

**GUIDANCE DOCUMENT
ON THE PROCESS FOR WORK-SHARING IN THE NORTHERN
ZONE IN THE REGISTRATION OF PLANT PROTECTION
PRODUCTS FOLLOWING INCLUSION OF AN ACTIVE SUBSTANCE
IN ANNEX I OF COUNCIL DIRECTIVE 91/414/EEC**

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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, nor any case law developed with regard to this provision. 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 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. Until the new Regulation on the placing of plant protection products on the market (EC 1107/2009) applies 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. The work-sharing provisions in this document will eventually be updated by the zonal authorisation process in the new Regulation to replace 91/414/EEC. It should be noted however, that new product applications ongoing 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 according to Directive 91/414/EEC. For details of transitional arrangements see Article 80.5 of regulation EC/1107/2009.

The document might be updated from time to time 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, during a transition period until 14 June 2011.

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 and in advance of assessment by other countries in the zone. The other countries will have the possibility to comment with focus on essential parts, e.g. areas of particular attention pointed out in the inclusion Directive, 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

CIRCA. The countries within the zone will be notified via e-mail. Other countries 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.

3.1 Re-registration of authorized products

3.1.1 Prerequisites for work-sharing

The minimum requirement 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 under development on the EU level. To facilitate the allocation of ZRMS the form and table in [Appendix II](#) should be completed by the applicant.

3.1.2 Application for re-registration

The latest deadline for submission of a full Annex III dossier should be 2 years prior to the final deadline specified in the inclusion Directive, which should allow time for the full Annex III assessment and for mutual recognition of the authorisations by other countries. 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.

3.1.3 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 group.

3.1.4 Zonal steering group

The zonal steering group is formed from representatives (usually the re-registration contacts) of the competent authorities of each country in the zone. Contact points are listed in [Appendix IV](#). 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 group has regular conference calls approximately every second month and meetings twice a year. The steering group is 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 group is also the primary contact point for the Central and Southern zones.

3.1.5 Communication with applicants

For any questions related to pre-submission issues of applications, applicants are recommended to contact the contact point in each respective country. Following the compliance check (Step 1 of the re-registration process) the individual competent authority in the respective countries should make the necessary contacts with registration holders possessing a valid registration certificate asking them to fill in the information sheet ([Appendix II: Form to notify zones of intended re-authorisation activity](#)). The information should be submitted at the latest 6 months before Step 2 submission deadline. The decision on ZRMS will be communicated to the applicants and published on the website of each competent authority. Subsequent communication during the evaluation of the core dossier should be between the applicant and the ZRM. For issues related to specific national requirements the applicant should contact the respective country.

3.1.6 Format for the application

Applicants are requested to submit documentation as specified in Appendix V 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 \(SANCO/6895/2009 rev 1 02 October.2009\)](#). This will allow the ZRMS and each country to use the submission document to prepare its own Registration Report. The common working language for the preparation and assessment of registration reports is English.

3.1.7 Evaluation of the dossier

For each application a completeness check is foreseen. 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 and the applicant. 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. 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.

3.1.8 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.

3.1.9 Commenting procedures

The other countries within the zone are requested to 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 Directive, and on new studies submitted to address data gaps identified in the review report or to cover data requirements for uses that have not been evaluated before. Comments should be submitted using the form in [Appendix III](#) – Reporting table and must be submitted before the agreed deadline (see timelines, 3.1.12) in order to be taken into consideration by the ZRMS. Bilateral discussions among experts during the evaluation are encouraged.

3.1.10 Decision making

The risk assessments and registration reports prepared by one country can be used by the others in order to get a regulatory decision. Nevertheless, national requirements, risk assessment schemes and risk mitigation measures and other restrictions or conditions are adapted to the national conditions and are implemented by each individual country. This means that an authorisation granted in one country not necessarily means that an authorisation also will be granted in another. For further details on risk mitigation options see [Appendix VIII](#): 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 other uses will be evaluated to check if acceptable uses are identified.

3.1.11 Time lines

Following the compliance check (Step I of the re-registration process) each country should take the necessary contacts with registration holders possessing a valid registration certificate asking them to fill in the information sheet ([Appendix II](#)). Replies from each registration holder will be collated into a table that contains the information requested for all products containing a specific substance. The table should be sent to the chair of the steering group, with copy to competent authorities of the other countries for their information, at the latest 4 months before Step 2 submission deadline.

On the basis of the information above a decision by the Steering group on the allocation of products/substances 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).

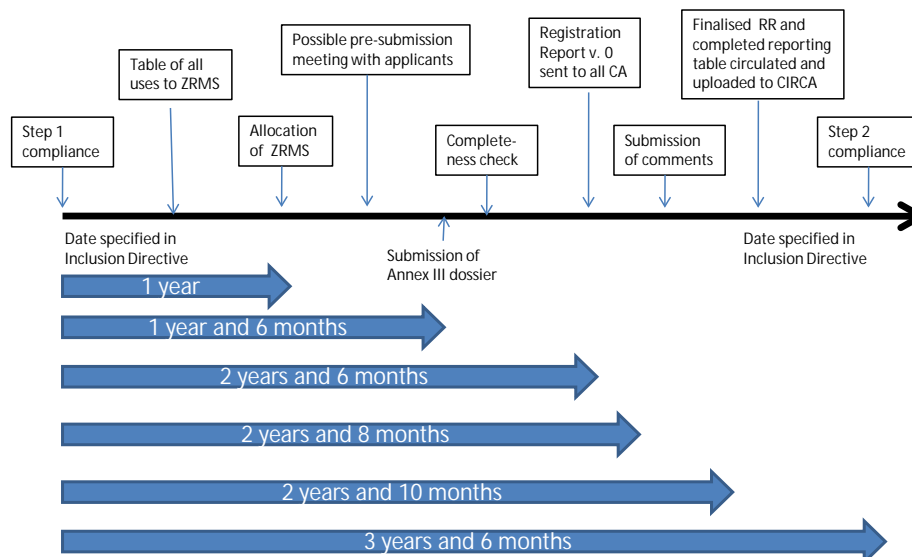
ZRMS should as soon as possible contact registration holders and discuss their applications. Pre-submission meetings are recommended to clarify GAPs and “risk envelope” approach. The evaluation of all products containing a specific substance should be organised by the ZRMS as an individual project setting 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 two month consultation period is foreseen during which competent authorities of other countries in the zone submit their comments.

ZRMS two months after the consultation period has expired prepare a reporting table (see [Appendix III](#)) with all received comments including a remark on whether the comment

has been accepted or not. A final version (revision 1) of the Registration Report is prepared with all changes that have been accepted 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



3.2 New product authorisations

3.2.1 Prerequisites for work-sharing

Until the new Regulation applies a decision on work-sharing 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. To facilitate the allocation of ZRMS the form and table in [Appendix I](#) should be completed by the applicant.

3.2.2 How to submit an application

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)** may be proposed. Applicants are encouraged to prepare a single dossier to cover all 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 under development on the EU level.

3.2.3 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 group.

3.2.4 Zonal steering group

See 3.1.4

3.2.5 Communication with applicants

Applicants are encouraged to make early contact with the respective contact point listed in [Appendix IV: Contact points](#). A notification 6 months in advance of submission should be done to the proposed ZRMS. Following agreement on a work-sharing project for an evaluation of an application in the steering group 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.

3.2.6 Format for the application

See 3.1.6

3.2.7 Evaluation of the dossier

See 3.1.7.

3.2.8 Commenting procedures

See 3.1.9.

3.2.9 Decision making

The risk assessments and registration reports prepared by one country can be used by the others in order to get a regulatory decision. Nevertheless, 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 in one country not necessarily means that an authorisation also will be granted in another. For further details on risk mitigation options see [Appendix VIII: 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 other uses will be evaluated to check if acceptable uses are identified.

3.2.10 Time lines

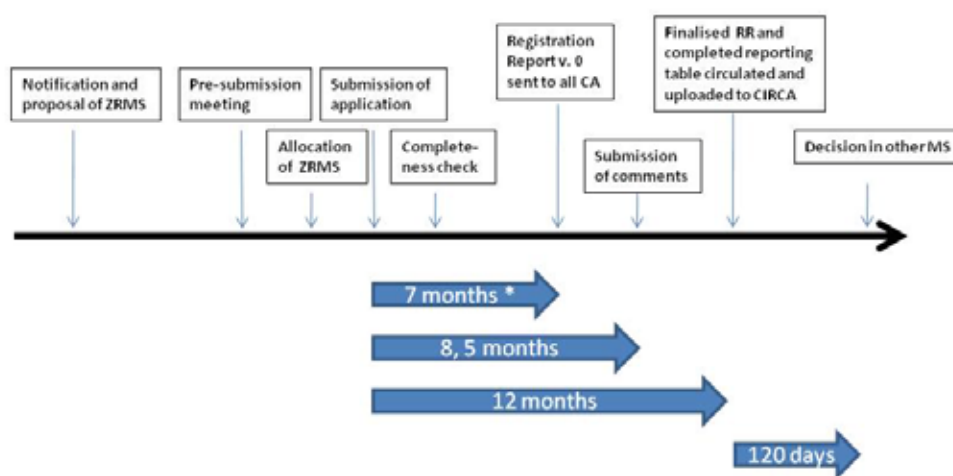
Submission of an application to more than one country in the zone for an authorization of the same product with the same use will be taken up by the Steering group. Until the new regulation enters into force a decision on a work-sharing project will be taken based on available resources and priorities 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 submit their comments. In case further information/studies are required a maximum six month period is given to the applicant to complement the application.

After the consultation period has expired the ZRMS prepares a reporting table (see [Appendix III](#)) with all received comments including a remark on whether the comment has been accepted or not. A new version (revision 1) of the Registration Report is prepared with all changes that have been accepted and 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



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

3.3 Inter-zonal uses

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.

3.4 Applications for mutual recognitions

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.

3.5 Provisional authorisations

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

3.6 Withdrawal and amendment of authorization based on zonal evaluations

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 group meetings.

4 Assessment

Applicants are required to submit a full Annex III dossier as required in Directive 91/414/EEC 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. supplementary national data requirements concerning the specific problems in a country, as indicated in **Appendix VI**: Supplementary national requirements for Annex III dossiers, have to be respected and data submitted for evaluation
- 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.

It is generally agreed that the latest version of EU guidance documents should be used by applicants. When new guidance is adopted the list of guidance in the relevant section will be updated and the date from when it should be used indicated. Nevertheless, in order to avoid unnecessary testing or repetition of tests, applications based on earlier versions of guidance documents might be accepted provided there is a scientific justification and this is

accepted by the ZRMS. Applicants are strongly recommended to take contact to discuss these cases before starting the preparation of dossiers.

4.1 Identity, physical chemical properties and analytical methods

The following guidance documents should be used:

- Manual on development and use of FAO and WHO specifications for pesticides, March 2006 revision of the 1st edition or further edition which expected to be available in 2010.
- Revision of AII and AIII to Directive 91/414/EEC. Sanco 10438. Draft Revision of Annex II and III to Directive 91/414/EEC. Physical and chemical properties.
- Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market - Physical and Chemical Properties 17 May 2006 *The EFSA Journal* (2006) 361, 1-17.
- SANCO/3030/1999 rev.4 11 July 2000. Technical Material and Preparations: Guidance for generating and reporting methods of analysis...
- SANCO/825/2000 rev.7 17 march 2004. Guidance document on residue analytical methods, further revision of 2010 is awaited.
- ISO 5725 ISO 5725-1 Accuracy (Trueness and Precision) of Measurement Methods and Results - Part 1: General Principles and Definitions
- Guidance document on Pesticide Residue analytical methods (Series on Pesticides, No.39, Series on Testing and Assessment; No.72; OECD 2007).
- Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission related to the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market – Analytical methods. 17 May 2006 *The EFSA Journal* (2006) 363, 1-18.

4.2 Toxicology

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

- SANCO/10328/2004-rev 5 2005. Guidance Document on the Evaluation of New Annex II Data Post-Annex I Inclusion of an Active Substance
- 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
- SANCO/222/200 rev. 7, 19 March 2004. Guidance Document on Dermal Absorption

The (draft) Registration Report (SANCO/6895/2009 rev 1 02 October.2009) should be followed. In addition the following principles have been agreed in order to provide an adequate level of protection and to harmonize the risk assessment in the Northern zone.

Specific national requirements are specified for each country in Appendix VI: Supplementary national requirements for Annex III dossiers and Appendix VIII: 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 and 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.

For products with several active substances and/or additives with serious health effects a cumulative risk assessment may be needed. Preparations containing more than one active substance, generating the same type of metabolites, are also an object for cumulative risk assessment.

According to Directive 91/414/EEC, complete data on safeners, synergists and adjuvants are not required. However, if data are available a risk assessment should be carried out. If this is not the case, Safety Data Sheet (SDS) are used.

In those cases where it might be necessary to reduce exposures through personal protective equipment (PPE), the exposures should be assessed both with and without the proposed PPE.

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

4.2.4 Operator Exposure (IIIA 7.3)

The following exposure models are acceptable:

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

As a first step the models should be used as they are with standard input parameters. As a second step, refinements could be accepted using common Nordic-Baltic areas (work rates/day, see section 4.2.8). If modelling indicates unacceptable risk, field measurements could be conducted in order to obtain more accurate and specific exposure data. For all calculations it should be assumed as a default that adults have a body weight of 60 kg.

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

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 m²
- Duration of exposure: 60 min but refinements can be done in higher tier assessment
- Body weight: 60 kg (adult)

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

4.2.6 Worker Exposure (IIIA 7.5)

The following exposure calculations and input parameters are acceptable:

- EURO POEM II Worker Re-entry Model¹
- Work duration: 6-8 hours depending on activity
- Work duration for crop inspection (cereals): 2 hours
- Body weight: 60 kg (adult)

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

4.2.7 Dermal Absorption (IIIA 7.6)

A short summary of each study should be included. The dermal absorption value in the list of endpoints could be used in some cases. However, if the dermal absorption study is performed on another product the composition of the two products, and a justification as to why the products can be considered as similar with regard to dermal absorption, should be included.

If it is not evident that the dermal absorption levels are decreasing, then skin bound residues should be included. If tape strips are to be included the two first tape strips may be excluded.

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

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

Specific national requirements are specified for each country in [Appendix VI](#).

4.3 Residues

Headlines not mentioned in this guidance document should be dealt with in accordance with the guidance document SANCO/6895/2009 rev1 from 2 October 2009.

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

- The "Lundehn guidelines":
- SANCO/7028/VI/95 rev.3. 22 July 1997. Appendix A – Metabolism and distribution in plants

¹ Post-Application Exposure of Workers to Pesticides in Agriculture – Report of the Re-entry Working Group. EUROPOEM II project, Fair3 CT96-1406, December 2002

- 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. 8. 01 February 2008. 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 [Appendix VI: Supplementary national requirements for Annex III dossiers](#).

4.3.1 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.

4.3.2 Residue trials (supervised field trials)

Supervised field trials from Northern Europe should be used. Cross reference to EU review or EFSA review of EU MRLs according to regulation (EC) 396/2005 can be made if this is completed and available. If not insert brief summary of supporting residue trials 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)

4.3.3 Livestock feeding studies

Insert brief summary of livestock feeding studies or cross reference to EU review.

4.3.4 Studies on industrial processing and/or household preparation

Insert brief summary of studies on industrial processing and/or household preparation or cross reference to EU review.

4.3.5 Studies for residues in representative succeeding crops

Insert brief summary of studies for residues in representative succeeding crops or cross reference to EU review.

4.4 Efficacy

The guidance for the efficacy section is available at (<http://agrsci.au.dk/en/institutter/institut-for-plantebeskyttelse-og-skadedyr/pesticidforskning-og-miljoekemi/guidance-on-requirements-for-efficacy-data/>)

Specific national requirements are specified for each country in **Appendix VI: Supplementary national requirements for Annex III dossiers.**

4.5 Fate and Behavior

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/EEC².
- 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). May 2003. 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 at present assessed as closed systems until a guidance document from EFSA is ready
- Risk mitigation is done on a national level since agricultural practices as well as environmental conditions vary between the countries.
- Field studies should be evaluated in the core assessment following the current guidance. Old field studies should be reevaluated.
- The interpretation of the acceptability/representativeness of the field study for the specific agricultural landscape and protection goals should be done for each country since the climatic conditions vary and field data might not be valid/representative for all countries.

4.5.1 Soil

For the core assessment PECsoil should be calculated according to FOCUS guidance and use of an accepted spreadsheet for PECsoil calculations. To cover the entire zone PECsoil should be calculated with worst case lab. OR field non-normalized DT50. The Finnish PEC-calculator with the Jokioinen soil temperature curve as a basis should be used when

² With the exception of DK (see Appendix VI) – all metabolites are considered relevant unless they are inherently non-relevant (see guidance).

assessing accumulation and plateau-concentrations. The Finnish PECsoil-calculator is available at <http://www.environment.fi/pecsoilcalculator>³.

4.5.2 Ground water

The following is the minimum number of exposure scenarios considered to cover the entire zone for exposure assessment purposes:

PEC_{gw} is to be calculated PEARL Jokioinen + PEARL/PELMO Hamburg (DK approach)⁴ + MACRO with Norwegian and Swedish scenarios⁵.

The DK approach is PEARL or PELMO Hamburg with 80 percentile for the degradation (not geometric DT₅₀), 20 percentile for sorption (not arithmetic) and 95 percentile of output (not 80th percentile).

For the special case golf greens, the program MACRO 5.x should be used with input parameters for Fullerö described below. MACRO 5.x is not to be used as higher tier for groundwater, only for modelling leaching from golf greens.

Specific national requirements are specified for each country in [Appendix VI: Supplementary national requirements for Annex III dossiers](#) and [Appendix VIII: List of mitigation options available in the countries in the zone](#).

4.5.3 Surface water

The following is the minimum number of FOCUS exposure scenarios considered to cover the entire zone for exposure assessment purposes.

PEC_{sw} is to be calculated with SWASH scenarios D1-D4 and R1-R3 and is considered to cover the zone with the exception of Denmark (see Danish requirements in appendix VI and VIII). Worst case values should be used in the aquatic risk assessment (see also section 4.5.2.).

Country specific FOCUS scenarios:

Estonia: D1, D3, D4, R1.

Sweden: D1, D4, R1

Norway: D1-D4, R1, R2, R3.

Lithuania: D1, D3, D4, R1.

Latvia: D1, D3, D4, R1, R2.

Finland: D1-D4, R1.

Spray free zones to mitigate drift vary between the countries in the zone and are summarized below:

Denmark: Max 20 m for field crops, 30 m for vegetables and 50 m for orchards.

Estonia: Max 30 m

³ After 7. January 2011 available at <http://www.tukes.fi/pecsoilcalculator>

⁴ Unless it is clear from the EU assessment that the risk of leaching is negligible (< 0.001 µg/L) included the uses applied for.

⁵ MACRO and Swedish scenarios are required UNLESS:

- risk for leakage to groundwater is not an area of concern pointed out in the EU review report
- and groundwater levels in PEARL (Hamburg) < 0.01 µg/l for active substance and relevant metabolites or < 1.0 µg/l for non-relevant metabolites
- and the K_{oc} < 100 L/kg.
- For the Swedish scenario Näsbygård several simulations with different starting dates are required if the K_{oc} < 500 L/kg and the DT_{50soil} < 50 days. Further guidance is available at www.kemi.se

- Finland: Based on aquatic toxicity, buffer zones 10 m (10-100 mg/l), 15 m (1-10 mg/l), 25 m (below 1 mg/l).
- Latvia: Max 50 m.
- Lithuania: Max 20 m for field crops and 40 m for orchards.
- Norway: Max 30 m.
- Sweden: 15 m (arable) and 20 m (orchards) (+ drift reducing nozzles).

For the core assessment PEC values for bufferzones of 15 m, 30 m and 50 m should be presented if needed for the risk assessment.

4.6 Ecotoxicology

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.

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 report. In most cases PPR opinions will be used for higher tier risk assessments and these should be highlighted in the check-list ([Appendix VII: Cover page including checklist](#)). Specific national requirements (e.g. National Guidance documents or specific PPR opinion which are not accepted) are specified for each country in [Appendix VI: Supplementary national requirements for Annex III dossiers](#)

4.6.1 Birds and mammals

The new EFSA guidance document for birds and mammals should be used for risk assessments submitted for the North zone. However, Denmark does not accept the use of the geometric mean approach. If the geometric mean approach refinement⁶ has been used this should be clearly highlighted by the rapporteur in

⁶ The geometric mean approach is not accepted by Dk

Appendix VII: Cover page including checklist.

At present a harmonised list of focal species to be used within the North zone is not available, thus higher tier risk assessment using focal species, PD and PT needs to be discussed on a case by case basis (country by country basis). Therefore refinements based on focal species should be reported in the national addenda.

The approaches based on ADME refinements (i.e. according to the Opinion of the Scientific Panel on Plant protection products and their residues (PPR) on a request from EFSA related to the evaluation of pirimicarb) is acceptable for the core assessment.

4.6.2 Aquatic ecosystems

In the core assessment a table containing all FOCUS step 3 (see section 4.5.3) and if necessary step 4 PEC-SW and PEC SED and corresponding TERs should be included. For the core assessment risk mitigation by spray drift buffer zones are accepted (see max buffer zones in sections 4.5.3).

If further mitigation (i.e. other than spray drift buffer zones) is needed then the TERs based on PECs resulting from the implementation of other nationally specific mitigation options should be presented in the national addenda.

Mesocosms

The RIVM guidance document⁷ for evaluating and reporting micro/mesocosm studies should in general be used (except the effect class method) for evaluating the studies.

The quality of mesocosm studies should always be evaluated or re-evaluated according to RIVM guidance (including "old" mesocosms for which a LoEP value already is available) and presented in the core dossier. The NOEC as well as the NOAEC (but with 4 week recovery⁸) should be identified.

For the risk assessment in the core dossier use the NOEC and an assessment factor of 2-3 for a high quality representative study.

Possibility of lowering the assessment factor when more species than required has been tested

If more species are tested than what is required by the directive then the method 1-2 as described in the EFSA opinion (The EFSA Journal, 2005, 301, 1-45) can be used to refine the acute risk assessment for aquatic plants, invertebrates and fish in the core assessment⁹.

Species sensitivity distributions

The results presented in Brock et al.¹⁰ indicates that LL HC5 (Lower Limit Hazardous Concentration 5 %) 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 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 factor¹¹.

⁷ 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

⁸ Used for risk assessment in Dk with an assessment factor of 5

⁹ Not accepted in DK – the assessment factor will be lowered based on further studies – but on a case to case basis based on the available data.

¹⁰ Brock, TCM, et al. 2006. Aquatic risks of pesticides, ecological protection goals and common aims in European Union legislation. 2006, Vol. 2, pp. 20-46

¹¹ Finland, Estonia, Denmark, Norway and Lithuania may use this assessment on a case to case basis

However, there is not enough scientific evidence showing that an adequate level of protection is maintained if the risk assessment for fish is refined using any of the methods described in the EFSA opinion (above) or with a LLHC5 / HC 5. Therefore these methods cannot generally be recommended for a refinement of the risk to fish.

Exposure profile

The advice given in the "Opinion of the PPR Panel on a request from EFSA related to the evaluation of dimoxystrobin" 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 dossier. However, it is also important to evaluate if the study conditions were acceptable (e.g. sediment-water ratio). This evaluation should be presented in the core assessment.

4.6.3 Bees

In the core assessment a risk assessment using HQ acute oral and contact should be presented. The evaluation of possible field studies should also be presented in the core assessment.

The interpretation of the acceptability/representativeness of the field study for specific agricultural landscape(s) and protection goals in countries should be done on a country specific basis. Therefore risk assessments using the field studies should be included in the national addenda.

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 Appendix VIII: List of mitigation options available in the countries in the zone.

4.6.4 Non target arthropods

In the core assessment, in-field and off-field risk assessments using HQ or 30 % trigger approach (ESCORT 2; standard lab glass plate studies) and 50 % trigger for higher tier studies should be presented. In the off-field risk assessment buffer zones of 5, 10, 15 and 20 m should be used if required (see [Appendix VIII](#): List of mitigation options available in the countries in the zone. The evaluation of field studies should 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 country. Therefore risk assessments using the field studies should be included in the national addenda.

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.

4.6.5 Earthworms and other soil organisms

In the core assessment a TER risk assessment using laboratory data should be presented. Refinement of the PEC based on crop interception (standard values given in FOCUS Surface Water) is acceptable for the core assessment. An evaluation of any field studies should also be presented in the core assessment. The field studies should be evaluated following the guidance given in "RIVM guidance document for summarizing earthworm field studies", part 2. Old field studies should always be reevaluated. The evaluation should include recovery times and % effect.

The interpretation of the acceptability/representativeness of the field study for the specific agricultural landscape and protection goals should be done for each country.

For the core assessment a refined risk assessment based on recovery within a year¹² for representative field studies should be presented. Further risk assessment using the field study should be included in the national addenda.

4.6.6 Non target plants

In the core assessment a risk assessment in accordance with the terrestrial guidance document should be presented. In the core assessment the off crop assessment can be performed including an assessment for buffer zones 5, 10, 15 and 20 m if required (see [Appendix VIII](#): List of mitigation options available in the countries in the zone.

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

4.6.7 Mixture toxicity

In order to account for mixture toxicity of products containing more than one active substance the following approach must be used in the core assessment¹³.

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

$$\text{"Trigger"}_A\text{-value}/\text{TER}_A + \text{"Trigger"}_B\text{-value}/\text{TER}_B + \dots = \text{SUM}$$

If $\text{SUM} < 1$ 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 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 the same taxonomic group (i.e. fish, crustaceans, algae and aquatic plants) for the most sensitive organisms or for mesocosms using the overall NOEC.

4.6.8 Home gardens

The data-requirements and risk assessment for home garden products differ among MS. If an assessment for the relevant active substance for agricultural use is available the core assessment should refer to this assessment (including bridging statement). The risk mitigation measures needed for use in home gardens should be considered.

Some MS require specific assessments to be included, e.g. with bird species relevant for gardens (all areas should be assessed) – this should be included in the national addenda.

In the national addenda countries should implement national policies for decision making, i.e. if the identified mitigation measure are needed or possible to achieve in home gardens.

¹² For Finland recovery within a season is required – for Dk initial effect less than 50 % and recovery within a season.

¹³ Not required by Latvia

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

– send to all countries where authorisation is required

Active substance:

Applicant:

Summary of products and uses – please complete table overleaf.

Within each zone, please detail which use represents the critical GAP – and thus can be used to establish the risk envelope. Please give *brief* details

For mixed active products, please highlight which country in the zone has an authorisation for the other active(s) (if any)

Please highlight if you apply for authorisation across more than one zone, since this could offer options for inter-zonal work-sharing.

Please indicate the likely date of submission

Appendix I (Table) – Information sheet for new product authorisations

Active substance:

Applicant:

Trade name	MS	Type of formulation	Content of a.s.	Date of application	Prov. auth. Yes/No	Authorised/intended uses

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

– send to all countries where authorisation is required

Active substance:

Applicant:

Summary of products and uses – please complete table overleaf.

Within each zone, please detail which MS approval represents the critical GAP – and thus can be used to establish the risk envelope. Please give *brief* details

For mixed active products, please highlight which MS in the zone has re-registered the other active(s) (if any)

Please highlight if the same product is approved across more than one zone, since this could offer options for inter-zonal worksharing.

If the ZRMS submission can be made before the Step 2 submission deadline, please indicate the likely date of submission (otherwise assume submission at the deadline)

Appendix II (Table) – Information about intended application for re-authorization

Active substance:

Authorization holder:

MS	Trade Name in that MS ¹	Type of formulation	Content of a.s. (name all actives)	Authorisation number	Authorised uses/Intended uses (brief summary)	Comments

¹ Please highlight where identical formulations are marketed in different MS

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

CONTACT POINTS OF FOR IMPLEMENTATION OF WORK-SHARING PROGRAMME IN THE NORTHERN ZONE

MS	CONTACT POINT
Denmark	<p>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</p>
Estonia	<p>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</p>
Finland	<p>Title: Senior Officer Name: Heini Vainio Authority: Finnish Safety and Chemicals Agency (Tukes) Address: P.O. Box 66, FI-00521 Helsinki, Finland Tel: +358 10 6052 000 E-mail: Heini.vainio@tukes.fi</p>
Iceland	<p>Title: Advisor Name: Bjorn Gunnlaugsson Authority: Environment Agency of Iceland Address: Sudurlandsbraut 24, 108 Reykjavik Tel (direct): 00354 5912082 E-mail: bjorngunn@ust.is</p>
Latvia	<p>Title: Director of Plant Protection Department Name: Inese Margevica Authority: State Plant Protection Service Address: Lielvārdes iela 36/38, Riga, LV-1006 Tel: 00371 67185478 E-mail: Inese.Margevica@vaad.gov.lv</p>
Lithuania	<p>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</p>
Norway	<p>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</p>
Sweden	<p>Title: Head of unit Name: Gunilla Ericson Authority: Swedish Chemicals Agency Address: P.O. Box 2, SE-172 13 Sundbyberg, Sweden Tel: +46 8 519 41 290 E-mail: gunilla.ericson@kemi.se</p>

9 Appendix V – Format for Annex III registration submissions

General requirements are as follows:

- (i) Covering letter, including brief summary of the application.
- (ii) Application form in English and/or in the language of the relevant MS.
- (iii) **Document C** – Master label in English and national labels
- (iv) **Document K-III** – individual test and study reports in accordance with the requirements specified in Annex III.
- (v) A list of references to new Annex II data if applicable.

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.

However the guidance document SANCO/10328/2004-rev. 6"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.

10 Appendix VI: Supplementary 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	<ul style="list-style-type: none"> · 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/teratogenicity and 5-10 for carcinogenicity. · The reduction factor for gloves while mixing and loading is 90 % and 60 % 		Yes Danish/English	Danish: http://www.mst.dk/Virksomhed_og_myndighed/Bekaempelsesmidler/Pesticider/Ansogningomgodkendelse/Vurderingsgrundlag/ English: http://www.mst.dk/English/PesticidesAndGeneTechnology/Pesticides/Health_and_environmental_evaluation_of_active_substances_and_products/

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
	<p>while spraying. The reduction factor for full body safety equipment is 50 %.</p> <ul style="list-style-type: none"> • Non-professional users will use handheld spray 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 cause severe damage to eyes (R41) can generally not be approved for any use. • Products which are corrosive, Carc./ Mut. Categori 1 and 2 can not be approved for non-professional use. <p>Dk does not accept the EU definition of non-relevance of metabolites.</p>	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			

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
	conditions. Bridging studies required for similar products.			
Fate and behaviour	Specific persistency assessment Specific groundwater modelling – including all metabolites Specific PEC _{sw} - drift	DT50 soil < 6 months – otherwise no approval Makro Danish scen. or PELMO Hamburg + specific input and output values All metabolites that are not inherently non-relevant Ganzelmaier drift – to 30 cm water body	Yes Danish/English	See above
Ecotoxicology	Specific aquatic risk assessment Higher tier guidance on risk assessment for birds and mammals Specific requirements for persistent substances	Based on drift PECs and 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

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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- 01/08/2009				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
Phys. Chem. properties and anal. method	NO			
Toxicology		<p><u>Exposure assessment:</u> The operator exposure assessment is done mainly by using EUROPOEM I, but when needed, UK POEM and German model can be exploited.</p> <p><u>Non-professional use:</u> Authorization of plant-protection product for non-professional use is done in case-by-case basis. However, plant protection products may not be authorized for non-professional users if those have any of the following characteristics:</p> <ul style="list-style-type: none"> - 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 ¹			
Ecotoxicology	NO			

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1 = PECsoil should be calculated by using the Finnish PECsoil calculator

Latvia- 29/10/2010				
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	Special guidance for products that may be used by non-professional users is given in the document "Regulation Procedures for Plant Protection Products" available on the SPPS website.	Yes English	http://www.vaad.gov.lv/english/about-us/plant-protection.aspx
Residues	NO			
Efficacy	Dossier must cover Latvian conditions	NO	No	
Fate and behaviour	Yes	Calculations with PEARL Hamburg and Jokioinen scenarios are required.		
Ecotoxicology	YES. For aquatic risk refinement.	The method 3-5 as described in the EFSA opinion (The EFSA Journal, 2005, 301, 1-45) can be used to refine the acute risk assessment for aquatic plants, invertebrates and fish. When calculating the AFspecies (covering inter-species variability using methods 3-5) a MFE of 5 % (mean factor of species whose endpoint would be exceeded) should be applied. 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 applicant must calculate the constants α_0 and λ_0 for the substances considered relevant with		

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Latvia- 29/10/2010				
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
		respect to the toxicity exerted by the substance of interest.		

Lithuania- 01/08/2009				
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		Packagings tested in storage stability tests are considered. The intended packagings of the product are acceptable if they are of the same material that was tested. Physical compatibility data of tank mixes (ASTM 1518 or alternative) is required unless bioefficacy data supports mixing of authorised products.	No	
Toxicology	Operator exposure: in Tier 2 refinement the German model with the geometric mean is acceptable. Non-professional use: Plant protection products in "common practice" may not be authorised for use by non-professional users which have any of the following characteristics: 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		No	

Lithuania- 01/08/2009				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
	<p>classified in categories 1,2 or 3;</p> <p>4. Product may cause harm to breastfed babies (R64);</p> <p>5. Product is danger of serious damage to health by prolonged exposure (T, R48 or Xn, R48);</p> <p>6. If the extent of operator exposure (without personal protective equipment) in handling and using the plant protection product under the proposed conditions of use, including dose and application method, exceeds the AOEL.</p>			
Residues	No			
Efficacy	BAD need to include data from countries with comparable conditions to Lithuania			
Fate and behaviour	Specific groundwater modelling – including all metabolites	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

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Lithuania- 01/08/2009				
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
Ecotoxicology	No			

Norway - 01/08/2009				
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	Yes	In the Norwegian legislation there is a requirement that efficacy trials must be performed in Norway (when considered necessary).). If the new EU regulation is implemented in Norway, this will no longer apply.	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			
Ecotoxicology	No			

Sweden - 01/08/2009				
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 given in the document "Support in applying for authorisation of plant protection products" available on the Keml 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		Special guidance for products that may be used by non-professional users is given in the document "Support in applying for authorisation of plant protection products" available on the Keml website.	Yes/English	Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +46 8 519 41 100, kemi@kemi.se
Residues	NO			
Efficacy		Guidelines for efficacy evaluation of plant protection products	Yes/English	The Swedish Board of Agriculture, 551 82, Jönköping, Sweden, +46 (0)36-15 50 00, Fax: +46 (0)36-19 05 46, jordbruksverket@sjv.se
Fate and behaviour	YES	MACRO and Swedish scenarios are required UNLESS all following criteria are fulfilled: - risk for leakage to groundwater is not an area of concern pointed out in the review report - and groundwater levels in PEARL (Hamburg) <0.01 µg/L for active substance and relevant metabolites or <1.0 µg/L for non-relevant metabolites. - and the KOC <100 L/kg For the Swedish scenario Näsbygård several simulations with different starting	YES/English	Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +46 8 519 41 100, kemi@kemi.se

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Sweden - 01/08/2009				
Section	Supplementary data requirements for Annex III dossier Yes/NO	Goal(s) of Guidance document	Guidance Document available Yes/No and language of the document	Address or contact point to obtain GD
		<p>dates are required if the KOC <500 L/kg and the DT50soil <50 days.</p> <p>Detailed information is found at www.kemi.se.</p>		
Ecotoxicology	Yes, possibility for refinement.	<p>The method 3-5 as described in the EFSA opinion (The EFSA Journal, 2005, 301, 1-45) can be used to refine the acute risk assessment for aquatic plants, invertebrates and fish. When calculating the AFspecies (method 3-5) a MFE of 5 % should be applied. 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 applicant must calculate the constant $\alpha 0$ och $\lambda 0$ for the substances considered relevant with respect to the toxicity exerted by the substance of interest.</p>	YES/English	Swedish Chemicals Agency, P.O. Box 2, SE-172 13 Sundbyberg, +46 8 519 41 100, kemi@kemi.se

Appendix VII: Cover page including checklist

	New studies	Endpoints other than LOEP	Higher tier risk assessment				
Toxicology							
Fate and Behaviour							
Ecotoxicology							
Birds							
Mammals	x	x	x				
Aquatic systems							
Non target arthropods							
Earth worms							
Soil microorganisms							
Soil macroorganisms							

X = indicates section highlighted for comments from other countries

11 Appendix VIII: List of mitigation options available in the countries in the zone

Denmark	Mitigation options	Drift reduction nozzles (if yes 50%, ...? %)
Toxicology		
Operator exposure	<ul style="list-style-type: none"> - 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 	
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	<ul style="list-style-type: none"> - It is prohibited to spray a plant protection product if wind speed exceeds 4 m/s unless it is permitted to use the plant protection product at a higher wind speed in the technical data provided in the user manual of the plant protection equipment. - It is prohibited to spray when the air temperature exceeds 25 °C.
Toxicology	
Operator exposure Worker exposure	<ul style="list-style-type: none"> - waiting periods for re-entry into treated areas - specific requirements on the use of protective equipment
Residues	- PHI
Fate	<ul style="list-style-type: none"> - the same plant protection product on the same field in consecutive years - it is prohibited to spray a plant protection product in a water protection zone closer than 20 meters from the water boundary of the Baltic Sea, Lake Võrtsjärv, Lake Lämmijärv, Lake Peipus and Lake Pskov, 10 meters from the water boundary of other lakes, reservoirs, rivers, brooks, springs, main ditches and channels, and artificial recipients of land improvement systems, 1 meter from the water boundary of artificial recipients of land improvement systems with a catchment area of less than 10 km² unless a wider buffer zone is noted on the labelling of the packaging of the plant protection product.
Ecotoxicology	- Buffer zone
Bees	<ul style="list-style-type: none"> - 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	Max accepted buffer zone for National registration	Drift reduction nozzles (if yes 50%, ...? %)
Ecotoxicology		
Surface water	Buffer zones are based on toxicity to water organisms: Max accepted buffer zone for National registration is 25 m for the very toxic (LC ₅₀ < 1 mg/l) active ingredients/metabolites. Buffer zone for the toxic (LC ₅₀ = 1-10 mg/l) substance is 15 m and for the moderately toxic (LC ₅₀ = 10-100 mg/l) substance 10 m. Also the following phrases are included: Filling device of the tractor may not be used when filling the sprayer tank from the waterbed. During the spraying the possibility of the wind drift must be excluded. Spraying mixture left-overs may not be released into water.	-
Non target arthropods	No specific national requirements.	-
Non target plants	No specific national requirements.	-
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 nozzles (if yes 50%, ...? %)
Ecotoxicology		
Surface water	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 20m for field crops.	Not an option see point 3.
Non target arthropods	Buffer zones for off-field risk reduction can be applied if needed. Currently 1-5m 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 see point 3.
Non target plants	A widespread system of using drift reducing nozzles for reduction of risk to environment is not implemented (testing and recognition of nozzles etc.). These techniques are formally not recognised as regulatory mitigation options in Latvia. Therefore risk refinement has to be done with HC5 approach or risk mitigation with bufferzones. From currently registered PPPs maximum bufferzone is 5m.	
Bees	-According to Cabinet Regulations Nr. 463 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 nozzles (if yes 50%, ...? %)
Toxicology		
Operator exposure	<ul style="list-style-type: none"> - requirements on special certification or background for professional users - restrictions of the daily work rate (time duration and/or treated area) - prescription the application of extra adequate personal protective equipment 	
Worker exposure	<ul style="list-style-type: none"> - waiting periods for re-entry into treated areas - prescription the application of adequate personal protective equipment 	
Residues	<ul style="list-style-type: none"> - 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 cereals, 40 m for orchards. Calculating on every 5 meters.	Drift reducing nozzles are not accepted
Non target arthropods	Buffer zones for the off-field non target arthropods. Min – 5m, max – 15m for cereals, 30 m for orchards. Calculating on every 5 meters.	-
Non target plants	Buffer zones: min – 5 m, calculating on every 5 meters. From currently registered PPP maximum buffer zone is 10 m.	-
Bees	If product is toxic to bees label signify as “dangerous to bees” (safety phrase). Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise. Restrictions of use on flowering weeds: no use on flowering weeds/destroy weeds before flowering. Cover bee hives during spraying time for a (indicate time). Regulation of use PPP: to inform beekeepers that have bees in radius of 1km	

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Lithuania	Mitigation options	Drift reduction nozzles (if yes 50%, ...? %)
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).	

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Norway	Mitigation options	
Ecotoxicology		
Surface water	Risk-mitigation options 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 as we currently lack 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 nozzles (if yes 50%, ...? %)
Surface water	In Sweden the risk mitigation options are area-specific spray-drift buffer zones (taking climatic conditions into account) and/or drift reducing equipment. In order for the operator to determine the area-specific buffer zones a tool called Hjälpredan (the Helper) have been produced. When the Hjälpredan is used it equals buffer zones up to 15 m (arable) and 20 m (orchards). Therefore, as a general rule, Keml does not grant authorization for products which need (FOCUS) buffer zones greater than 15/20 m.	50, 75 or 90%
Non target arthropods	Drift reducing equipment Hjälpredan (see point 1, Surface water) may also be used.	50, 75 or 90%
Non target plants	Drift reducing equipment Hjälpredan (see point 1, Surface water) may also be used.	50, 75 or 90%
Bees	Restrictions of use during flowering and foraging activity. Including restrictions in time: use only after sunset to sunrise.	