.11.06/Zonegodkendelse/vurderingsrammer.htm
NO: For approval of non-professional use: When evaluating such products persistence is especially important. Products that have a mean DT_{50}lab in soil of more than 100 days will not be authorized for outdoor use.

4.5.2 Ground water

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

The core assessment should contain all national scenarios for the countries where authorisation is applied for as listed in Table 1.1.2-1. Data requirement may be revised after finalization of the Nordic-Baltic groundwater scenario project.

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

Table 4.5.1. National requirements for PECgw simulations.

Country	Country specific approach	Country specific approach needed:
FI:	**PEARL** 4.4.4 OR **PELMO** 4.4.3 Hamburg & Jokioinen	
DK:	**PELMO 4.4.3** Hamburg OR **MACRO** Karup and Langvad. As input the following shall be used: 80th percentile for the degradation (not geomean DT_{50}), 20th percentile for K_{foc} and 80th percentile for 1/n (not arithmetic) and number of years that exceed 0.1 µg/l out of 20 years as output (not 80th percentile). Further guidance available at www.mst.dk	- if it is clear from **PELMO 4.4.3** Hamburg that there is a risk of leaching (> 0.001 µg/L) for the uses applied for. All metabolites need to be covered by the assessment. Only 1 year out of 20 may exceed 0.1 µg/l

Country	Country specific approach	Country specific approach needed:
SE:	**MACRO**[5] Önnestad, Krusenberg and Näsbygård For the Swedish scenario Näsbygård several simulations with different starting dates are required if the K_{OC} < 500 L/kg and the DT_{50}soil < 50 days (modeling endpoint). These simulations shall cover the earliest and latest possible treatment period applied for, as well as additional treatment periods in between if the time interval between the first and the last treatment period is more than 40 days. The time interval between the starting dates of the simulated treatment periods shall not exceed 30 days. If only a single simulation is required, the starting date of the simulated treatment period has to be chosen to represent a worst case situation considering contamination of groundwater.	- if risk for leaching to groundwater is an area of concern pointed out in the EU review report - if groundwater levels from **PEARL**[6] OR **PELMO 4.4.3** Hamburg > 0.01 µg/l for active substance and relevant metabolites or > 1.0 µg/l for non-relevant metabolites - if the K_{oc} >100 L/kg. The conditions apply independently of each other.

[5] Until a revised FOCUS MACRO package is released (see the FOCUS webpage), both MACRO 4.4.2 and MACRO 5.5.3 are accepted. FOCUS_MACRO v 5.5.3 users need to manually replace the value 0.7 with 0.49 for the 'exponent for moisture response' parameter in the 'pesticide properties' and 'pesticide metabolite properties' input screens of the MACRO shell, before executing MACRO runs. For more information, see the FOCUS webpage.

[6] In applications after 11 April 2012, PEARL 4.4.4. simulations are required.

Country	Country specific approach	Country specific approach needed:
NO:	**MACRO** Norwegian scenarios Heia and Rustad Relevant files and background information is available at www.mattilsynet.no	- if risk for leakage to groundwater is an area of concern pointed out in the EU review report - if groundwater levels from **PEARL**[6] OR **PELMO 4.4.3** Hamburg > 0.01 µg/l for active substance and relevant metabolites or > 1.0 µg/l for non-relevant metabolites - if the K_{oc} >100 L/kg. The conditions apply independently of each other.
LV:	**PEARL** 4.4.4 OR **PELMO** 4.4.3 Hamburg & Jokioinen	
LT:	**PEARL** OR **PELMO 4.4.3** Hamburg for active substance and metabolites. As input the following shall be used: 80th percentile for the degradation (not mean DT_{50}), 20th percentile for K_{foc} (not mean) and 80th percentile of output.	- if risk for leakage to groundwater is an area of concern identified in the review report.
EE	**PEARL** 4.4.4 OR **PELMO** 4.4.3 Hamburg & Jokioinen	

Table 4.5.2. Example of summary table for the PECgw results.

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

Modelling endpoints in accordance with FOCUS degradation kinetics report (SANCO 10058/2005 v2.0) should be used. All input values used for the simulations have to be reported.

When using field DT_{50} values as model input, an evaluation of the representativeness and of the appropriateness of the data for modelling purposes according to CTB criteria[7] and to chapter 9 in FOCUS degradation kinetics (Sanco/10058/2005, version 2.0, June 2006) must be performed.

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

If one or both of the limit values (0.1 µg/L for each individual substance and 0.5 µg/L for the sum of substances) are exceeded, the product cannot be approved for the proposed use, unless other studies (e.g. lysimeter studies, field studies, and/or monitoring data) convincingly demonstrate that unacceptable leaching will not occur in a Northern Zone context. When evaluating such studies, consideration must be given to whether soil properties, climate conditions and application (crops, vegetation cover, application method, formulation of the product, dose and time of application) correspond to Northern Zone conditions.

4.5.3 Surface water

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

PECsw is to be calculated with the FOCUS STEP3 scenarios D1-D4 and R1-R3 in accordance with the country specific requirements (Table 1.1.3-1).

Step 2 PEC calculations are sufficient for parents and metabolites IF the resulting TER-threshold values for aquatic ecotoxicology are exceeded by a factor of 10.
For DT_{50} in soil, sediment and water, modelling endpoints in accordance with the FOCUS degradation kinetics report (SANCO 10058/2005 v2.0) should be used. 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 countries where authorisation is applied for:

Table 4.5.3. Country specific requirements for FOCUS scenarios considered in the assessment of surface water and sediment exposure.

Country	Scenarios						
	D1	D2	D3	D4	R1	R2	R3
Denmark			X	X			
Estonia	X		X	X	X		
Sweden	X			X	X		
Norway	X	X	X	X	X	X	X
Lithuania	X		X	X	X		
Latvia	X		X	X	X		
Finland	X			X	X		

Table 4.5.4. Accepted width of spray free buffer zones, vegetated filter strips for run-off mitigation and acceptance of usage of drift reducing nozzles in the countries of the Northern zone.

Country	Spray free zones to mitigate drift (m)								
	2	10	15	20	30	40	50	Runoff	Drift reducing nozzles
Denmark	F	F		F	V		O		
Estonia					FVO				
Sweden			F	O				10	*yes*
Norway					FVO				
Lithuania				F		O		10	
Latvia					F	O			
Finland				F	B		O		*yes*

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

The documentation must be well structured and transparent in order to demonstrate which scenarios and mitigation measures are relevant for each country. It should be clear which PECsw are to be used in the aquatic risk assessment. An example of a summary table is given in Table 1.1.2-2.
In addition, the TOXSWA output files should be provided.

Table 4.5.5. Example of a summary table for the obtained maximum PECsw [µg/L] and PECsed [µg/kg] which are to be used in the risk assessment.

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

S = single application, M =multiple applications

For products containing more than one active substance, mixture toxicity assessment must be performed in addition to the single compound TER calculations. These calculations shall combine the global maximum PECsw for all active substances in the product. If required the calculations may include the consideration of non-coinciding of peak maxima in time, but still ensuring that realistic worst case PECsw combinations of the substances in terms of resulting TER (mix) values are captured. The choice of combinations of PECsw must be clearly motivated and presented in the fate section. For more details it is referred to the corresponding sections in the Ecotoxicological part of this guidance document.

4.5.4 Monitoring data

Available monitoring data from the zone concerning fate and behavior of the active substance and relevant metabolites, degradation and reaction products should be reported. The data might be used in support of the groundwater and surface water modelling.

4.6 Ecotoxicology

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

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

- SANCO/3268/2001 rev. 4 (final). 17 October 2002. Guidance Document on Aquatic Ecotoxicology in the context of the Directive 91/414/EEC.
- SANCO/10329/2002 rev. 2 final. Guidance Document on Terrestrial Ecotoxicology. Under Council Directive 91/414/EEC.
- Guidance of EFSA Risk assessment for birds and mammals. EFSA Journal 2009; 7(12) 1438.
- Pesticide Risk Assessment for Birds and Mammals. Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009, 23 January, 2013.

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

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

National requirement (Denmark): Specific requirements for persistent substances[8]; 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, available on the Danish EPA homepage).

4.6.1 Mixture toxicity

If it has not been demonstrated that only one active substance is contributing to the product's potential acute or long-term toxicity, combination effects should be accounted for in the core assessment. In the following situations combination effects must be considered:

- If the product contains more than one active substance,
- if the product contains toxic formulants,
- if the active substance produce metabolites of similar toxicity as the parent substance,
- if the active substance produce metabolites with similar mode of action or with common adverse effects as the parent substance.

[8] Persistent active substances can affect the environment over long periods of time as such substances can be distributed and accumulated within and outside the areas in which they are used. Persistent substances constitute a long-term and difficult-to-quantify risk of spreading in the environment and effects on organisms (standard ecotoxicological endpoints may now capture the full effects of prolonged exposure). Persistent substances can also cause effects on and lead to residues in subsequent crops. This also applies to the metabolites of an active substance.

For areas where there is no test of the product, cumulative risk for ecotoxicological effects for relevant groups of organisms should be calculated based on the model of concentration addition using the following equation:

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

If SUM < 1 the risk assessment is acceptable.

Where:
Trigger-value represent the uncertainty factor of chemical A, B etc. For standard assessment this is equal to Uniform Principle trigger (e.g. 100 for acute risk assessment of fish).

TER is the Toxicity Exposure Ratio calculated from the effect concentration (EC50, NOEC) divided by the Predicted Environmental Concentration (PEC).

For aquatic organisms SUM is calculated for each taxonomic group (i.e. fish, crustaceans, algae and aquatic plants) for the most sensitive organisms or for mesocosms using the overall NOEC.

For birds and mammals the guidance in appendix B of Guidance of EFSA Risk assessment for birds and mammals (EFSA Journal 2009; 7(12) 1438) can be used.

4.6.2 Non-professional use/Home gardens

No harmonized approach for risk assessments of non-professional/home garden products have yet been agreed within the Northern zone. Therefore, the risk assessment needs to follow national requirements and will be assessed at a member state level. The risk assessment should therefore be presented in the national addenda. If an assessment for agricultural use is presented, the assessment should also include a bridging statement clarifying how the agricultural use can be considered to cover the use in home gardens. It should be considered if the risk mitigation measures for agricultural use are applicable and/or necessary for the home garden use.

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

4.6.3 Birds and mammals

The risk assessments for birds and mammals should be presented in the core assessment. The EFSA guidance document for birds and mammals (EFSA Journal 2009; 7(12)

1438) should be used for the assessments [9] with a few amendments. If a product will be used in late growth stages of maize (BBCH 30), the bird species willow warbler has to be added to the package of species presented in the EFSA guidance document. The reason for this is that this species is frequently detected in late growth stages of maize in the Northern Zone and it is not covered by the species presented in the EFSA guidance document.

When refinements of the risk assessment are necessary, the new Northern Zone higher tier document (Pesticide Risk Assessment for Birds and Mammals, Selection of relevant species and development of standard scenarios for higher tier risk assessment in the Northern Zone in accordance with Regulation EC 1107/2009, 23 January, 2013) can be used and should be used from 1st of October 2013.

Link to the Birds & Mammals Guidance Document:
http://www.mst.dk/NR/rdonlyres/9DC03E57-EE43-4899-A5C4-7BF408C58CC7/0/BirdsandmammalshighertierriskassesmentNorthernZone20130123ver1.docx

Link to the calculation spreadsheet: http://www.mst.dk/NR/rdonlyres/3AA92121-F049-4448-8442-089C2B5318A2/0/Spreadsheetbirdandmammals2013.xls

4.6.4 Aquatic ecosystems

In the core assessment a table containing all relevant FOCUS PEC SW and PEC SED (see section 4.5.3) and corresponding TERs should be included.

In the risk assessment, toxicity data from the technical active substance or toxicity data from formulation studies could be used. As a general rule, the lowest available endpoint (expressed in terms of active substance) should be used in the risk assessment. For products with one active substance, the following should be followed:

1) Formulation less toxic than technical active substance, based on active substance content; The active substance endpoint should be used in the aquatic risk assessment.
2) Formulation more toxic than technical active substance (due to additives in the formulation that increases the toxicity compared to the active substance):
   a) Acute risk assessment; the risk assessment should be based on toxicity of the formulation and exposure considering only spray drift. In addition, a risk assessment using toxicity of the active substance and full FOCUS simulations should be provided, to take account of all potential exposure routes.
   b) Chronic risk assessment; If it is a single application, the risk assessment should be based on toxicity data and FOCUS simulations for the active substance. In the case of multiple applications, the risk assessment should be based on formulation toxicity data and exposure estimates based on spray drift only. In addition a chronic risk assessment using toxicity of the active substance and full FOCUS simulations should be provided.

For products containing more than one active substance, mixture toxicity assessment must be performed in addition to the single compound TER calculations (see section 4.6.1).

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

These calculations shall combine the global maximum PECsw for all active substances in the product (see section 4.5.3).

For certain herbicides (those that are used against dicotyledonous weeds), tests on dicotyledonous macrophytes are required in addition to the standard laboratory tests on *Lemna sp.* This is also pointed out in the Guidance Document of Aquatic Toxicology (Sanco/3268/2001 rev.4 (final), 17 October 2002).

If refinements are needed in the aquatic risk assessment, the following refinement options could be used in the core assessment:

Refinement of the exposure by different risk mitigation options

For the core assessment risk mitigation by spray drift buffer zones are accepted (see Member State specific buffer zones in section 4.5.3). Other nationally specific mitigation options (run-off reduction and spray drift reducing nozzles) are accepted in some Member States. TER calculations based on these mitigation options should also be presented in the core assessment. The documentation must be well structured and transparent in order to demonstrate which scenarios and mitigation measures that 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, the risk should always be presented in a tiered approach, with the first tier of the risk assessment based on the initial/maximum PEC values.

For the higher tier assessment, a scientifically based justification for the use of PEC_{TWA}, for each group of organisms, must be submitted. This statement must demonstrate that time weighted concentrations are more appropriate measures for the observed effects than initial/maximal concentrations. It is important to show that peak exposures do not cause the negative effects in the organisms. It is also important to consider time to onset of effect and implications of multiple applications when using a TWA- approach.

If the criteria above are fulfilled the default TWA period should be 7 days in the core assessment. For national assessments a longer TWA period may be accepted. However, the length of the TWA period should never be longer than the duration of the study that triggered the refined assessment or longer than the life stage of concern.

Refinement with mesocosms

Mesocosm studies (including "old" mesocosms for which a LoEP value already is available) should always be reported and evaluated according to RIVM guidance document[10] and presented in the core dossier. However, the effect class method described in the RIVM document should not be used. The NOEC and an assessment factor of 2-3 for a high quality representative study should be used in the core risk assessment. Additionally, the NOAEC (with 4 weeks recovery) should be identified and used in the core risk assessment together with an assessment factor of 5 to cover for the national requirements of Denmark.

Refinement when more species than required have been tested

There are two possible options to refine the toxicity data if more species have been tested than what is required by the Regulation (EU) No 545/2011. These two methods include; 1.) the use EFSA opinion (The EFSA Journal, 2005, 301, 1-45) and 2.) the use of

[10] RIVM Report 601506009/2008A. Guidance for summarizing and evaluating aquatic micro- and mesocosm studies. F.M.W. de Jong, T.C.M. Brock, E.M. Foekema, P. Leeuwangh

Lower Limit Hazardous Concentration 5 % (LL HC5) from a species sensitivity distribution. A compilation of when the two different methods are considered acceptable is presented below (for further details, see text below).

Table 4.6.1. Method accepted (marked with X) in the Northern zone for refinement of toxicity data when more data than required is available:

Aquatic organism	Acute/Chronic	EFSA Opinion[1]	LL HC5
Algae		X[2]	X
Aquatic plants		X[2]	X
Invertebrates	Acute	X	X
	Chronic		X
Fish	Acute	X	
	Chronic		

[1] The EFSA Journal, 2005, 301, 1-45

[2] Only method 1-2 described in the EFSA Opinion is acceptable

EFSA Opinion (The EFSA Journal, 2005, 301, 1-45): If more species are tested than what is required then the method 1-5 as described in the EFSA opinion can be used to refine the acute risk assessment for invertebrates and fish in the core assessment[11]. For algae and aquatic plants the EFSA method 1-2 can be used. When calculating the AFspecies (method 3-5) a mean fraction of species whose endpoint would be exceeded (MFE) of 5 % should be applied (table 6 in EFSA Opinion). The AFother = 10 is maintained for the risk assessment. In case of method 4, the table 7 in the EFSA opinion cannot be used. Instead the constants α_0 och λ_0 must be calculated for the substances considered relevant with respect to the toxicity exerted by the substance of interest.

The EFSA Opinion cannot be used for the chronic risk assessment of fish and invertebrates. The reason is that further research on whether the measurement errors in the NOECs roughly follows a normal distribution is needed before the use of a geometric mean (method 1) or similar (method 2) can be recommended, as is stated in the EFSA guidance document for Birds and mammals (EFSA Journal 2009; 7(12):1438). Regarding EFSA methods 3-5, no recommendation of which part of the assessment factor that can be attributed to the variation in sensitivity between species can currently be made. Hence, the EFSA Opinion cannot yet be used for chronic risk assessment of invertebrates and fish.

Lower Limit Hazardous Concentration 5 % (LL HC5) from a Species sensitivity distribution: The results presented in Brock et al.[12] indicates that LL HC5 in general provides a similar level of protection as the NOEC from microcosms with invertebrates, algae and aquatic plants with an assessment factor of about 3. In the core assessment a LL HC5 can therefore be used to refine both the acute and chronic risk assessment for algae, aquatic plants and invertebrates and compared to a PEC without the application of an assessment factor. It has to be decided in a case by case manner if a LLHC5 based on acute LC50 data also covers the chronic risk assessment. It can in general be considered to cover the chronic risk if the substance is acting and dissipating fast, with a DT50 in water of less than 1 day and if the treatment is a single application. However, if it can be assumed that the substance has a mode of action inducing long term effects which will not be observed in an acute study (for example IGRs) then a LLHC5 based on LC50 will not cover the chronic risk assessment.

[11] The EFSA methods 1-2 are not accepted by Denmark – the assessment factor will be lowered based on further studies – but on a case to case basis based on the available data.

[12] Brock, TCM, et al. 2006. Aquatic risks of pesticides, ecological protection goals and common aims in Europen Union legislation. 2006, Vol. 2, pp. 20-46

There is not enough scientific evidence showing that an adequate level of protection is maintained if the risk assessment for fish is refined using a LL HC5. Therefore this method cannot be used for a refinement of the risk to fish.

Refinement by using studies including sediment

The advice given in the "Opinion of the PPR Panel on a request from EFSA related to the evaluation of dimoxystrobin" (The EFSA Journal (2005) 178, 1-45) should be followed for evaluation of studies that include sediment (i.e. the exposure profile in the experiment needs to be compared to that from the FOCUS simulations). Therefore graphs of the exposure profile in the study as well as from the FOCUS simulations should be included in the core dossier. It is also important to evaluate if the study conditions were acceptable (e.g. sediment-water ratio). The measured water concentrations, and not nominal concentrations, should be used to determine the toxicity endpoint from the study.

4.6.5 Bees

In the core assessment a first tier risk assessment using HQ acute oral and HQ acute contact should be presented. If necessary, also a higher tier risk assessment should be presented, including the evaluation of higher tier studies, e.g. semi-field or field studies.

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

A common mitigation option for all countries is the restriction in timing of application, this mitigation measure can therefore be used in the core assessment. However the countries differ in their view on whether flowering weeds should be considered when restrictions on application in flowering stages are implemented as mitigation, see **10 Appendix VI: List of mitigation options available in the countries in the** zone.

4.6.6 Non target arthropods

In the core assessment, first tier in-field and off-field risk assessments using HQ (ESCORT 2; standard lab glass plate studies) and 30 % trigger approach (Regulation (EU) No 546/2011; standard lab glass plate studies) should be presented. If necessary, higher tier studies should be presented and evaluated against the 50 % trigger value for negative effects.The evaluation of field studies and the higher tier risk assessment should also be presented in the core assessment.

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 **10 Appendix VI: List of mitigation options available in the countries in the** zone). If further mitigation (i.e. other than buffer zones) is needed, the risk assessment implementing nationally specific mitigation options should be presented in the national addenda.

4.6.7 Earthworms and other soil organisms

In the core assessment a first tier risk assessment using laboratory data should be presented. If required also a higher tier risk assessment based on higher tier field studies could be presented and evaluated in the core assessment. The field studies should be evaluated following the guidance given in part 2 of the document by de Jong *et. al* (A

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

4.6.8 Non target plants

In the core assessment a risk assessment in accordance with the terrestrial guidance document (SANCO/10329/2002 rev 2 final) should be presented. If required, non-spray in field buffer zones of 5, 10, 15 and 20 m could be used as risk mitigation measure. See **10 Appendix VI: List of mitigation options available in the countries 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.

5 Appendix I: Form to notify zones of intended authorisation activity

Please use the pre-notification form available at:

http://www.mst.dk/NR/rdonlyres/8B69BBC3-96CA-42C4-9485-920DD34FC840/0/Notificationformforzonalapplications2.doc

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

Please use the pre-notification form available at:

http://www.mst.dk/NR/rdonlyres/8B69BBC3-96CA-42C4-9485-920DD34FC840/0/Notificationformforzonalapplications2.doc

7 Appendix III – Reporting table

Active substance:
Trade name/Formulation type:
Rapporteur:

Annex III point	Country	Comment	Reply rapporteur	Accepted Yes/No

8 Appendix IV: Contact points

Pre-notifications and applications should be submitted to:

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

[13] Address for transfer of documentation: Norwegian Food Safety Authority, National Registration Section, Moervn 12, N-1430 Ås, Norway.

CONTACT POINTS OF FOR STEERING COMMITTEE IN THE NORTHERN ZONE

MS	CONTACT POINT
Denmark	**Title:** Coordinator for National Approvals **Name:** Vibeke Møller **Authority:** Danish EPA **Address:** Strandgade 29, 1401 Copenhagen K, Denmark **Tel:** + 45 72544578 **E-mail:** vm@mst.dk
Estonia	**Title:** Chief specialist of Plant Protection Department **Name:** Rain Reiman **Authority:** Estonian Agricultural Board **Address:** Teaduse 2, Saku 75501 Estonia **Tel:** +372 6712 653 (direct) (ext. 612 for teleconference) **E-mail:** rain.reiman@pma.agri.ee
Finland	**Title:** Senior Officer **Name:** Heini Paloheimo **Authority:** Finnish Safety and Chemicals Agency (Tukes) **Address:** P.O. Box 66, FI-00521 Helsinki, Finland **Tel:** +358 29 5052000 **E-mail:** Heini.Paloheimo@tukes.fi
Iceland	**Title: A**dvisor **Name:** Bjorn Gunnlaugsson **Authority:** Environment Agency of Iceland **Address:** Sudurlandsbraut 24, 108 Reykjavik **Tel (direct):** 00354 5912082 **E-mail:** bjorngunn@ust.is
Latvia	**Title:** Director of Plant Protection Department **Name:** Inese Margevica **Authority:** State Plant Protection Service **Address:** Lielvardes iela 36/38, Riga, LV-1006 **Tel:** 00371 67185478 **E-mail:** Inese.Margevica@vaad.gov.lv
Lithuania	**Title: :** Deputy head of Plant Protection products authorization division **Name:** Kristina Valioniene **Authority:** State Plant Service under Ministry of Agriculture **Address:** Ozo str.4A, LT-08200 Vilnius, Lithuania **Tel:** +370 5 26 24 940 **E-mail: :** kristina.valioniene@vatzum.lt
Norway	**Title:** Head of Section **Name:** Tor Erik Jörgensen **Authority:** Norwegian Food Safety Authority **Address:** P.O.Box 3, N-1431 Ås **Tel:** +47 64944393 **E-mail:** tejor@mattilsynet.no
Sweden	**Title:** Head of unit **Name:** Johan Axelman **Authority:** Swedish Chemicals Agency **Address:** P.O. Box 2, SE-172 13 Sundbyberg, Sweden **Tel:** +46 8 519 41 348 **E-mail:** johan.axelman@kemi.se

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

Denmark				
Section	**Supplementary requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
Toxicology	• The Danish EPA use the German model with the geometric mean when calculating the operator exposure. • Usually the AOEL determined in EU is appropriate, however if there are critical effects and when applying extra assessment factors the AOEL is lower than the one in the DAR, then the lower one is used. The extra assessment factors are 3 for reprotoxicity/ter-atogenicity and 5-10 for carcinogenicity. • The reduction factor for gloves while mixing and loading is 90 % and 60 % while spraying. The reduction factor for full body safety equipment is 50 %. • Non-professional users will use handheld spray		Yes Danish/English	Danish: http://www.mst.dk/Virksomhed_og_myndighed/Bekaempelsesmidler/Pesticider/Ansøger+efter+den+14.11.06/Zonegodkendelse/vurderingsrammer.htm English: http://www.mst.dk/English/Pesticides/Applications+for+authorisation+after+14+June+2011/Evaluation+framework/

Denmark				
Section	**Supplementary 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**
	equipment, have no PPE and work for one hour/d. Products that are acute toxic can not be approved for non-professional use. • Products which are corrosive, Carc./ Mut. Categori 1 and 2 (categories 1a and 1b according to the CLP regulation) can not be approved for non-professional use. Dk does not accept the EU definition of non-relevance of metabolites.	Therefore PECgw calculations demonstration limit values < 0.1 ug/L are needed for all metabolites that are not inherently non-relevant (see guidance under fate)		
Residues	Dossier must cover Danish conditions			
Efficacy	Dossier must cover Danish conditions. Bridging studies required for similar products.			
Fate and behaviour	Specific persistency assessment Specific groundwater modelling – including all metabolites	DT50 soil < 6 months – otherwise no approval The following requirements should be included in the core assessment: Makro Danish scen. or PELMO Hamburg + specific input and output values All metabolites that are not inherently	Yes Danish/English	See above

Denmark				
Section	**Supplementary requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		non-relevant needs to be covered by the assessment.		
Ecotoxicology	Specific aquatic risk assessment Higher tier guidance on risk assessment for birds and mammals Specific requirements for persistent substances	Specific assessment principles for mesocosm studies Danish scenarios and spreadsheet for calculation available Field effect studies for substances with DT50 soil between 3 and 6 months	Danish/English	See above

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

Finland				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	NO			
Toxicology		Exposure assessment: The operator exposure assessment is done mainly by using EUROPOEM I, but when needed, UK POEM and German model can be exploited. Non-professional use: Authorization of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be authorized for non-professional users if those have any of the following characteristics: - Product is acutely toxic or very toxic - Product is carcinogenic, toxic to reproduction or mutagenic - The operator exposure (without personal protective equipment) under the proposed conditions of use exceeds the AOEL.	No	
Residues	NO			
Efficacy	Dossier must cover Finnish conditions			
Fate and behaviour	NO	The following requirements should be included in the core assessment:	Fate and behaviour	**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**
		PECsoil should be calculated by using the Finnish PECsoil calculator		
Ecotoxicology	NO			

Latvia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	**NO**			
Toxicology	**Yes**	The following products can not be accepted for non-professional use: -classified with any of the following R23–R28; R40;R45;R49;R46; R68;R60; R61; R62; R63; R41; R64; R48; R33 -or if classified with CLP equivalents as indicated in the National Regulation No.509 from point 11.2.1 to 11.2.10. - if operator risk during use of PPP or after it when not using individual personal equipment exceeds allowable value PPP can not be authorised for non-professional use;	Yes national regulation, Latvian	2012.gada 24.jūlija MK noteikumi Nr.509 „Noteikumi par augu aizsardzības līdzekļu laišanu tirgū saskaņā ar Regulu Nr.1107/2009”

Latvia				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
		- if PPP is classified with R65 it can only be authorised for non-professional use if its packaging/opening has construction safe for children; - if PPP is classified as Harmful, Highly flammable or Extremely flammable it can only be authorised for non-professional use if its packaging has clearly palpable danger symbol.		
Residues	NO			
Efficacy	No			
Fate and behaviour	**Yes**	The following requirements should be included in the core assessment: Calculations with PEARL Hamburg and Jokioinen scenarios are required		
Ecotoxicology	**No**			

Lithuania				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	No			
Toxicology	Operator exposure: in Tier 2 refinement the German model		No	

Lithuania				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
	with the geometric mean is acceptable. **Non-professional use:** **Plant protection products in "common practice" may not be authorised for use by non-professional users which have any of the following characteristics:** 1. Product is acutely very toxic or toxic (T+, R26-28, R39 or T, R23-25, R39); 2. Product is corrosive and cause burns or severe burns (C, R34 or R35); 3. Product is carcinogenic, toxic to reproduction or mutagenic and is classified in categories 1,2 or 3; 4. Product may cause harm to breastfed babies (R64); 5. Product is danger of serious damage to health by prolonged exposure (T, R48 or Xn, R48); 6. If the extent of operator exposure (without personal protective equipment) in handling and using the plant			

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**
	protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.			
Residues	No			
Efficacy	No			
Fate and behaviour	Specific groundwater modelling – including all metabolites	The following requirements should be included in the core assessment: If risk for leakage to groundwater is area of concern identified in review Report, PELMO and PEARL for Hamburg scenario with specific input parameters (80 percentile for the degradation (not geomean DT_{50}), 20 percentile for sorption (not arithmetic) and 80 percentile for output) are required	No	Specific groundwater modelling – including all metabolites
Ecotoxicology	No			

Norway				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Phys. Chem. properties and anal. method	No	The following plant protection products may not be authorised for use by non-professional users: - Products that are explosive (E) or oxidizing (O).	Yes, in Norwegian	

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**
Toxicology	No	<u>The directions for approval of non-professional use:</u> Important issues are: -use of substitutional principle - evaluation regarding storage of the plant protection product - evaluation regarding personal protection equipment for non professional users lacking skills in handling plant protection products. <u>The following plant protection products may not be authorised for use by non-professional users:</u> - Products that are acute very toxic (T+), toxic (T) or corrosive (C). - Labelled with one of the following sentences: - R40: Limited evidence of a carcinogenic effect. - R41: Risk of serious damage to eyes. - R42: May cause sensitisation by inhalation - R48: Danger of serious damage to health by prolonged exposure. - R62: Possible risk of impaired fertility. - R63: Possible risk of harm to the	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**
		unborn child. - R68: Possible risk of irreversible effects For products containing substances carcinogenic, repro-toxic or toxic by prolonged exposure below the classification limit, estimating exposure without personal equipment will be done. If the exposure is above the AOEL, the product will not be approved for non-professional use. The following products can be accepted for non-professional use: Ready for use: Plant protection products without classification/labelling, or with irritating characteristics (if there are no better alternatives). These products will not be approved if the there is extensive need for personal protection equipment. Concentrate: Plant protection products with irritating characteristics may be approved. Products labelled as harmful to health may be approved if there are no better alternatives (health). These products will not be approved if the there is extensive need for personal protection equipment.		

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**
		Powder soluble in water: Powder soluble in water is not suitable for non professional use because of the danger for exposure. But if the products are delivered in small disposable packages as water soluble bags they may be accepted for non professional use.		
Residues	No			
Efficacy	Yes	In the Norwegian legislation there is a requirement that efficacy trials must be performed in Norway (when considered necessary).	No	The Norwegian Food Safety Authority is the responsible authority. The Norwegian Institute for Agricultural and Environmental Research is responsible for the evaluations and trials.
Fate and behaviour	No	Directions for approval of non-professional use: When evaluating such products persistence is especially important. Products that have a mean half-life in soil of more than 100 days will not be authorised for outdoor use.		
Ecotoxicology	No	Directions for approval of non-professional use: As a general rule, products that are in focus because of their ecotoxicological profile, should not be authorised for non-professional use. When evaluating such products, toxicity to bees is especially important. Products that are very toxic too bees/pollinating insects (LD50 <1.0 µg/bee) will not be authorised for outdoor use.		

Sweden				
Section	**Supplementary data requirements for Annex III dossier Yes/NO**	**Goal(s) of Guidance document**	**Guidance Document available Yes/No and language of the document**	**Address or contact point to obtain GD**
Products which may be used by non-professional users		Special guidance for products that may be used by non-professional users is available on the KemI website.	Yes/English	Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +46 8 519 41 100, kemi@kemi.se
Phys. Chem. properties and anal. method	NO			
Toxicology	NO			
Residues	NO			
Efficacy	NO			
Fate and behaviour	YES	See core text in chapter 4.5.2		
Ecotoxicology	NO			

10 Appendix VI: List of mitigation options available in the countries in the zone

Denmark	**Mitigation options**	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology		
Operator exposure	- limits on spraying methods authorized - requirements on special permits for spraying personnel - requirements on special packaging (dimensions, design, possibly water-soluble packaging) - treatment periods and periods of retainment - waiting periods for re-entry into treated areas - specific requirements on the use of protective equipment	
Residues	- PHI	
Fate		
Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications	
Ecotox		
Surface water	Buffer zones, max width 20 m for field crops, 30 m for vegetables and 50 m for orchards	Not accepted
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	

Estonia	Mitigation options
General	- It is prohibited to spray a plant protection product if wind speed exceeds 4 m/s unless it is permitted to use the plant protection product at a higher wind speed in the technical data provided in the user manual of the plant protection equipment. - It is prohibited to spray when the air temperature exceeds 25 ºC.
Toxicology	
Operator exposure Worker exposure	- waiting periods for re-entry into treated areas - specific requirements on the use of protective equipment
Residues	- PHI
Fate	- the same plant protection product on the same field in consecutive years - it is prohibited to spray a plant protection product in a water protection zone closer than 20 meters from the water boundary of the Baltic Sea, Lake Võrtsjärv, Lake Lämmijärv, Lake Peipus and Lake Pskov, 10 meters from the water boundary of other lakes, reservoirs, rivers, brooks, springs, main ditches and channels, and artificial recipients of land improvement systems, 1 meter from the water boundary of artificial recipients of land improvement systems with a catchment area of less than 10 km^2 unless a wider buffer zone is noted on the labelling of the packaging of the plant protection product.
Ecotoxicology	- Buffer zone
Bees	- Person must notify the user of a plant protection product of the existence of his or her apiary (whose apiaries are located at a distance of up to two kilometers from the field where it is planned to use the plant protection product) at least 48 hours before starting spraying. - It is prohibited to spray areas where there are blooming flowers with a PPP unless there is a notation on the labeling of the packaging of the plant PPP that the PPP may be used during the blooming period of flowers and fluttering period of bees.

Finland	**Mitigation options**	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	Buffer zones, max width 20 m for field crops, 30 m for bush berries, nurseries and 50 m for orchards. Drift reducing equipment can be used to further reduce the risk from spray drift.	Nozzles with 50, 75 and 90 % reduction, certain types of air assistant sprayers
Non target arthropods	No specific national requirements.	-
Non target plants	Spray drift buffer zones alone or in combination with drift reducing equipment could be used to reduce the risk.	Nozzles with 50, 75 or 90% reduction, certain types of air assistant sprayers
Bees	If the substance is toxic to bees and other pollinating insects, use nearer than 60 m to the beehives is forbidden without the beekeeper's permission. Restrictions of use during flowering and foraging activity including restrictions in time: plants may be sprayed after the flying time of bees between 21 and 6 o'clock. The beekeepers within a radius of 3 kilometres must be informed not later than 24 hours before application.	-
Birds and mammals	For seed treatments: mitigation options that can be applied - removals of spills. Other uses: no use during breeding season.	-
Soil organisms	A restriction on the use in the consecutive years can be set for the plant protection products, if risk for the soil organisms occurs after use in consecutive years (calculated according to the Finnish PEC soil calculator).	
Fate and behaviour		-
Ground water	If the substance/the metabolite is mobile in the soil: the product may not be used in the groundwater areas used or suitable for water supply (groundwater area classes I and II). The product is not allowed to be used nearer than 30-100 metres to the wells and springs used for drinking water. The use of the product should be avoided in fine sand soils or soils coarser than fine sand.	

Latvia	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	There is no limit for the maximum buffer zone width set in the national legislation. Protection Zone Law sets minimum widths of surface water body protection zones. Therefore a 10 m bufferzone is a requirement for all PPPs. If risk assessment result is that bufferzone 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 bufferzone 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 bufferzones. There is no limit for the maximum buffer zone width set in the national legislation. From currently registered maximum PPP bufferzone is 5 m for field crops.	Not an option.
Bees	-According to Cabinet Regulations No. 950 a person using PPP with phrase “Toxic to bees” or R57 in its instruction for use, informs those beekeepers that have bees in radius of 2km and that have registered their hives according to cabinet regulations for registering animals, livestock etc. -In other cases (other phrases than “toxic to bees” or R57) user has to comply with Spe8 requirements in PPP instructions of use. And those are usually restrictions of use during flowering and foraging activity. Including restrictions in time: use only from 22.00-05.00. Restrictions in use on flowering weeds are also used.	
Birds and mammals	For seed treatments: mitigation options that can be applied - removals of spills. Other uses: no use during breeding season.	

Lithuania	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Toxicology		
Operator exposure Worker exposure	- requirements on special certification or background for professional users - restrictions of the daily work rate (time duration and/or treated area) - prescription the application of extra adequate personal protective equipment - waiting periods for re-entry into treated areas - prescription the application of adequate personal protective equipment	
Residues	- when PPP is used in forestry and for berries, mushrooms PHI is established more then 1 day, the treated are must be noted with warning symbols - in some cases restrictions for straw or haulm from treated crops as animal feed or bedding at all or for some period after last application - in some cases all livestock keeping out of treated areas for some period after treatment	
Fate		
Groundwater	Restrictions in timing (e.g. no fall use), restrictions in dose and number of applications, in use in some soils (pH, fine sand soils)	
Ecotoxicology		
Surface water	Buffer zones, which are based on toxicity to water organisms. Min – 5m, max – 20 m for field crops and vegetable, 40 m for orchards. Calculating on every 5 meters. Mitigation of run-off: 10 m of vegetative buffer zone is acceptable. Step 4 modelling must be provided with SWAN.	**Drift reducing nozzles are not accepted**
Non target arthropods	Buffer zones for the off-field non target arthropods. Min – 5m, max – 15m for field crops and vegetable, 30 m for orchards. Calculating on every 5 meters.	-
Non target plants	Buffer zones: min – 5 m, calculating on every 5 meters. From currently registered PPP maximum buffer zone is 10 m.	-
Bees	If product is toxic to bees label signify as “dangerous to bees” (safety phrase). Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to	

Lithuania	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
	sunrise. 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 use PPP: to inform beekeepers that have bees in radius of 1km	
Birds and mammals	For pellets and seed treatments: fully insert in to the soil; remove off spills. Other uses: no use during breeding season.	
Soil organisms	If product is toxic to earthworms, soil macro- or micro- organisms, or if there is a possibility that product will accumulate in soil, use a restriction in time and rate: don't use product, or other products with the same active substance more than (indicate time and frequency).	

Norway	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Ecotoxicology		
Surface water	Risk-mitigation options in Norway include buffer zones to mitigate spray drift: up to 30 meters (we do not make use of drift reducing nozzles or other mitigation measures for spray drift or run off as we currently lack both knowledge of the efficiency of different measures under Norwegian conditions and the means to control such measures).	Not an option
Non target arthropods	N/A	Not an option
Non target plants	N/A	Not an option
Bees	To protect bees, mitigation options include restrictions of use during flowering and foraging activity. This also includes restrictions in day-time applications: No use between 0400 and 2300 if temperatures exceed 10°C, or no use between 0600 and 2200 if temperatures do not exceed 10°C.	Not an option
Birds and mammals	N/A	Not an option

Sweden	Mitigation options	Drift reduction equipment e.g. nozzles (if yes 50%, …? %)
Surface water	See text in chapter 4.5	
Non target arthropods	Spray drift buffer zones could be used to reduce off-field risks. In Sweden, wind adjusted spray drift buffer zones are used. In order for the operator to determine the wind adjusted spray drift buffer zones a tool called Hjälpredan (the Helper) have been produced. When the Hjälpredan is used it equals FOCUS spray drift buffer zones up to 15 m (arable crops) and 20 m (orchards). Therefore, KemI does not grant authorization for products which need (FOCUS) spray drift buffer zones greater than 15 for arable crops and 20 m for orchards. If necessary, drift reducing equipment could be used in combination with spray drift buffer zones to further reduce the risk (if the efficacy is maintained)..	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
Non target plants	Spray drift buffer zones alone or in combination with drift reducing equipment could be used to reduce the risk (see point “Non target arthropods” above).	Arable crops: 50, 75 or 90% Orchards: 25, 50, 75, 90 or 99%
Bees	Risk mitigation options in SPe 8 in Appendix III of “Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labeling requirements for plant protection products” could be used. Additionally, spray drift buffer zones could be used to reduce the risk for bees (see point “Non target arthropods” above).	