Danish Ministry of the Environment
Environmental Protection Agency

Framework for the Assessment of Plant Protection Products

Department of Pesticides and Biocides
Danish Environmental Protection Agency

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Editing log - Framework for the Assessment of Plant Protection Products

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Date	**Version**	**Issues changed**	**Responsible**	**Implementation date**
2011-06-10	1.0	Revised framework for assessment of plant protection products published. Text on legal framework still pending. The Framework for Human health only contains changes in the assessment practise, and needs to be supplemented with existing practise.	AAA	2011-06-10
2011-06-24	1.0	Introduction has been updated with legal framework and references to the data requirements published in June 2011 has updated.	AAA	2011-06-24
2012-11-19	1.1	The framework for human health assessment has been updated to encompass the entire risk assessment of the mammalian toxicology.	KRJBO	2013-08-01*
2013-02-18	1.2	Updated fate and ecotox: - Assessment of persistency - Specify GW assessment of metabolites - Chronic bird and mammal risk assessment in relation to autumn use	LOUIS/AAA	2013-08-01*
2014-02-13	1.3	Updated Human health assessment Bystanders and residents p. 13	KREGR	2015-01-01*
2014-04-01	1.3	The decision on the division of PPP's into products for either professionals or non-professional users has been included into the Framework on Human health assessment.	KRJBO	2015-06-01
2014-04-01	1.3	Modelling of leaching – model versions, refinement due to crop rotation	ANLGI	2015-01-01*
2014-04-01	1.3	Updated birds and mammals section Buffer zones for nta and ntp has been linked to annex 11 which has been updated for the terrestrial environment	AAA	2015-01-01*
2015-06-01	1.4	Non-professional use of product containing co-formulant assessed as sensitiser	KREGR	2016-05-01
2015-06-01	1.4	Estimation of exposure for non-professional users	KRJBO	2016-05-01
2015-06-08	1.4	For field studies non-normalised DT_{50} values must be used in the persistency assessment	ANLGI	2016-05-01
2015-06-08	1.4	PEC_{soil} must be calculated in accordance with the Northern Zone guidance	ANLGI	2016-05-01
2015-06-08	1.4	Input for SW modelling should follow FOCUS guidance (the same as in the rest of EU)	ANLGI	2016-05-01
2015-08-05	1.4	The aquatic section has been updated in accordance with NZ GD and the revised EFSA aquatic GD. Main changes: • Use of RAC is accepted • Criteria developed for when and how TWA can be used to refine exposure • Geometric mean can be applied in a Weight of Evidence approach	AAA	2016-05-01
2015-08-05	1.4	The environmental data requirements have been revised.	AAA	2016-05-01
2016-01-29	1.4	Harmonisation within the EU and/or Northern Zone: 1) Estimation of operator, worker, bystander and resident exposure using the EFSA calculator, 2) no special safety factors for establishing AOEL (e.g. cancer), 3) no special protection factors for PPE, 4) cumulative risk assessment irrespective of similar effects of active substances, 5) Seed treat-	MIKJA	2016-05-01

		ment as in NZ GD.		
2016-05-04	1.4	Editorial corrections in ERA	AAA	2016-05-04
2017-05-03	1.5	Use of drift reducing equipment in human health risk assessment. Use of gloves for workers and re-entry as a risk mitigation measure, as well as waiting periods for roof fogging application in greenhouses. Clarification of buffer strips.	MIKJA/KRJBO	2017-11-01
2016-08-31	1.5	Clarification concerning cumulative chronic Birds and Mammals risk assessment	AAA	Already in force
2016-08-31	1.5	How to assess data on beneficial arthropods	SABLA	Already in force
2017-05-03	1.5	Update of fate and behaviour and toxicology concerning persistency and leaching of metabolites.	ANLGI	2017-05-03
2018-04-30	1.6	Guidance on the human toxicological evaluation of ground water metabolites up to 0.75 µg/L. Clarification on when acute inhalation toxicity information is required and clarification on requirements to alternatives to vertebrate studies. Update of Annex 14 to only consider CLP classification, clarification on buffer strips for human health reasons as well as clarification on home & garden evaluation. Mitigation measures for potential endocrine disrupting in-door products. Explanation of tunnel-use.	MIKJA	2018-05-01

* New applications should at the latest follow the framework from this date. Applications are assessed according to the framework from the date of publication on the DEPA's webpage (25. February 2013 for version 1.2; 3. April 2014 for version 1.3; 1. May 2016 for version 1.4, 3. May 2017 for version 1.5, and May 2018 for version 1.6).

Contents

Introduction

Purpose of this document

The aim of this document is to provide the principles framework for the assessment of plant protection product for national registration in Denmark. The document may serve as guidance to applicant on how to perform an assessment for human health and for the environment for plant protection products. I.e. which issues shall be addressed and how. Moreover, the document shall facilitate a harmonised assessment by the Danish EPA.

Legal framework

The legal basis for authorization and evaluation of plant protection products is provided in the plant protection product regulation (Regulation (EC) No. 1107/2009 of The European Parliament and of The Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC). Regulation 1107/2009/EC is directly applicable and binding in all member states and the framework is therefore not necessary to implement into national legislation.

Article 29 of Regulation 1107/2009/EC establishes the main criteria for authorization of plant protection products. Article 29 (1) determines that a plant protection product is only acceptable if it according to the uniform principles as mentioned in Article 29 (6), meets the requirements set out in Article 29.

Article 29 (6) determines that the uniform principles for evaluation and authorization of plant protection products shall contain the requirements set out in Annex VI to Directive 91/414/EEC and shall be laid down in Regulations adopted in accordance with the advisory procedure referred to in Article 79 (2) without any substantial modifications, as determined by regulations adopted under the advisory procedure in Article 79 (2). Subsequent amendments to these Regulations shall be adopted in accordance with Article 78 (1) (c) in Regulation 1107/2009/EC.

Annex VI to Directive 91/414/EEC is now transferred to the Commission Regulation (EU) No. 546/2011 of 10 June 2011 on the implementation of the European Parliament and Council Regulation (EC) No 1107/2009 as regards the uniform principles for evaluation and authorization of plant protection products. Therefore, the Regulation 546/2011/EU will henceforth set out the framework for evaluation and authorization of plant protection products.

The uniform principles shall ensure that all member states make a uniform evaluation of each applied plant protection product, whatever country you apply in.

This document expands and complements Regulation 546/2011/EU, which transfer the uniform principles from Directive 91/414/EEC to Regulation 1107/2009/EC, and also takes into account the specific Danish conditions that are important for the evaluation of the impacts on human and animal health and of the impact on the environment the plant protection products may have. The document applies to all plant protection products which are to be approved under the Regulation 1107/2009/EC, including products authorized or re-authorized in accordance with the transitional provisions as laid down in Regulation 1107/2009/EC.

Framework for the human health risk assessment

Background

This part of the document concerns the human toxicological assessment of plant protection products (PPP) in accordance with Regulation (EC) No 1107/2009. The main toxicological related updates in this version 1.6 concerns guidance on the specific Danish requirements to identify groundwater metabolites of no toxicological concern, clarification on alternatives to vertebrate studies and clarification on requirements for acute inhalation toxicity information, update of Annex 14 to only consider CLP classification, clarification on buffer strips for human health reasons as well as clarification on home & garden evaluation and management of potential endocrine disrupting in-door products. Explanation of Tunnel-use has been added.

LEGISLATIVE USER RESTRICTIONS

To comply with EU regulations the PPPs are split into two user groups as follows:
Group 1) For professional users: Products which can only be purchased and used by professional users who possess a valid spraying certificate or spraying permit.
Group 2) For non-professional users: Products which can be purchased and used by everyone, including garden owners without a spraying certificate or spraying permit.
PPPs intended to be sold to and used by non-professional users have to fulfil the criteria outlined in Annex 14.
Furthermore, Ministry of Environment's Statutory Order on pesticides[1] states that PPPs classified acute toxic in categories 1, 2, or 3 or with specific target organ toxicity SE in category 1 according to the CLP regulation[2], may not be used in private gardens, public areas and similar areas which are accessible to the public, areas around residential buildings, childcare institutions and similar, or to treat vegetation on borders with public roads or private gardens, except for professional control of rats, water voles and moles. In addition, these products cannot be sold to, or used by, non-professionals.

General approach to human health risk assessment

In order to carry out a risk assessment of the effects of a PPP on humans, information on the PPP's effects and of the active substance's intrinsic properties must be available as well as an estimate of the exposure.

The human health risk assessment is traditionally made up of hazard identification, hazard characterisation, exposure assessment, risk characterisation and risk management.

The overall principles for assessing these areas are described individually in the following.

HAZARD IDENTIFICATION – classification

Hazard identification is the determination of the potentially adverse effects of the PPP based on studies on the PPP and active substance.

The data requirements are provided in Commission Regulation (EU) No 283/2013 for the active sub-

[1] Statutory order no. 1750 of 14 December 2015 on Pesticides as amended
[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures amending and repealing 67/548/EC and 1999/45/EC and amending

stance and Commission Regulation (EU) No 284/2013 for the PPP. The criteria for classification of the adverse effects are described in the CLP regulation.

Alternatives to vertebrate studies

The use of vertebrate studies for authorisation and classification of PPPs shall be minimised according to the Pesticide Regulation 1107/2009, article 62, the data requirements Regulation 284/2013 and the CLP regulation 1272/2008, article 7. Since guidance is lacking in this area MS will enforce the requirement differently. In DK the following applies:

Vertebrate studies should be seen as a last resort and applicants have to provide a sound justification if they decide to conduct them. The method of choice should be internationally accepted, validated and justified.

Acute oral, dermal and inhalation toxicity (data requirement 7.1.1, 7.1.2 and 7.1.3)

The following step-wise approach should be applied:

1) Available test data for the whole mixture

2) Bridging principles

   Only data on closely similar formulations are accepted[3]. The compositions and bridging case should be stated in Part C of the dRR.

3) Calculation of classification

   Acute toxicity information is required for all relevant[4] components in the PPP. In contrast to the CLP regulation no unknowns are accepted[5]. LD_{50} or LC_{50} values may be searched for in relevant databases or predicted by non-test methods such as (Q)SAR, read-across and grouping. The information, predictions and calculations should be made systematically and be transparent.

4) New tests

   When accepted and validated alternative test methods are or become available, they prevail vertebrate studies. If vertebrate studies cannot be avoided, tests using signs of non-lethal toxicity should be preferred over the current standard acute toxicity test guidelines using mortality as endpoint.

   These documents could be consulted: OECD 2017, no. 237 and ECHA 2017, R.7a section 7.4.

Skin and eye irritation/corrosion (data requirement 7.1.4 and 7.1.5)

The step-wise approach in the data requirements should be complied with:

1) Existing data

   Besides a weight of evidence approach, including information from acute dermal toxicity or sensitization studies on the PPP or pH, it could also include classification based on knowledge of the skin/eye irritation properties of all components in the PPP and on the theory of additivity[6].

Regulation (EC) No 1907/2006

[3] For example the composition must not change more than indicated in Table 1.2 of CLP regulation 1272/2008, paragraph 1.1.3.6.

[4] According to CLP regulation 1272/2008, Annex I, paragraph 3.1.3.3 a)

[5] According to CLP regulation 1272/2008, Annex I, paragraph 3.1.3.6.2.2

[6] The additivity approach from the CLP Regulation does not apply to mixtures containing acids, bases, inorganic salts, aldehydes, phenols and surfactants (CLP Regulation 3.2.3.3.4.1 and Table 3.2.4).

2) Sequential testing

Validated *in vitro* methods are already existing and should be used before conducting vertebrate studies. When future validated *in vitro* methods are available these will also prevail *in vivo* studies. A vertebrate study shall only be performed when the *in vitro* tests could not reveal or exclude the hazard of the PPP.

These documents could be consulted: OECD 2014, no 203, OECD 2017, no 263, OECD 2017, no. 237, and ECHA 2017, R.7a section 7.2.

Skin sensitization (data requirement 7.1.6)

If a PPP contains substances that are known sensitizers in amounts that elicit classification with H317 according to the CLP regulation, it should not be tested. When new validated alternative test methods are available they shall also prevail vertebrate studies.

These documents could be consulted: ECHA 2017, R.7a section 7.3 and OECD 2016, no 256.

Acute Inhalation toxicity when PPP is applied by spraying

Until a change in Regulation (EU) No 284/2013 (the data requirements) section 7.1.3, condition i) or a harmonised EU interpretation is established, information on acute inhalation toxicity should always be submitted when a Ready-to-Use PPP is to be applied by spraying. All other PPPs that are to be applied by spraying should undergo the pre-evaluation as described below before gathering further information on acute inhalation toxicity.

The pre-evaluation is based on the dilution rate of the GAP and a worst case assumption of acute inhalation toxicity Cat. 1 classification of the product and of the co-formulants with unknown acute inhalation toxicity. If the spray is classifiable based on this assumption, further information on acute inhalation toxicity will be required according to the data requirements to address the classification of the product.

The information should be given according to the step-wise approach in the CLP-regulation as outlined above.

If the information leads to classification of the product, MS will decide whether the product can be authorised for professionals and set out conditions for use.

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

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

1. > 1000 times dilution of the product (assumes ATE 0.005 mg/L).
2. If less than 1000 times dilution, the acceptable amount of ingredients having a classification of acute inhalation tox cat. 1 and unknown acute inhalation toxicity can be calculated with the following equation assuming an ATE of 0.005 mg/L. The 5 mg/l is reflecting the upper limit of cat. 4 classification and hence if above, the dilution is not classifiable:

Acceptable amounts [Aa] of ingredients with unknown and cat 1 classification:

$$\text{Aa \%} < \frac{dilution\ x\ 0.005\ mg/l}{5\ mg/l} x100\%.$$

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

3. It is possible to refine the assumptions of worst case by assuming an ATE of 0.05 mg/L when the compound is not considered orally acute toxic (LD50>2000 mg/kg bw). Then the acceptable amount of ingredients having a classification of acute inhalation tox cat. 1 and unknown acute inhalation toxicity can be calculated with the following equation:

   Acceptable amounts [Aa] of ingredients with unknown and cat 1 classification:

$$\text{Aa \%} < \frac{dilution\ x\ 0.05\ mg/l}{5\ mg/l} x100\%.$$

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

Endocrine disrupting properties

If an active substance is an endocrine disrupter it shall not be approved or reapproved in the EU according to Regulation 1107/2009. However, criteria and guidance in this area have not been adopted and a consistent evaluation has not yet been performed. Even so, during the EU (re-)evaluation of active substances endocrine disrupting properties are assessed and mentioned in the EFSA conclusions.

Until harmonised criteria are set and guidance on the evaluation of endocrine disrupting properties of active substances is adopted at the EU-level this end-point will be included in the hazard identification of the PPPs in DK. Those active substances for which the EU (re-)evaluation could not rule out endocrine disrupting properties (e.g. due to data gaps) or for which this end-point has not been evaluated in the EU will be considered. Especially those active substances, that fulfil the interim criteria as an endocrine disrupter based on harmonised or EFSA proposed classifications, are of concern. The interim criteria give two sets of endocrine disrupting criteria 1) a.s. classified Repr. 2 and Carc. 2 or 2) a.s. classified Repr. 2 and has toxic effects on endocrine organs. However, also substances with a wide documentation in the open literature can be included.

The concern is focused on the in-door worker scenario as the spraying and work tasks in-door give rise to higher and longer-term exposures than out-door use and since Danish greenhouses employs many fertile persons.

When an active substance is considered of concern the PPP use is evaluated and restrictions such as longer re-entry intervals and use of gloves will be set.

HAZARD CHARACTERISATION – setting of the AOEL and AAOEL

Hazard characterisation is the determination of a level of systemic exposure to the active substance that

is acceptable based on the critical effect, the dose-effect level, route, duration, and timing (e.g. teratogenicity studies) of exposure. For risk assessment of PPPs these levels are called the acceptable operator exposure level (AOEL) and the acute AOEL (AAOEL).

The basis for the AOEL is the no observed adverse effect level (NOAEL). The NOAEL is defined as the highest daily dose of the active substance that does not cause an adverse effect in the most sensitive species. In case of several adverse effects, then the lowest relevant NOAEL is used. Usually the basis for the AOEL is studies where the animals have been given the active substance via the oral route (gavage or diet) for a sub-chronic period of time. Sub-chronic exposure is considered an appropriate model for the actual operator exposure.

After determining the relevant NOAEL a default uncertainty factor (UF) of 100 is usually applied. This factor is made up of a 10-fold factor for interspecies variability and a 10-fold factor for intra-human variability. The 10-fold factors for variability cover toxicokinetics as well as toxicodynamics. Sometimes additional UFs[7] can be attributed if there are severe irreversible effects such as toxicity to reproduction/teratogenicity or carcinogenicity. They could also be applied if the data package is too limited or a LOAEL (lowest observed adverse effect level) is used to derive the AOEL.

The AOEL is refined if the oral absorption is less than 80 %.

The acute AOEL was introduced with the EFSA guidance on operator, worker, bystander and resident exposure assessment and the EFSA calculator. Guidance on the setting of an acute AOEL is being developed in the EU.

The Danish EPA applies the AOEL and the acute AOEL determined in the EU.

EXPOSURE ASSESSMENT

Exposure assessment is the estimation of the exposure to the active substance. The estimation takes the dermal absorption, the worst-case use and the possible use of personal protective equipment (PPE) or other risk mitigating measures into consideration. To estimate the exposure different models have been developed. These are considered more reliable than field studies due to statistical power. In general, field studies are not accepted, when the application scenario is included in the Northern Zone Guidance Document (newest version).

Usually exposure assessment and comparison to the AOEL or the acute AOEL is conducted in one step. However, for simplicity risk characterisation is discussed in the next section.

Exposure assessments should be conducted for the operator, worker, bystander, and resident. For the two latter both child and adult exposure are considered. The exposure assessments should be performed for each active substance present in the PPP. As a first tier the worst-case scenario should be used, this is defined from the intended use and application method of the product. Spraying technique and equipment should be indicated on the label.

Exposure assessments are performed according to the Northern Zone Guidance Document (newest version).

[7] EFSA Scientific Committee; Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data. EFSA Journal 2012;10(3):2579.

Dermal absorption

For operators, workers, bystanders and residents dermal exposure of pesticides is considered being the major route of exposure. Therefore, an estimate of the dermal absorption of the concentrated PPP and the in-use dilution of the PPP is necessary to refine the estimate of the exposure (See Northern Zone Guidance Document, newest version).

Operators

Operators are persons involved in activities related to the application of the PPP, including mixing, loading the PPP into the application machinery, as well as operating and repairing the application machinery. Operators might be professionals or non-professional users (home and garden users). Non-professional users are assumed to use handheld spray equipment and have no PPE to protect them.

Workers

Workers are persons who, as part of their employment, enter an area that has previously been treated with a PPP or who handle a crop that has been treated with a PPP. Examples of exposure scenarios are re-entry into treated crops (e.g. crop inspection in fields or handling of crops in greenhouses) and sowing of treated seeds (assessed as part of the exposure assessment of seed treatment).

The main routes of exposure during post-application activities are dermal and inhalation. The sources of dermal exposure are contact with foliage (leaves and fruits), soil and possibly dust. Inhalation exposure occurs by vapour and/or airborne aerosols (including dust).

After outdoor application of PPPs, there will be a more rapid dissipation of vapour and aerosols, leading to a lower inhalation potential than from indoor treatments.

Bystanders

Bystanders are persons who are located within or directly adjacent to the area where application or treatment is in process or has recently been completed, whose presence is quite incidental and unrelated to work and who take no action to avoid or control exposure.

Relevant exposure sources are spray drift at the time of application, vapour, surface deposits, and entry into treated crops.

Residents

Residents are persons who live, work or attend school or any other institution adjacent to an area that is or has been treated with a pesticide, whose presence is quite incidental and unrelated to work involving pesticides, who take no action to avoid or control exposure and might be in the location for 24 hours per day.

Relevant exposure sources are spray drift at the time of application, vapour, surface deposits, and entry into treated crops. However, it is assumed that there is no re-entry into treated cereal fields. The exposures are summed.

Persons walking, playing, sitting, lying on lawns in gardens and public areas are recreational residents. The relevant exposure to PPPs used directly on these lawns are dermal contact to the lawn (both adults and children) and hand to mouth as well as object to mouth (children).

Out-door treatment - fields, lawns, orchards

EFSA Guidance Exposure Calculator (EFSA calculator) is used for the exposure estimation of operator (professional), worker, bystander (child and adult) and resident (child and adult). Application techniques outdoor are upward and downward spraying by tractor mounted equipment or manual spraying by e.g. knapsack.

Recreational resident exposure on turf, other sports lawns, amenity turf and lawns where members of the public are likely to have access should also be assessed for both child and adult. However, golf courses are not considered public recreational lawns for which children has access to. Hence, a risk assessment for child is not required. Turf

In-door treatment - greenhouse

Until the new greenhouse model is incorporated into the EFSA calculator the Dutch model is used to estimate professional and non-professional operator exposure. However, already now the EFSA calculator is used for worker exposure assessment. Resident and bystander exposure assessments are not considered relevant for in-door use.

Spraying techniques in greenhouses are manual e.g. lance sprayers or knapsack or automated application e.g. roof fogger or low-volume mist sprayer.

Contrary to out-door treatment, inhalation exposure of the worker is important after indoor treatment. Both the spraying technique and the following crop handling may result in airborne pesticide droplets/particles.

In the EFSA calculator task specific factors are used for the worker exposure assessment (see Table 14 in the EFSA GD[8]). The factors are depending on the application method and tasks to be performed e.g. handling ornamentals. Be aware, that none of these task specific factors apply to volatile pesticides or products applied as vapours. In such cases additional data may be required.

In general, a worst case worker exposure scenario will be cutting, sorting and bundling of ornamentals after roof fogger application.

Consult the Northern Zone Guidance Document when the in-door spray scenarios, in the EFSA calculator, do not take the inhalation contribution into consideration.

Tunnel-use

In DK tunnels are normally 8-9 meters wide and could be 100 meters or more long. The tunnels are capable of opening and closing in the ends often electronically, which is important to regulate for the temperature. However, the size and equipment vary.

Strawberries are the main crops in the tunnels in DK. However, tunnels are also used for raspberries and other berries and in the future lettuce and vegetables are expected also to be cultivated in tunnels. The main reason is the wet and cold weather and the better possibility to control climate and pests.

The worst case exposure scenarios for operator, worker, bystander and resident are indicated in the NZ GD (2018).

Tunnel-use has to be applied for and specifically mentioned in the GAP.

[8] EFSA (2014), Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products. EFSA journal 2014; 12(10):3874, 55 pp.

Home and Garden – non-professionals

EFSA calculator does not apply to non-professional operators. Hence, the Northern Zone has agreed on acceptable models for this exposure assessment (see Northern Zone Guidance Document, newest version). Only operator assessment is relevant for products used by non-professionals. Except for recreational resident exposure on lawns (see above), no worker, bystander or resident exposure assessment is necessary for these PPP.

Seed treatment

SeedTROPEX model is used for both operator (during the treatment or coating of seeds with the PPP) and worker (handling and sowing of treated seeds) exposure assessment.
Exposure from all operator tasks (mixing, calibration, bagging and cleaning) should be summed as it is assumed the same person performs these tasks. The same is applicable for all the worker tasks (loading, sowing).

RISK CHARACTERISATION

Risk characterisation is the comparison of the actual exposure to the effect level/exposure limit. It is concluded if and when there is a risk of harmful effects, and if there is options to circumvent the risk (e.g. PPE).

If safe use is not demonstrated after taking PPE into consideration or PPE is not accepted as a refinement (bystander and resident), then exposure assessment considering risk mitigation measures such as buffer strips, drift-reducing nozzles or re-entry interval can be performed (see below). If a risk mitigating measure is necessary to demonstrate safe use, the risk mitigation measure shall be mentioned on the label as specified in the text below.

If the level of exposure does not become less than 100% of the AOEL or AAOEL taking PPE or other acceptable risk mitigation measures into consideration then the use of the PPP is unacceptable, and the PPP cannot be approved.

Risk characterisation is determined in two levels – acute risk and long term risk. In addition, cumulative risk should be assessed if more than one active substance is present in the PPP (see Northern Zone Guidance Document, newest version).

Acute risk

The acute risk assessment should be performed for the operator, worker, bystander and resident if the PPP is potentially acute systemic toxic. However, acute exposure of residents is essentially the bystander scenario and thus covered by the bystander risk assessment in the EFSA calculator.

For the operator scenarios not included in the EFSA calculator, e.g. seed treatment and application in greenhouses, it is not possible to assess acute exposure because the underlying data might not be sufficient for acute exposure assessment.

Acute worker exposure cannot be assessed in the EFSA calculator because the current data are not adequate.

Currently, acute risk assessment can only be performed for those PPPs containing an active substance for which a reference value (acute AOEL) is set in the EU.

Long term risk

Comparison between the exposure assessment and the AOEL should be done for operators, workers, bystanders and residents. However, long term exposure of bystanders is essentially the resident scenario and thus covered by the resident risk assessment in the EFSA calculator.

Out-door Treatment - fields, lawns, orchards

Operators:

As a first tier the estimated exposure using workwear but no gloves is compared to the acceptable operator exposure level (AOEL). If the level of exposure is greater than 100% of the AOEL, then a second or higher tier can be conducted taking PPE into consideration:

Tier1 – workwear during mixing and loading and application but no gloves

Tier 2 – workwear during mixing and loading and application and gloves during mixing and loading

Tier 3 – workwear and gloves during mixing and loading and application

Higher Tier – e.g. head protection, respiratory PPE, closed cabin, or drift reducing equipment[9].

Workers:

As a first tier the estimated exposure with normal working clothing, but no gloves is compared to the acceptable operator exposure level (AOEL). If the level of exposure is greater than 100% of the AOEL, then a refinement of the exposure considering gloves or a consideration of a realistic re-entry interval is appropriate depending on the task.

The table below specifies that gloves are not considered realistic for crop inspection tasks in cereals and other field crops, but shorter re-entry intervals of 1-3 days are realistically reflecting re-entry to check the result of spraying or start-up of irrigation.

The availability and use of gloves during manual harvest activities varies, thus gloves cannot be considered to demonstrate safe use. However, a calculated re-entry interval is considered realistic if it is within the pre-harvest interval and thereby indicating acceptable exposure at harvest. This re-entry interval should not be stated on the label, as work is not performed in the crops before harvest.

Cropping, reduction and propping up is performed in trees and bushes, tasks that require working gloves, but they are not chemical resistant gloves. Hence, gloves cannot be considered for refinement in this type of scenario. Therefore, re-entry intervals should be calculated to demonstrate safe use. Re-entry intervals should be stated on the label.

Ornamentals are a very diverse group and both gloves and re-entry interval can be considered depending on the ornamental and timing of spraying. It is for example possible to require gloves for a limited interval until a re-entry interval demonstrate safe use without gloves. Both re-entry interval and use of gloves should be stated on the label.

Table 1: Realistic risk mitigation measures for the outdoor worker scenario.

Task	**Crop***	**Chemical resistant gloves**	**Re-entry**
Crop inspection/ irrigation (2 hour scenario)	Cereals, root and tuber vegetables, oilseeds,	No	1-3 days

[9] In the EFSA calculator drift reducing nozzles reduces the drift by 50%.

Manual harvest (8 hour scenario)	Vegetables (brassica, bulb, fruiting, legume), strawberries	No	A realistic re-entry interval should be within the PHI**
Searching, reaching, picking including cropping, reduction and propping (8 hours)	Pome and stone fruit, berries, Christmas trees	No	Yes
Cutting, sorting, bundling, carrying (8 h)	Ornamentals	Yes	Yes

*list not exhaustive **When the re-entry interval is within PHI it should not be stated on the label. A re-entry interval exceeding the PHI reflects unacceptable exposure at harvest and the PPP cannot be authorised. All the other re-entry intervals in the Table should be stated on the label.

Re-entry is calculated from the equation for dermal exposure with an extra factor for decay using dissipation time or half-life. A default dissipation half-life of 30 days should be used for organic substances only if no DT_{50} value or half-life data representative of the supported use(s)[10] are reported. Link to a spreadsheet for calculation of re-entry will be available.

Bystanders and residents:
Bystanders and residents are not likely to use PPE. However, a risk mitigation measure could be to increase the buffer strip from the default 2 meter in a tiered manner to either 5 or 10 meters. It is possible to reduce the buffer strip by the use of drift reducing equipment from 10 meters to 5 meters and from 5 meters to 2 meters if this is confirmed in the exposure assessment. The buffer strip in orchards is per default 5 meters and can similarly be increased to10 meters and be reduced from 10 to 5 meters with the use of drift reducing equipment. However, it cannot be reduced from 5 to 2 meters because of lack of data. If a 10 meters buffer strip is not sufficient, drift reducing equipment can be added.
Should the use of drift reducing equipment be necessary as a risk mitigation measure for the operator then this can be used for bystander and resident as well - instead of a buffer strip.
When the risk assessment requires buffer strip or both buffer strip and drift reducing equipment to ensure safe use this should be indicated on the label.

Buffer strip to roads, residential and public areas etc. should be indicated on the label, in one of the following cases:

1) Based on hazard:
   The product is acute toxic in categories 1, 2 or 3 or is classifiable specific target organ toxicity (STOT) SE in category 1. If an ARfD is set, but not an AAOEL[11], this should be considered in line with the acute toxic classifications. The default 2 meters (or 5 m for orchards) is required unless the risk assessment results in a larger buffer strip.
2) Based on risk assessment:
   The risk assessment for bystander/resident requires 5 or 10 meter buffer strips to ensure exposures below 100% of the AOEL or AAOEL.

[10] Supported use includes crop type and dose according to GAP
[11] If an AAOEL is set the acute toxic effect will be covered by the risk assessment in the EFSA calculator, and the ARfD should then not be considered triggering the default buffer strip.

3) Based on risk assessment – exposure is below 100 % of the AOEL and AAOEL at the default buffer strip:
    a. In orchards the default buffer strip is 5 meters and should be stated on the label. This cannot be reduced as no data are available below 5 meters.
    b. In fields the default buffer strip is 2 meters. Depending on the exposure this may be reduced as follows:
        i. The exposure is between 10 (included) and 100 % of the AOEL or AAOEL. The default 2 meters buffer strip should be stated on the label.
        ii. The exposure is between 1% and 10% of the AOEL or AAOEL. A buffer strip of 1 meter should be stated on the label unless one of the hazard categories above (1) is allocated to the product.
        iii. The exposure is below 1% of the AOEL or AAOEL. No buffer strip should be stated on the label unless one of the hazard categories above in (1) is allocated to the product.

The sentence is as follows: ”Må ikke anvendes nærmere end x meter fra veje, boliger, institutioner og offentlige arealer for at beskytte beboere og forbipasserende”.

Higher tier risk assessment using EUROPOEM II or German Guidance (Martin et al) is not accepted for bystander and resident. Neither is the use of re-entry interval as a refinement for recreational resident risk assessment.

Home and Garden – non-professional operators:
As a first tier a garden size of 0.1 ha should be assumed and a working day of 1hr. The size of packaging should fit the size of treated area. Hence, maximally correspond to a treated area of 0.1 ha. If the risk assessment is acceptable only for a smaller area than the 0.1 ha then the packaging should likewise be smaller. See also Annex 14 Criteria for pesticides that can be used by and sold to non-professional users.

In-door treatment - greenhouse

Operators:
As a first tier the estimated exposure using work wear but no gloves is compared to the acceptable operator exposure level (AOEL). If the level of exposure is greater than 100% of the AOEL, then a second tier assessment can be conducted taking gloves into consideration and third tier considering RPE.

Workers:
As a first tier the estimated exposure with normal working clothing, but no gloves is compared to the acceptable operator exposure level (AOEL). If the level of exposure is greater than 100% of the AOEL, then a second tier with normal working clothing and gloves should be considered. However, gloves are not considered realistic risk mitigation measure when harvesting strawberries, raspberries and other small berries which smash easily when handled.

The risk assessment also has to show that re-entry is safe. This includes both a) the re-entry interval to do work and b) the waiting period with no access to the greenhouse for roof-fogging application.

Re-entry

If work is not safe even when using gloves, a re-entry interval can be used as a risk mitigation measure and this should always be indicated on the label. Re-entry is calculated from the equation for dermal exposure with an extra factor for decay using dissipation time or half-life. The inhalation exposure should be added without considering decay. A default dissipation time value of 30 days should be used for organic substances only if no data are reported for DT_{50} or half-life representative for the proposed uses. Link to a spreadsheet for calculation of re-entry will be available.

Waiting period

The greenhouse will always be closed-off during spraying and for at least 8 hours afterwards. Spraying is assumed to be performed in the evening where there is no access until the next morning. Hence, it is not relevant to assess a waiting period. Whereas, when fogging equipment is used and the contribution from inhalation exposure is greater than1% of the AOEL a waiting period is relevant. The reason is that the data set behind the model is from 16 h after application. If the greenhouse should be closed for all access for more than 8 h, such a waiting period should be indicated on the label.

Table 2: Realistic risk mitigation measures for the in-door worker scenario.

Crop	**Chemical resistant gloves**	**Re-entry**
Ornamentals	Yes	Yes
Edible crops (except berries at harvest)	Yes	Yes*
Berries (Harvesting)	No	Yes*

* A re-entry interval exceeding the PHI reflects unacceptable exposure at harvest and the PPP cannot be authorised.

Endocrine disrupting properties

In case PPPs contain one or more active substances that are potentially endocrine disrupting the following should be considered:

Is the exposure exceeding 10% of the AOEL then a potential endocrine disrupting hazard should be explored for the in-door worker. If not, no special action is needed.

Endocrine disrupting effects have in most cases not been included in the considerations when setting the AOEL at EU level. Therefore, the first task is to check if this endpoint is considered covered by the AOEL and thus by the risk assessment.

a) If the concern is founded on a proposed classification as both Repr 2 and Carc 2 then new calculated AOELs based on the effects on reproductive toxicity (UF=300) and carcinogenicity (UF=500) should be compared to the original AOEL.
b) If the concern is founded on a proposed classification as Repr. 2 and a toxic effect on an endocrine organ, then a new calculated ED AOEL based on the most sensitive endocrine mediated effect level (UF=300-500) should be compared to the original AOEL.

When the calculated AOELs are larger than the original AOEL, then the risk is covered by the assessment and no further action is needed. However, when the calculated AOELs are lower, then the endocrine disrupting properties are most likely not covered by the risk assessment and distinct risk mitigation measures will be required for the in-door worker until endocrine disrupting properties are included in the EU evaluations.
The in-door worker should therefore not re-enter the green house until minimum 10 days after spraying, and gloves should always be worn during handling of crops and soil regardless of the stage of the production. In case of touch-sensitive crops such as strawberries, raspberries and other small berries, which are not harvested with the use of gloves, 21 days should elapse from spraying to picking. Gloves, re-entry interval and if relevant the spraying-picking interval should be stated on the label.

Metabolites of no concern – Groundwater contamination

For metabolites without pesticide effects which fulfil specific Danish requirements for no toxicological concern a limit value of 0.75 µg/L can be set based on an "ad hoc" assessment.
It must be demonstrated that such metabolites do not give rise to harmful effects on human health.
See Annex 16 for guidance.

RISK MANAGEMENT – Decision making

The final decision on approval and possible risk mitigation measures, restrictions on and requirements to the use of the PPP are made on the basis of the risk assessment. Restrictions and requirements should be indicated on the label if they are necessary for demonstrating safe use.

These are for example;

- use of personal protective equipment
- specification of the application methods
- specification of by whom (professional or non-professional) and where the product is to be used
- reduction of exposure by use of drift reducing equipment and/or increasing of buffer strips
- specification of re-entry intervals and/or waiting periods
- reduced work rate, i.e. by limitation of the area sprayed/day or reduction in e.g. time to perform at task

Framework for the environmental assessment

Background

This part of the document concerns the environmental assessment of plant protection products in accordance with Regulation (EC) No 1107/2009 (hereafter 'The Regulation') replacing Directive 91/414/EEC by 14 June 2011.

This document was major revised in June 2011 in order to accommodate the new Regulation and facilitate more harmonized risk assessments in the Northern zone. The main change in this revision of the framework for environmental risk assessment includes use of FOCUSsw modelling tools to predict surface water exposure, inclusion of the Non Target Arthropods and Not Target Plants in the environmental risk assessment. It is noted that it is a living document with continues need for updates. The basis of an environmental risk assessment is the data requirements provided in Commission Regulation (EU) No 283/2013 for the active substance and Commission Regulation (EU) No 284/2013 for the product.

As its point of departure, the environmental assessment of plant protection products covers areas considered to be of crucial environmental importance and on which sufficient knowledge for an assessment is available. This particularly applies to persistence and mobility in soil, to bioaccumulation and to effects on terrestrial and aquatic plant and animal species considered not to be pests (non-target organisms). In order to carry out risk assessment of the effect of plant protection products on the environment, information on the products' effects on plants and animals must be available as well as adequate information to calculate exposure, i.e. expected concentrations in soil, water, sediment and relevant animal food items. According to the Uniform Principles[12], assessment of the fate and distribution/behaviour in the environment must consider all parts of the environment. To the extent possible therefore, the assessment should also cover dispersal to other parts of the environment, such as air.

The assessment of the individual products in Denmark is based on their areas of use, so that only the subordinate areas considered relevant to a given area of use are assessed (requirements on data for the different areas of use are shown in Annex 1)[13].

In principle, risk assessment should be carried out on the basis of a realistic worst case. In practice, a tiered approach is used (cf. the Uniform Principles), in which assessment from a simple worst-case is gradually refined towards a more realistic worst case.

This is done by initially carrying out an assessment of the substance's intrinsic properties (based on laboratory results), which is possibly compared to a rough worst-case estimate of the expected concentration in the environment (PEC). If this is immediately acceptable the procedure stops at this tier - if not, the procedure continues to higher tiers, where the assessment is gradually made more re-

[12] Laid down in Regulation 546/2011 (see Article 29,6 in The Regulation), which was former Annex VI of Directive 91/414/EEC.

[13] Further guidance for registration of Plant Protection Products in the Northern zone will be given in the 'Guidance Document on the process for work-sharing in the Northern zone in the registration of Plant Protection Products following approval of active substance in EU in accordance with the Plan Protection Regulation (EC) No. 1107/2009/EEC.

alistic by refining the estimate of the environmental concentration (exposure) towards a more realistic value (e.g. by including degradation of the substance or by applying buffer zones) and by including studies conducted under more realistic conditions (e.g. field studies).

The active substance, any metabolites[14] and the product must all be considered in the risk assessment.
The requirements on data (and, thus, on the areas to be covered by the assessment) for the active substance are clearly defined. The concept of metabolite is defined very broadly in the Uniform Principles, where the concept of "relevant metabolites, degradation and reaction products" is used. The Uniform Principles also place metabolites on the same footing as active substances, when the metabolites are "of toxicological or environmental significance". Thus, there are no precise guidelines for this assessment in the Uniform Principles. Subsequent to the Uniform Principles, in 2003 the Commission published a guidance document on relevant metabolites which focuses on groundwater and discusses the criteria that are relevant for metabolites and sets limits for the occurrence of relevant metabolites in groundwater. In the opinion of the Danish Environmental Protection Agency this document does not deal with the problem in accordance with the intentions of the Directive, especially in regards of contamination of groundwater (for more details see the section “Mobility”) and consequently this document is not used by the Danish Environmental Protection Agency in its national evaluations. The Danish Environmental Protection Agency carries out ad hoc appraisals of the extent to which metabolites are significant with respect to health and the environment. As a rule, a metabolite is included in the assessment (either in the form of considerations based on studies of the active substance or on the basis of independent studies of the metabolite) if one of the following conditions apply: a) Metabolites, which account for more than 10 % of the amount of active substance added in soil at any time during the degradation studies; or b) which account for more than 5 % of the amount of active substance added in soil in at least two sequential measurements during the studies; or c) for which at the end of soil degradation studies the maximum of formation is not yet reached. If, based on the available documentation, there are indications that metabolites accounting for lower levels could prove problematical (e.g. in relation to groundwater pollution), they must also be assessed. The Danish Environmental Protection Agency has decided that metabolites that occur commonly in nature (for example pyrimidine) or which are simple substances such as saccharine are not to be considered as relevant.

The environmental assessment is divided into two main areas:

- Fate and distribution/behaviour in the environment
- Effects on non-target organisms.

The overall principles for assessing these factors are described individually in the following.

Fate and distribution/behavior in the environment: persistence, mobility and bioaccumulation

A plant protection product containing a persistent or bio-accumulating active substance can impact the environment over a long period, whereas a mobile active substance can pollute groundwater.

[14] Metabolites are defined here as all degradation, reaction and transformation products of pesticides that differ from the ultimate mineralisation products, i.e. CO_2, H_2O and mineral salts.

These properties are appraised to determine whether there is any risk of the limit values or cut-off values (called "triggers" in the Uniform Principles) being exceeded by a given use.

According to the Uniform Principles, products can be authorized despite the fact that they exceed the cut-off values for persistence and bioaccumulation, provided that it can be shown scientifically or by an appropriate risk assessment that the proposed use will have no unacceptable impact/effects on the environment (a so-called “unless clause”).

For active substances that are subject to a national reassessment, the Danish Environmental Protection Agency find that it is not at present possible to appraise the long-term consequences of the use of highly persistent substance (i.e. with half-lives of more than six months). Neither does the Danish Environmental Protection Agency find it possible to assess the long-term consequences of the bioaccumulation of active substances.

The Danish Environmental Protection Agency therefore continues to be of the opinion that authorization cannot be granted to products with an active substance that is very persistent (DT_{50} > 6 month) or where the bioaccumulation of the active substance exceeds the cut-off value (see section on Bioaccumulation), if the products will be used in a way that involves exposure of the external environment.

Concerning mobility (pollution of groundwater), there is no actual "unless clause" in the Uniform Principles, as only reference is made to the fact that it must be possible to observe the limit values under relevant field conditions.

Effects on non-target organisms: aquatic and terrestrial organisms

Plant protection products may constitute a risk of unacceptable impact on aquatic and terrestrial non-target organisms. For the effect area, the main risk assessment's point of departure is the so-called quotient method, in which the toxicity towards a given organism is compared to the level to which that organism can be expected to be exposed (i.e. the Toxicity Exposure Ratio, TER, cf. the Uniform Principles)[15].

Assessment is done for relevant areas (soil, water, sediments etc.), with the point of departure in the (few) species tested in connection with the application for authorization. There is, however, great variation in sensitivity to different substances between individuals within a species and, especially, between species within the same taxon/in different taxa. In order to protect more species than just the species tested, the risk assessment includes an assessment factor (also called safety factor or uncertainty factor), according to which the risk is assessed on the basis of comparing the quotient (TER) with the assessment factor (cut-off value)[16].

When determining toxicity or exposure, the quotient method gives no consideration to a number of issues, for instance:

- extrapolation is done from only a few species to all species

[15] Following the revised Aquatic GD (EFSA PPR, 2013) Regulatory Acceptable Concentration (RAC) will be referred to in the aquatic section, in accordance with the Northern zone Guidance Document.

[16] An assessment factor is incorporated in the Regulatory Acceptable Concentration (RAC). I.e. the RAC can be directly compared to a use specific PEC value.

- no compensation is made for differences between laboratory tests and the actual conditions in nature
- the method cannot be used to estimate indirect effects (interactions through the food chain, etc.)
- uncertainties cannot be fully quantified
- exposure is often estimated on the basis of uncertain assumptions.

For these reasons, a risk assessment based on the quotient method can only yield an approximate estimate of whether or not a particular pesticide could carry the risk of unacceptable effects in the environment.

According to the Uniform Principles, the so-called triggers must not be used as actual cut-off criteria, and products can be authorized despite the fact that triggers cannot be complied with, if an appropriate risk assessment can clearly demonstrate that there are no unacceptable effects after using the plant protection product under the proposed conditions of use (an unless clause). The Uniform Principles do not, however, offer a more specific definition of how this should be proven.

In order to clarify the unless clauses in the Uniform Principles, EU guidance documents are drafted on an on-going basis and are used in the EU assessments when substances are approved for the European marked (Regulation (EC) No 1107/2009) . The guidance documents are not legally binding but are used as a starting point in the EU assessments and to a growing degree also in the Danish assessments. However, for areas without guidance documents it can be extremely difficult to conduct a risk assessment and to determine which effects are acceptable or unacceptable. Therefore trigger values from the Uniform Principles will in practice act as cut-off values.

The guidelines for the environmental risk assessment and decisions for the individual areas are described in the following. It should, however, be emphasised that each individual decision will be based on an overall assessment of the risk constituted by the product.

Assessment of cumulative ecotoxicological effects of products containing chemical mixtures are required for groups of organisms where the risk assessment is based on a quotient calculation, i.e. birds, aquatic organisms, mammals, earthworms and bees (see annex 12).

ENVIRONMENTAL RISK ASSESSMENT AND DECISIONS

Fate and behaviour/distribution in the environment

The assessment of a substance's fate and behaviour/distribution is based on laboratory and field tests, which investigate the degradation, mobility and bioaccumulation of the active substance and its possible metabolites.

Each individual area is described in greater detail in the following sections.

Fate in air

When recommendations on the assessment of evaporation and degradation in air are included in the EU-assessments (FOCUS Air 2008), these issue will be included in the Danish assessments.

Persistence in soil

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. Persistent substances can also cause effects on and lead to residues in subsequent crops. This also applies to the metabolites of an active substance. Therefore active substances with a DT_{50} above 180 days cannot be approved in Denmark.

The persistency evaluation is based on an assessment of available reliable half-lives from both laboratory and field studies. All half-lives should be normalised to 20 °C and pF2. Assessment of persistency should not be based on average or percentiles of the data. Instead data are assessed by considering the soil types used and focusing on soil types representative for Danish conditions. If in general these soils have a DT_{50} above 180 days, the active substance cannot be approved. If only some of the soil DT_{50} values are above 180 days, an ad hoc assessment is performed to decide if these data constitute the major part of data and if it is likely that DT_{50} for Danish soils is above 180 days under field conditions relevant to the intended use.

The persistency evaluation should be performed for both the active substance and metabolites. However, metabolites which fulfil the following requirements are considered to be of no concern regarding persistence if:

- The metabolite fulfil the Danish requirements for metabolites of no toxicological concern (see section on human health risk assessment)
- The metabolite does not constitute a risk of leaching to groundwater in concentrations > 0.1 µg/L.
- The metabolite does not constitute a risk to soil living organisms (i.e. it does not trigger a higher tier risk-assessment)

If the active substance or metabolites has a DT_{50} < 180 days they do **not constitute an unacceptable risk to the environment, from the standpoint of persistence**.

If a metabolite of no concern has a DT_{50} > 180 days it does **not constitute an unacceptable risk to the environment, from the standpoint of persistence**.

If the active substance and metabolites of concern have a DT_{50} > 180 days they do **constitute an unacceptable risk to the environment**, and products containing such an active substance cannot be authorised for outdoor use.

Biological effects require that there is bioavailability, i.e. that exposure of biota occurs. Therefore a distinction is made between substances that are persistent because they degrade slowly and sub-

stances that are not bio-available. It is therefore important to consider the extraction methods used in the degradation tests. The extraction method can lead to substances being extracted from the soil regardless of where and how they reside in the soil matrix. Even substances that are more or less bio-unavailable can be extracted by some methods and thereby the normally bio-unavailable portion is included in the pool of substances that define persistence. This can result in a substance being assessed as persistent. On the other hand, extraction methods that are too harsh can destroy the molecular structure of an active substance and thereby lead to an underestimation of the percentage of active substance in the soil. Applicants must therefore be able to document that this is not the case.

Therefore, in 2002, the Danish Environmental Protection Agency decided to change its practices (cf. meeting of the Pesticide Advisory Board 7 March 2002) because sufficient information is available on some substances that it must be concluded that the connection between degradation, adsorption and bioavailability is well documented. In such cases an ad hoc assessment can be carried out with a view to make an exception from the persistence criteria below.
Therefore, in special circumstances an exception can be made if adequate information is available on the connection between the substance's rate of degradation and adsorption, such that it is possible to assess with certainty the degradation rate of a substance in its free (i.e. non-adsorbed) state. Furthermore the connection between adsorption (including possible saturation of binding sites), extraction methods and bioavailability must be fully documented.

PEC_{soil}
Calculation of PEC_{soil} follows the Northern Zone guidance document.

Groundwater/Mobility

Mobile active substances entail a risk of unacceptable leaching through the soil to groundwater, watercourses and lakes, which can cause pollution of groundwater and/or undesirable effects on the environment. The same applies to mobile metabolites.

The Uniform Principles specify limit values[17] for the pollution of groundwater. These values are:

- 0.1 µg/l for each individual substance
- 0.5 µg/l for the sum of substances[18].

Limit values may however be lower for some substances, if the limit values are set by specific health risk assessments of the individual substances, cf. footnote 7.

[17] Point C 2.5.1.2 of the Directive mentions that authorization cannot be granted if the concentration of the active substance or its relevant metabolites, degradation or reaction products in groundwater resulting from the proposed use, can be expected to exceed the lowest of the following limit values: i) the maximum permissible concentration laid down in the Directive on drinking water (80/778 /EEC), ii) the maximum concentration which the Commission has set on entry of the active substance in Annex I or, where such a limit is not set, one tenth of the ADI that was set on entry in Annex I.
[18] To be interpreted as the sum of the active substance and its metabolites.

For metabolites without pesticide effect which fulfil the Danish requirements for no concern (see section on human health risk assessment) and which do not constitute a risk to non-target organisms (see section above) a limit value of 0.75 µg/L can be set based on an "ad hoc" assessment.

If the proposed use entails exposure of the external environment, the Danish Environmental Protection Agency (cf. below) considers whether or not there is an unacceptable risk of the concentration of the active substance and/or its metabolites exceeding the above limit values for groundwater.

The risk of leaching is assessed from mathematical modelling. The requirements of the Danish Environmental Protection Agency's for mathematical modelling are listed in annex 6. The most important requirements are:

- The PELMO 5.5.3 model (or comparable model) with the Hamburg scenario or MACRO 5.5.3 with the Danish scenarios. If both models are used then the results of both models must fulfil the limit values.
- Substance specific parameters: 80 percentiles for degradation rates and sorption ratios (1/n) must be used and for K_{OC} 20 percentiles must be used[19].
- Separate model runs must be executed for at least three individual days of the period in which use of the product is proposed.
- Use every 2nd, 3rd and 4th year can only be used as a refinement option if the crop can only be grown 2nd, 3rd og 4th year. A list of crops where this refinement option can be used can be found in Annex 13.
- The results must be reported as annual averages. This also applies if the substance is used every second, third or fourth year. All output files must be submitted.

In this way the assessment is done for a realistic worst-case situation, based on the annual average concentration in the water that percolates to the ground water. If this concentration does not exceed the limit values in more than 1 of 20 years, the product is considered **not to constitute an unacceptable risk of polluting groundwater** for the proposed use. If one or both of the limit values are exceeded, the product cannot be approved for the proposed use, unless other studies (lysimeter studies, field studies, and/or monitoring data) very convincingly demonstrate that unacceptable leaching will not occur in the Danish context. When evaluating such studies, consideration must be given to whether soil, climate and conditions of application (crops, vegetation cover, application method, formulation of the product, its quantity and time of application) correspond to Danish conditions. Data from the Pesticide Leaching Assessment Programme[20] (PLAP) can be used in the assessments. When evaluating risk of leaching to groundwater only data from the groundwater installations in PLAP are used and not samples from drains or suction cups. Considerations may also be given to conditions of use (e.g. use on paved areas[21]). The assessment is done for a realistic worst-case situation, based on the annual average concentration in the water that percolates down from the root zone (a depth of about 1 metre).

[19] Formation factions and DT_{50} values should be from the same tier (i.e. lab or field) if data are available.
[20] http://pesticidvarsling.dk/om_os_uk/uk-forside.html
[21] Special documentation is required for paved areas and a special assessment is carried out, see Annex 4 (cf. Newsletter, Nov. 1999).

Surface water

Assessment of the concentration of an active substance or its metabolites in surface water is not an end in itself but must be considered in relation to the ecotoxicity data of the active substance or metabolites. The assessment of the concentration in surface water follows the guidance by FOCUS (2001). The assessment is a stepwise approach with 4 steps. Step 1 accounts for an 'all at once' worst-case loading without specific additional characteristics. The Step 2 calculation accounts for a more realistic loading based on sequential application patterns, while no specific additional characteristics of the scenario are defined. Step 3 performs an estimation of the PECs using realistic worst case scenarios but taking into account agronomic, climatic conditions relevant to the crop and a selection of typical water bodies. Finally, Step 4 estimates the PECs based on specific scenarios including risk mitigation, which should be used on a case-by-case basis if Step 3 fails.

The special requirements of the Danish EPA are describes below. Aside from this the assessment follows the FOCUS guidance document (2003).

FOCUSsw Step 1 and 2: The assessment follows the FOCUS guidance.

FOCUSsw Step 3: Scenarios D3 (sandy soil, Vredepeel, Netherlands) and D4 (loamy soil, Skousbo, Denmark) are considered to be the relevant scenarios representing geological and climate conditions of Danish agricultural soil, i.e. only inputs from spray drift and drainage are considered relevant for Danish conditions. The highest PECsw derived from D3 and D4 is used in the aquatic risk assessment. Noted that FOCUSsw Step 3 operates with default crop specific distances between crops and the top of the bank that defines the edge of the water body (0.5-3m). If the aquatic risk assessment is based on FOCUSsw Step 3, a no-spray zone of 2 meters has to be added on the label in order to cover the FOCUSsw Step 3 model assumptions. It is noted, however, that if a FOCUSsw Step 3 risk assessment is requested to ensure a FOCUSsw Step 2 risk assessment where the TER value is not 10x the required trigger (to take account of possible higher PEC values at FOCUSsw Step 3), a 2 meter buffer zone is not required. Step 4: Risk mitigation measures can be applied at this step. In accordance with the recommendations in the FOCUS Landscape and Mitigation report (2007), up to 95% drift reduction (compared to Step 3) based on no spray buffer zones can be applied[22]. Guidance on crop type specific maximum acceptable no spray buffer zones is provided in Annex 9. Mitigation of drainage contributions shall follow the recommendations in the FOCUS Landscape and Mitigation report (2007) i.e. maximum 90% reduction of drain contributions (e.g. prohibit application to drained soil).

Input parameters must be in accordance with FOCUS surface water guidance.

Metabolites are modelled in accordance with FOCUS surface water guidance.

Bioaccumulation

Bio-accumulating active substances entail a risk of accumulation in organisms. Accumulation can occur when aquatic organisms absorb the active substance from water and accumulate it in tissue in a concentration higher than the concentration in the water. Similarly, an active substance can accumulate in the food chain, so that the highest levels of the chain receive higher concentra-

[22] DK EPA does not approve PPP's intended for spot application in field crops, since it is not considered realistic or practically possible, that such an application restriction would be respected.

tions in tissue than the lower levels (biomagnification). The same applies to bio-accumulating metabolites.

Tier 0: Potentially bio-accumulating substances (i.e. log Kow > 3) are assessed on the background of laboratory tests to determine whether the active substance or relevant metabolites:

- can be expected to accumulate in aquatic organisms with a bio-concentration factor of greater than 1000[23], if they are easily degradable[24]
- are expected to accumulate in aquatic organisms with a bio-concentration factor of greater than 100, if they are not easily degradable
- are expected to accumulate in terrestrial food chains with a biomagnification factor (BMF) of greater than 1[25], [26]

If the above values are not exceeded, products containing the relevant active substance are not considered to constitute any unacceptable risk to the environment with respect to bioaccumulation. If any of the values are exceeded, the procedure continues to Tier 1.

Tier 1: The active substance or its metabolites are evaluated to determine whether the elimination rate for the organ from which elimination is slowest has a $DT_{50} < 3$ days and a $DT_{90} < 14$ days (the latter trigger is used in the Uniform Principles). If this is the case, products containing the relevant active substance are considered not to constitute any unacceptable risk to the environment, from the standpoint of bioaccumulation. If these elimination rates are exceeded, products containing the relevant active substance cannot be authorized for outdoor use.

Effects on non-target organisms and risk assessment.

Plant protection products may present a risk of unacceptable effects to non-target organisms in the aquatic and terrestrial environments. Appraisal of the extent to whether these effects are unacceptable (or not) is based on laboratory tests in a number of standard organisms. The risk is estimated on basis of toxicity towards tested organisms, predicted exposure (which is modelled on the basis of the product's use/dossing and substance properties) and use of an Assessment Factor (AF) in order to take account of uncertainties. A tiered assessment is carried out, in which the estimate of toxicity and exposure are gradually refined towards a more realistic worst case or introduction of risk mitigation measures, as described below.

Assessment of toxicity

The toxicity assessment is initially (Tier 0) carried out on the basis of the available laboratory endpoint. These endpoints will in many cases have been derived and agreed during the EU process of the active substance; in such case, the studies are appraised to determine whether they are representative of the metabolites and product. In the cases for which studies of the active substance and metabolite, or studies of the product, are available, assessments are made for each of the subordi-

[23] Assessed on the basis of bioaccumulation studies in fish, in which whole fish are the point of departure.
[24] Cf. the OECD guidelines for the testing of chemicals, see Annex 8.
[25] See EFSA guidance on Risk Assessment for Birds and Mammals (EFSA, 2009).
[26] Biomagnification and food chain behaviour for birds and mammals are addressed in the section on risk assessment for

nate areas to determine whether it is most likely that exposure will be to the active substance and/or metabolite or to the product (e.g. birds will be exposed to the product, where seed dressings/granulated formulations are concerned and non-target arthropods are exposed to sprayed formulations) and consideration is given to this in the risk assessment.

The risk assessment includes data for all relevant test organisms. The risk assessment is normally made on the basis of the most sensitive organism. The assessment includes the short-term (acute) effects and effects over longer periods (chronic), if such data are available and if there is a question of exposure for longer periods.

The LD_{50}, LC_{50} or EC_{50} values obtained from laboratory tests are used as the initial measure of *acute toxicity*. In the case of *chronic toxicity*, the no observed effect level (NOEL) or no observed effect concentration (NOEC) have hitherto been used, but in the future more and more chronic studies are expected where an EC_x (x is normally 5 or 10) is derived and should be used in the chronic risk assessment (cf. the data requirements and test guidelines). When ECx values are available from chronic studies they should be used in the chronic risk assessment.

The Danish Environmental Protection Agency does check that no effects are really observed for the NOEC or NOEL. The mathematical/statistical NOEC can be disregarded if there is an obvious but not statistically significant effect, which can be the case if the statistical uncertainty is high. If the NOEC value is considered credible (i.e. if it is only a question of marginal numerical differences relative to the control group), it is used in the risk assessment; if not, the data can be re-analysed, for instance, to determine the EC_5 or a corresponding value considered to constitute a negligible effect level when viewed from the standpoint of the population (the determination of this level demands expert assessment for each individual species).

Use of acute geometric mean effect endpoints is accepted in line with recommendation in the Northern zone GD (2016).

At higher tiers, the toxicity data from additional laboratory tests and subsequent semi-field and field studies of effects on aquatic and terrestrial organisms are included in the risk assessment.

If formulation toxicity data are not available, mixture toxicity should always be considered for acute and long-term risk assessment in accordance with the Northern zone GD (2016).

Assessment of exposure

With regard to *exposure*, the concentration and bioavailability of a given substance in the environment will vary considerably, depending on local conditions and the substance's intrinsic properties. It goes without saying that it is not possible to include all of the conditions that determine the concentration when estimating exposure and neither is it possible to work with a large number of different values. To allow for the probably considerable variations in environmental concentrations, a

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birds and mammals.

"normal use" situation with respect to the dose and crop will be treated as a realistic worst-case situation.

In the aquatic compartment the estimation of exposure follow the tired approach provided for FOCUSsw modelling (see fate section). When adjusting the PECsw, consideration must always be given to the toxicity value with which it will be compared (e.g. consideration must be given to the form of exposure used in the test (static or flow-through, etc.) and to the point in time at which the effects start). Possible use of a time weighted average (TWA) exposure when conducting risk assessments of *chronic effects* should follow the recommendations in the EFSA PPR (2013) and the Northern zone GD (2016) i.e. addressing all concerns regarding use of TWA.

Additional information (in the form of specific laboratory, semi-field or field studies of the substance's fate) can be included at higher tiers in a realistic worst-case estimate of the PEC. In addition it is possible to include mitigation measures.

Since June 2016 DEPA has accepted the use of drift reducing equipment as a mean to reduce buffer zones stated on the label in accordance with statutory Order no. 1750 of 14/12/2015 and the associated guidance document 17 (2016)[27]. However, as drift may not be mitigated more than 95% in total (no-spray buffer zones and/or use of drift reducing equipment) compared to drift estimated in FOCUSsw Step 3 it is not possible to further mitigate the risk by imposing drift reducing techniques.
The following section describes risk assessment and decision making for each individual subordinate area in more detail.

Aquatic organisms

The Danish risk assessment for aquatic organisms generally follows the Northern Zone GD that again builds on the guidance given in the EFSA aquatic GD (2013). Only specific national requirements and exceptions to the Northern zone GD regarding aquatic risk assessment are given below.

Details on how to perform exposure estimates required for Denmark are given in fate section of this document. Aquatic risk assessments relevant for Denmark require PEC estimates for the FOCUSsw scenarios D3 and D4.

Mesocosm and Assessment Factor

The Danish EPA accept the use of Ecological Recovery Option (ERO) derived from mesocosm studies. However, the recovery period must not exceed 4 weeks. The appraisal of the quality of the tests study is given in the EFSA Aquatic GD (2013).

The assessment factor (AF) is associated with an ERO[28] from a mesocosm studies. As the point of departure, a minimum assessment factor of 5 will be used (as individual tests cannot be expected to be representative of all of the organisms or biotopes in the landscape at any time that may be exposed).

[27] http://www2.mst.dk/Udgiv/publikationer/2016/06/978-87-93435-79-7.pdf
[28] The Ecological Threshold option (ETO) is used by all other MS in the Northern zone and the AF is set in accordance with the Northern zone GD (2016) for this option.

Further advice regarding application of AF is given in annex 10.

If the data on a specific substance does not indicate that fish are more sensitive than invertebrates, mesocosm studies of invertebrates are considered to be representative of fish in connection with a higher-tier risk assessment.

If there are signs that fish are more sensitive, for example to endocrine disrupters, the total data set is assessed for the specific case.

If specially designed semi-field or field tests are available, an ad hoc assessment will be made on the basis of a realistic worst-case situation.

Accepted mitigation
Risk mitigation of spray drift should follow the specifications in Annex 9, including the limitations on maximum no-spray buffer zones for different types of crop.

If several mesocosm tests of high quality have been submitted that illustrate the difference there can be between the various natural systems, the assessment factor can be reduced in accordance with the guidelines in Annex 10. Tests that are different in terms of time and space can be used to lower the assessment factor if they represent different population mixes or biotopes.

If there is considered to be no question of unacceptable effects (possibly conditional on the use of preservation zones) and the studies are satisfactory, the product is **not considered to constitute any unacceptable risk to aquatic organisms**, in the proposed use.

If no such documentation is available, or if it is not possible to ascertain on the basis of the available documentation that no unacceptable effects will occur, the product cannot be authorized for outdoor use.

For cumulative risk assessment of combination products, follow the Northern zone GD (2016).

Sediment-dwelling organisms
Following the data requirements the risk for sediment-dwelling organisms should be assessed if a substance can accumulate in sediment (see Annex 13).
PECsed values are derived from FOCUSsw modelling (see fate section).

For cumulative risk assessment of combination products, follow the Northern zone GD (2016).

Terrestrial organisms

The risk assessment for terrestrial organisms is based on standard laboratory tests in birds, mammals, earthworms, micro-organisms and, possibly, arthropods.
Typical conditions of significance to the concentration and bioavailability of active substances and metabolites in terrestrial environments include adsorption, mobility, run-off, vegetation cover, absorption by plants, evaporation and chemical, biological or photolytic degradation, etc.

Birds and mammals

The toxicity assessment is based on standard laboratory tests in birds and mammals. In the case of spray products, it is assumed that birds and mammals are exposed through their food, due to deposition of pesticide on plants or insects, including residual concentrations in plants. For granules and dressed seeds, the exposure is assessed on the basis of ingestion of these.

The risk assessment is carried out as a tiered risk assessment on the basis of the scenarios and principles that are used in the Community assessments in accordance with the revised guidelines in " Guidance of EFSA on Risk Assessment for Birds and Mammals" (EFSA, 2009). The initial risk assessment - Screening tire and Tier 1 risk assessment - follows the Guidance Document (EFSA, 2009).

If higher tier refinements are required in order to address the risk to birds and/or mammals from an applied use of a product, guidance is give in the Northern zone guidance 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" and an associated calculation tool is provided in the form of an Excel spreadsheet[29].

The intention of the guidance is to provide risk assessments for birds and mammals, based on Northern zone focal species relevant for the crop type and its growth stage. Biological background information on crop stage specific relevant focal species and available refinement options are presented in this document and it is applied in the calculation tool.

All the higher tier refinement options given in this document are agreed among the Northern zone member states and as such accepted in the core assessment.

If needed, further higher tier refinements, accepted by Denmark, are given in "Guidance Note on Higher Tier Birds & Mammals Risk Assessment in Denmark"[30]

The risk from food chain poisoning shall be addressed for products with potential for bioaccumulation (see section on bioaccumulation for definitions). The risk assessment shall follow the Guidance Document (EFSA, 2009).

If TER values are greater than the trigger values in the Uniform Principles, the product is considered not to constitute any unacceptable risk to birds or mammals for the proposed use.

For the acute cumulative risk the assessment shall follow the Bird and Mammal Guidance Document (EFSA, 2009). For the chronic cumulative risk the assessment shall follow guidance given in Annex 12.

Bees

The risk assessment for bees follows the Guidance document on terrestrial Ecotoxicology (2002).

[29] Available on the Danish EPA website
[30] Available on the Danish EPA website

For products applied as sprays where risk as assessed according to the HQ approach exposure should be established as the maximum single application rate of the product expressed as g/ha because the HQ was validated on this measure.

For systemic plant protection products, exposure considerations and calculations should be based on the a.s. (or metabolite) present in the respective plant parts (e.g. nectar, pollen) to which honeybees could be exposed.

The hazard quotient is stated to be application rate/oral LD50 or application rate/contact LD50, where the LD50 is expressed as ug a.s./bee and the application rate is in g a.s./ha. As stated above, the maximum single application rate should be used to calculate the oral and contact HQ-values. If the oral and contact HQ < 50, low risk to bees is concluded and no further testing is required. If the oral or contact HQ > 50, further higher tier testing is required to evaluate the risk to bees. The critical HQ of 50 was validated against incidents (EPPO 2002b); it is only applicable to spray products.

Higher tier refinements should follow the Guidance document on terrestrial Ecotoxicology (2002).

Arthropods[31]

The initial risk assessment for non-target arthropods (NTA) is based on glass plate tests with the two standard species (*Aphidius rhopalosiphi* and *Typhlodromus pyri*) in accordance with the Guidance Document on Terrestrial Ecotoxicology (SANCO 10329/2002). By comparing the endpoint of these studies are LR50 values (i.e. lethal rate that causes 50 % mortality) which the predicted exposure both in-field and off-field, hazard quotients (HQ) are derived. Hence, the assessment of risk for arthropods living in- and off-field is conducted separately.

If the resulting HQ is greater than or equal to 2, then further data and/or risk management measures are required.
There are several options for higher-tier testing or combinations of adequate tests: extended laboratory tests (tests with natural substrate aiming at lethal and sub-lethal effects), aged-residue studies, semi-field tests and field tests. Depending on the individual case testing on additional species might be triggered.

For further details please refer to the Guidance Document on Terrestrial Ecotoxicology (SANCO 10329/2002) and the recommendations of ESCORT 2.

Mitigation:
In order to reduce effects in off-field areas, Danish EPA considers that buffer zones, as described in Annex 9, specifically to protected paragraph3-habitats[32] must be considered in order to mitigate exposure to non-target arthropods.

Beneficial arthropods:
The appraisal of beneficial arthropods other than bees is described in annex 15.

[31] beneficial arthropods, which are a natural part of integrated pest control. The compatibility of greenhouse products with the principles of biological pest control set by the Danish Institute of Agricultural Sciences (DJF) is assessed.
[32] habitat types encompassed by section 3 of The Protection of Nature Act, with exception of aquatic habitats like lakes, ponds, streams etc.

In-soil organisms

The assessment is based on standard laboratory tests of earthworms (chronic tests). The exposure of earthworms is assessed on the basis of deposition of the substance on soil and, in the case of spray products, subsequent exposure through the soil. In the case of dressed seeds and granulates, exposure is assessed on an ad hoc basis.

Tier 0:
PEC is estimated in accordance with the Northern zone GD (2016) If dressed seed or granulate is used an ad hoc assessment is carried out. In the case of active substances that bind strongly to soil (log Kow > 2), correction for this is made by dividing the effect values by 2, as laboratory tests in earthworms are conducted in artificial soil with a high content of organic material (and, thus reduced availability of the test substance).

The toxicity exposure ratio (TER) is estimated on the basis of the toxicity data and the PEC and is compared to the relevant assessment factor as shown below:

Chronic toxicity: TER = NOEC or ECx/PEC > 5

The chronic toxicity for earthworms is assessed on the basis of reproduction studies.

If the quotient is greater than the assessment factors used, the product is considered not to constitute any unacceptable risk to earthworms/terrestrial invertebrates in the proposed use. If, on the other hand, the TER quotient is lower than the assessment factors, the procedure continues to Tier 1.

Tier 1:
The PEC is adjusted with respect to the vegetation cover (see Annex 11) (as the test is regarded as a simulation test, in which the exposure is expected to reflect a natural degradation process, the PEC is not initially adjusted with respect to degradation of the substance) and compared to the toxicity. If the TER value is greater than the assessment factors used, the product is considered not to constitute any unacceptable risk to earthworms/terrestrial organisms in the proposed use. If, on the other hand, the quotient is lower than the assessment factors, the procedure continues to Tier 2.

Tier 2:
If relevant data is available in the form of specially designed laboratory, semi-field or field tests, an ad hoc assessment of a realistic worst-case situation is carried out. In this connection, the Danish Environmental Protection Agency has set an acceptable effect level of a 50 percent reduction in earthworm populations ("Probable high risk", in the classification proposed in "Earthworms as ecotoxicological test organisms", Christensen & Mather, 1994), on condition, however, that recovery occurs within one season/within the intervals between spraying (cf. EPPO Bulletin). The assessment factors that are associated with this effect level depend on the quality of the toxicity studies. In this context, consideration must be given to the fact that this assessment is not necessarily representative of other terrestrial organisms. For other species, ad hoc assessments of the effect levels are carried out.
If there is not considered to be any question of unacceptable effects and the studies are satisfactory, the product is considered not to constitute any unacceptable risk to earthworms/soil-dwelling organisms in the proposed use.
If no such documentation has been presented, or if the available documentation does not make it possible to ascertain that no unacceptable effects can occur in earthworms and other soil-dwelling invertebrates, the product cannot be approved for outdoor use.

For cumulative risk assessment of combination product, where product effect data are not available, follow the guidance in Annex 12.

Microorganisms

The assessment of effects on microorganisms is based on an appraisal of microbial processes, in which an evaluation is carried out of whether or not the microbial metabolisation of N and C are influenced by the active substance or its metabolites. In the case of spray products, the exposure of microorganisms is assessed on the basis of the deposition of the substance on soil and the resulting exposure through the soil. Where granulates and dressed seeds are concerned, the exposure assessment is based on a mixture of the active substance in the soil, unless special tests are available.

Tier 0:
PEC is estimated in accordance with the Northern zone GD (2016)
The trigger for effects on the microbial metabolisation of N (N mineralisation) is set to 25 per cent reduction after 100 days. The Danish Environmental Protection Agency will initially use this trigger as a cut-off value in risk assessments in relation to the initial concentration in the soil. If the inhibition of microbial processes is below 25 per cent, the product is not considered to constitute an unacceptable risk to microorganisms in the proposed use. If the inhibition exceeds 25 per cent, the procedure continues to Tier 1.

Tier 1:
As the test methods used are a simulation test (in which the exposure is expected to reflect a natural degradation process), the PEC is not adjusted in relation to degradation of the substance unless there are major differences in the degradation rates between laboratory and field tests. The PEC is adjusted in proportion to how great a quantity of the sprayed product/active substance is deposited on the soil for a given crop, at a given time of application (see Annex 11 for a more detailed description).

Tier 2:
An ad hoc appraisal of specially designed laboratory, semi-field or field tests is carried out. These tests must be able to demonstrate that, in the proposed use, the product has no unacceptable influence on microbial activity with respect to the microorganisms' reproductive capacity.
If there are not considered to be any unacceptable effects and if the study is satisfactory, the product is not considered to constitute any unacceptable risk to microorganisms in the proposed use.
If no such documentation is available, or if it is not possible ascertain on the basis of the available documentation that no unacceptable effects will occur, the product cannot be authorised for outdoor use.

Biological methods of wastewater treatment

Within the scope of the Regulation (EC) No. 1107/2009 the risk to Biological Methods of Wastewater Treatment will be assessed where use can cause exposure of the wastewater treatment plant (e.g. for greenhouse products and post-harvest use). There are no specific guidelines for risk assessment of this area, and therefore an ad hoc assessment will be done on the basis of whether a realistic worst-case PEC can cause unacceptable effects.

Non-target plants (NTP)[33]

The risk assessment shall follow the Northern zone GD (2016) regarding NTP. I.e. repeated application needs to be considered in a risk assessment, by relating drift values to number of applications (See appendix IV in Escort 2 (Candolfi et al., 2001).

[33] Non-target plants are considered to be non-crop plants located outside the treatment area.

In order to reduce effects in off-field areas, DEPA considers that buffer zones, as described in Annex 9, specifically to protected paragraph 3-habitats[34] should be considered in order to mitigate exposure to non-target plants.

[34] Habitat types encompassed by section 3 of The Protection of Nature Act, with exception of aquatic habitats like lakes, ponds, streams etc.

List of Annexes

Annex 1: Data requirements on plant protection products

The basis for the specific data requirements are provided in the Commission regulations (EU) laying down the data requirements for the dossier to be submitted for the approval of active substances contained in plant protection products (COMMISSION REGULATION (EU) No 283/2013) and for the authorisation of plant protection products (COMMISSION REGULATION (EU) No 284/2013).

In the tables below, the main data requirements are listed according to the application form and subdivided into the following areas of use:

1. Agriculture; outdoor use
   Forestry; outdoor use
   Fruit growing; outdoor use
   Nursery gardens, market gardening; outdoor use[35]
   Soil disinfection; outdoor use[1]

2. Private use in gardens[36]
   Greenhouses
   Soil disinfection; indoor use
   Products for controlling algal growth; indoor use
   Products for controlling algal growth; outdoor use

3. Seed dressings

4. Granulates

5. Repellents
   Insecticides; indoor use
   Insecticides; in stored grain

Please notice, the tables only give an initial overview without details and are no intended to replicate the formal data requirements.

[35] For these uses the standard data requirements apply as a rule, but an ad hoc assessment can be carried out based on the extent/crop etc. of the use.
[36] For private use in gardens data on adsorption/desorption is also required.

Data requirements on active substance for area of use:	**1**	**2**	**3**	**4**	**5**
Plant metabolism	x		x	x	
Metabolisation in 1 soil type	x	x	x	x	
Degradation, 3 soil types, aerobic	x		x	x	
Photolysis on soil	x			x	
Adsorption/desorption	x		x	x	
Accumulation of active substance and significant metabolites[37] in soil(if DT50 > 3 months)	x		x	x	
Evaporation from soil (only if vapour pressure > 10^{-3} Pa)	x			x	
Biological degradation in water/water-sediment studies	x		x	x	
Effects on water treatment plants	x	x	x	x	
Acute toxicity in fish	x	x	x	x	
Long-term toxicity in fish	x		x	x	
Acute toxicity in daphnia (and additional species for insecticides)	x	x	x	x	
Reproduction test in daphnia	x		x	x	
Acute toxicity in algae (and macro-algae for herbicides)	x	x	x	x	
Effects on other aquatic organisms	x			x	
Bioaccumulation (Kow > 1000)	x	x	x	x	
Long-term effects in earthworms	x		x	x	
Effect on soil micro-organisms	x		x	x	
Acute toxicity in one bird and mammal species	x		x	x	
Reproduction test in one bird and mammal species	x		x	x	
Effect on honey bees	x		x	x	
Any information on toxic effects towards other useful species	x	x	x	x	

Data requirements on product for area of use:	**1**	**2**	**3**	**4**	**5**
Content of substances harmful to honey bees	x		x	x	
Other ecotoxicological effects	x		x	x	
Non-target arthropods *(Aphidius rhopalosiphi and Typhlodromus pyri*).	x		x	x	
Non-target plants	x		x	x	
Acute toxicity in fish	x	x	x	x	
Acute toxicity in daphnia	x	x	x	x	
Acute toxicity in algae	x	x	x	x	

[37] See p.2 for description of significant metabolites.

Annex 2: Soil classifications in Denmark

The Danish soil types are classified according to the distribution of their particle sizes and humus content:

Texture definition for soil type	Symbol (insert footnote here: Abbreviations refer to the Danish text)	JB No.	Clay less than 2 μm	Silt 2-20 μm	Fine sand 20-200 μm	Sand 20-2000 μm	Humus 58.7 % C	Cultivated land in DK*, %
Coarsely sanded	GR.S.	1	0 - 5	0 - 20	0 - 50	75 - 100	< 10	24
Finely sanded	F.S.	2	0 - 5	0 - 20	50 - 100	75 - 100	< 10	10
Coarse clay-mixed sand	GR.L.S.	3	5 - 10	0 - 25	0 - 40	65 - 95	< 10	7
Fine clay-mixed sand	F.L.S.	4	5 - 10	0 - 25	40 - 95	65 - 95	< 10	21
Coarse sand-mixed clay	GR.S.L.	5	10 - 15	0 - 30	0 - 40	55 - 90	< 10	4
Fine sand-mixed clay	F.S.L.	6	10 - 15	0 - 30	40 - 90	55 - 90	< 10	20
Clay	L.	7	15 - 25	0 - 35		40 - 85	< 10	6
Heavy clay	SV.L.	8	25 - 45	0 - 45		10 - 75	< 10	1
Very heavy clay	M.SV.L.	9	45 - 100	0 - 50		0 - 55	< 10	-
Silt	SI.	10	0 - 50	20 - 100		0 - 80	< 10	-
Humus	HU.	11					> 10	7
Special	SPEC.	12						-

Source: Ministry of Agriculture; Bureau of Land Data (1980)

** From: The Danish Agricultural Advisory Service (2005)*

Percentage content of sand and clay in Danish soils:

Sand content, percentage of top soil.	Samples with more than:	Clay content, percentage of top soil.	Samples with more than or equal to:
40 % sand	> 99 %	2% clay	= 99 %
50 % sand	= 99 %	5% clay	= 70 %
60 % sand	= 97 %	10% clay	= 35 %
70 % sand	= 81 %	15% clay	= 10 %

80 % sand	= 49 %	20% clay	= 2 %
90 % sand	= 9 %	30%clay	= 0.4 %
95 % sand	< 1 %	50% clay	= 0.01 %
Total number of samples is	38927	Total number of samples is	38930

Source: Danish Institute of Agricultural Sciences (personal communication).

Annex 3: Climate conditions in Denmark

Average precipitation (mm):

Normal	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year
1971-00*	53	34	43	35	42	55	54	59	70	69	65	59	641
1961-90**	57	38	46	41	48	55	66	67	73	76	79	66	712
1931-60**	55	39	34	39	38	48	74	81	72	70	60	55	664

* *Cappelen (2002)*

** *Frich et al. (1997)*

Average air temperature (°C):

Normal	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year
1971-00*	0.9	0.8	2.7	6.1	11.0	14.2	16.3	16.3	12.9	9.1	5.0	2.4	8.1
1961-90**	0.0	0.0	2.1	5.7	10.8	14.3	15.6	15.7	12.7	9.1	4.7	1.6	7.7

* *Cappelen (2002)*

** *Cappelen (1997)*

Average soil temperature at a depth of 10 cm (°C) (1988-2006):

	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Year
Average	2.0	2.0	3.1	7.2	12.2	15.8	17.9	17.4	14.4	10.2	6.1	3.5	9.3

Source: University of Aarhus, Faculty of Agricultural Science

Average soil temperature at a depth of 10 cm (°C):

Normal	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
France 1993	6.1	5.9	8.4	12.8	18.6	22.3	24.8	2.3	20.3	15.1	9.4	6.9
Germany * 1982-92	2.7	3.5	6.0	8.3	13.8	16.8	19.8	20.2	15.0	9.8	5.5	2.2
Sweden 1973-85	-0.9	-1.3	-0.6	2.3	9.1	13.9	15.9	14.7	10.5	6.0	2.2	0.0
England 30 years	2.6	3.0	4.6	8.3	12.5	17.1	18.6	17.1	14.6	9.8	6.1	3.7

* Landwirtschaftliche Untersuchungs- und Forschungsanstalt (LUFA) Speyer.

Annex 4: Pavements and similar use areas

Curbsides along major roads, bare soil with old topsoil and railways are considered special (and seldom/never applied for) areas of usage, which The Danish Environmental Protection Agency will consider on an ad hoc basis on the receipt of applications.

The following categories are acknowledged by The Danish Environmental Protection Agency:

- "Real" paved areas comprised of flag or cobblestones, laid over gravel directly on the earth from which the topsoil has been removed. This includes asphalted areas. These areas are characterised by having a bearing layer which is impermeable. Water which falls on these areas must be lead away, usually via a sewer. It is vital for the stability of these paved areas that water does not permeate the layers otherwise they lose their load- bearing capability. There is therefore no risk of leaching in areas such as these, which are typically roads or larger parking areas.

- Partially paved areas of flag or cobblestones laid directly onto the earth, from which the top-soil has been removed, or gravel or stone covering laid directly onto topsoil. These types of areas are typically driveways, terraces, smaller footpaths, storage depots, etc. The private areas are often so small that it is not necessary to perform any risk assessment in accordance with the Framework for assessment, as they constitute a negligible exposure of the general environment.

Applications for the use on paved areas will always be assessed on an ad hoc basis and specific evaluations based on available data will be carried out.

References:

Miljøstyrelsens "Notat til Bekæmpelsesmiddelrådet om ophævelse af gældende praksis for befæstede arealer af 10. november 2008".

Annex 5: Appraisal of field studies and lysimeter tests for pollution of groundwater

Experience has shown that field studies and lysimeter tests do not yield incontrovertible descriptions of the risk of polluting groundwater. Several active substances are frequently found (in concentrations above the limits) in groundwater, even though lysimeter tests with the same substances have not indicated unacceptable leaching. The probable reason for this is that the degradation conditions in the lysimeters were more favourable than those in the field. It is, therefore, vital that the results of such tests be appraised very carefully and compared to the other information (intrinsic properties, mathematical modelling and monitoring results).

In the case of lysimeter tests (which are conducted according to standardised principles) it is especially important to decide whether they were conducted under conditions that were representative of Danish conditions and that were "realistic worst cases". As far as field studies are concerned (where there are no guidelines), it is also important to ensure that the sampling resolution is sufficiently high with respect to time and depth - especially in relation to the pattern of precipitation - to permit the detection of any leaching of the active substance and its metabolites.

The following requirements on scenarios and tests must be satisfied:

- the soil type must be representative of Danish conditions (see Annex 2) and must represent a realistic worst case for the specific active substance or its metabolites, with respect to degradation rate and sorption conditions (for instance, if the substance degrades slowly at a relatively high pH or in sandy soil, the test must be conducted in such a soil type)
- the climate conditions must be representative of Danish conditions (including precipitation and temperature, and including trends over the year, cf. Annex 3)
- the use must represent a realistic worst case with respect to the time of spraying (e.g. early spring or in the autumn), crop (including vegetation cover, root development), as well as the dose and number of applications. Furthermore, the formulation of the product must correspond to that of the product for which authorization is sought (e.g. for granulates)
- the test must extend over a period long enough to permit assessment of the leaching of the active substance and metabolites (2 years, minimum)
- compensatory watering must be comparable to realistic worst-case precipitation under Danish conditions, with respect to the quantity and timing
- sampling and assays of eluate or soil/water samples must be arranged so that there is no significant degree of degradation of the active substance or metabolites
- the detection threshold for the active substance and metabolites must be << 0.1 µg/l.

In the case of lysimeter tests, appraisal must be based on the annual average concentration of the active substance and/or metabolites in the eluate.
No such appraisal is possible for field tests. When appraising field tests, every effort must be made to estimate the areal leaching. This also means that the individual samples must be appraised in relation to the heterogeneity of the field.

Annex 6: Appraisal of mathematical modelling of risk of pollution of groundwater

The leaching of active substances and metabolites will be assessed based on mathematical modelling.

The following requirements on modelling and scenarios must be satisfied:

- Models: a model code, usable for Danish conditions must be used. The PELMO model with the Hamburg scenario from FOCUS can be used, and the MACRO and MIKE-SHE models. If another model code is used, the report must document the way in which the calibrated water balance corresponds to the Danish scenarios.
- Soil types and localities: the soils/localities specified by the Danish Environmental Protection Agency are used - at present, two typical Danish soils, representing sandy soil (Karup) and boulder clay with preferential flow (Langvad) or the Hamburg scenario from FOCUS.
- Climate data: time series over 30 and 24 years, respectively, for the two Danish localities must be used and 20 years (+ 6 years' calibration) for the Hamburg scenario.
- If a substance is used every second year the time series is run for 40 years in PELMO with use every second year. If use is every third year the time series is for 60 years with use every third year. If use is every fourth year then this cannot be modelled within the PELMO shell and at tier 1 use is every third year. If refinement is required then the run must be completed outside the shell by constructing weather files and running 80 years with application every fourth year.
- Substance specific parameters: 80 percentiles for degradation rates and sorption ratios (1/n) must be used and for K_{OC} 20 percentiles must be used. All available data should be included, but a refinement can be made by selecting the studies that are relevant/representative for Danish conditions e.g. with respect to soil texture or pH. If there are less than three endpoints available then a worst case value should be used for modelling.
- Crop: where several crops are involved, the worst-case crop (with respect to vegetation cover, root development, etc.) must be used where possible. Alternatively, all crops must be modelled.
- Application: application of the highest dose for which authorization is sought must be modelled. In order to investigate the sensitivity to changes in the application date, separate model runs must be executed for at least three individual days of the period in which use of the product is proposed.
- The results must be reported as annual averages. This also applies if the substance is used every second, third or fourth year. All output files must be submitted.
- All use of values/input other than those set by the Danish Environmental Protection Agency/default values must be justified.

The appraisal is done on the basis of the average annual leaching below the root zone (a depth of about one metre). The number of occasions when leaching exceeds the limit value is compared against the total number of runs. If the limit is exceeded on more than a specified proportion of the occasions (1 of 20 years), the model runs cannot be used to support authorization for the proposed use.

If unacceptable leaching occurs in just one of the scenarios (sandy soil or moraine clay) the Danish Environmental Protection Agency will generally conclude that it is not possible to grant authorization on the grounds that there is a risk of leaching.

Annex 7: Groundwater monitoring data

When assessing the leaching of pesticides and their metabolites to groundwater, relevant monitoring data must be used. However, it is crucial that the pesticide use/dose can be linked to the monitoring data in a clear and unambiguous way.

Normally results are used from the national monitoring programmes (groundwater monitoring, the Agricultural Watershed Catchment Areas), drinking water abstraction wells and the Danish Pesticide Leaching Assessment Programme (PLAP). If the Danish Environmental Protection Agency has knowledge of other data, e.g. from GEUS or foreign studies, these data are also included/assessed.

The results are either gathered directly from the GEUS or PLAP website or by contacting GEUS, who have the possibility of carrying out a data run for individual substances.

The monitoring data should either be presented in a separate study report, or they can be included in the groundwater modelling report. Data should be a part of the Registration Report. The presentation of the monitoring data should start by specifying the monitoring programmes in which the substance has been included and how many filters or boreholes have been examined. For results from PLAP the locations, crops and application rates and timing should be presented. In the presentation of the monitoring results the following should be included:

- Total number of analyses
- Number of detections above the limit of detection but below the limit value
- Number of detections above the limit value

If there are no results this must be reported so that it can be seen that the area has been investigated.

The number of results over the limit value is compared with the total number of analyses. If there are more than very few sporadic results, then the results must be examined to see which monitoring systems are involved, depth, times etc.

There are no fixed guidelines for the assessment of monitoring results, but the overall assessment of the risk of leaching to groundwater is based on a comprehensive assessment of all information on a substance/metabolites. This includes knowledge about patterns of use and possible changes in the pattern of use.

In addition to this the Danish Environmental Protection Agency also uses monitoring data on surface water from the NOVANA programme in connection with risk assessment for aquatic organisms.

Annex 8: Definition of readily biodegradable

The extent to which an organic substance is ready biodegradable is determined in accordance with the OECD (OECD guidelines for testing of chemicals, section 3, OECD TG No. 301):

The assessment is done on the basis of the following tests, in which the substance must be able to attain the following levels of biodegradation within 28 days*:

Test	No.	Level
DOC Die-Away	301 A	70 % (DOC)
CO_2 Evolution	301 B	60 % (BOD)
MITI (I)	301 C	60 % (BOD)
Closed Bottle Test	301 D	60 % (TOD)
Modified OECD Screening	301 E	60 % (CO_2)
Manometric respirometry	301 F	70 % (DOC)

* With the exception of MITI (I), degradation must occur within a 10-day window after an initial degradation of 10 per cent has been attained.

These tests include ultimate degradation to CO_2 and not just primary degradation to possible metabolites or bound residual products.

Annex 9: Non-spraying buffer zones to the aquatic and terrestrial environment

Maximum no spray buffer zones covering both the aquatic and terrestrial environment are set in relation the type of crop (see table below)[38].

Crop type and maximum no spray buffer zones accepted as risk mitigation measure.

Crop type	**Maximum buffer zone**
Agriculture	20 metres
Fruit trees	50 metres
Vegetables, ornamental plants, fruit bushes	30 metres

Aquatic environment
Non-spraying buffer zones to the aquatic environment of 2, 5, 10, 20, 30, 40 and 50 metres are used.

The two-metre zones correspond to the uncultivated zones that extend to the aquatic environment. In Denmark spraying booms are typically divided into sections of 3, 4, 5 or 6 metres for which reason, it is not possible to use non-spraying zones around the aquatic environment that are tailored to all sprayer types.

Terrestrial environment
No-spraying buffer zones to the terrestrial environment of 1, 3, 5, 10, 20, 30 and 50 metres are used (see table below for single application). If GAP uses include more than one application, please find specific drift values for repeated application in Appendix IV of the Escort 2 GD (Candolfi et al., 2001).

Basic drift values for one application Ground deposition in % of the application rate (90th percentiles)									
Distance	Field crops	Fruit crops		Grapevine		Hops	Vegetables Ornamentals Small fruit		Field crops
[m]		Early	Late	Early	Late		Height < 50 cm	height > 50 cm	Water > 900 L/ha
1	2,77						2,77		4,44
3		29,20	15,73	2,70	8,02	19,33			
5	0,57	19,89	8,41	1,18	3,62	11,57	0,57	3,62	0,18
10	0,29	11,81	3,60	0,39	1,23	5,77	0,29	1,23	0,05
20	0,15	2,77	1,09	0,13	0,42	1,79	0,15	0,42	
30		1,04	0,54	0,07	0,22	0,56	0,10	0,22	
40		0,52	0,32			0,25			
50		0,30	0,22			0,13			

[38] A standard, 2 meter buffer zone should be applied if FOCUSsw Step 3 is used as basis for the aquatic risk assessment. See the section on surface water in the fate section.

Annex 10: Assessment factor in mesocosm studies

The assessment of mesocosms and derivation of an endpoint should follow the recommendations given in EFSA aquatic GD (2013). The association of an assessment factor to an Ecological Recovery option (ERO) endpoint (to give a Regulatory Acceptable Concentration (RAC)) deviates from the EFSA guidance. The procedure is described below.

The assessment factor that is associated with the endpoint established from a mesocosm study is set on the basis of an appraisal of the study's quality. If the study does not live up to the recommendations, ”penalty points” are given in the form of a higher assessment factor.

The NOEC or alternatively NOAEC (no observable adverse effect concentration) is used as the endpoint from mesocosm studies. If NOAEC is determined there must only be relatively limited effects and recovery must occur within a period of maximum four weeks.

If a specific mesocosm study has been given ”penalty points” because it diverges from the recommendations, it is possible to lower the assessment factor in the overall risk assessment if, for example:

- the mesocosm study covers two different periods of time (summer/autumn) in the same locality such that different stages of growth (e.g. newly hatched organisms) or different maximum/minimum population sizes of the same organisms are investigated.
- other higher-tier studies are available that support the NOEC/NOAEC value determined.
- other single species laboratory studies of most sensitive organisms or tests with the most sensitive stages of these (e.g. newly hatched larvae) are available.

As the point of departure a minimum assessment factor of 5 will be used for some mesocosm studies as individual tests cannot be expected to be representative of all of the organisms or biotopes.

The assessment factor can be reduced if several studies of high quality are submitted that shed light on the difference between different natural systems. Studies that differ in terms of both time and space can be used to lower the assessment factor if they represent different population mixes or biotopes.

Annex 11 Vegetation cover and deposition on soil

The proportion of a spray product deposited on the soil beneath different crops at different times depends on the vegetation cover. The Danish Environmental Protection Agency uses upper 80 per cent confidence intervals for pesticide deposition on soil based on the measured values in Jensen and Spliid (2003). Values for crops for which no Danish measured value for deposition is available are based on the plant cover estimates in Olofsdotter and Streibig (1997). Values for crops that are not covered by the above two reports are taken from FOCUS (2002). When using values from FOCUS groundwater (2002), the assessment takes account of the fact that these are average values and do not therefore represent realistic worst-case situations, but instead represent an average situation.

Deposition of spray product on soil beneath various crops. The table shows averages, 95 per cent upper and lower confidence interval, and approximated 80 per cent upper confidence interval[1] for each growth stage interval (based on data from Jensen & Spliid, 2003).

Crop	**Growth stage**	**Deposition (% of sprayed)**			
Winter wheat	(BBCH)	95 % lower	Average	95 % upper	80 % upper
Winter barley	11-13	41.1	59.6	86.7	77
Winter rye	23-28	38.5	50	65.3	60
	30-32	30.6	36.9	44.7	42
	33-34	14.5	18.4	22.9	21
	38-45	6.4	8.2	10.2	10
	51-57	2.7	3.4	4.2	4
	61-71	3.5	4.1	4.7	4
	87	11.3	14.7	19.1	18
Crop	**Growth stage**	**Deposition (% of sprayed)**			
Spring barley	(BBCH)	95 % lower	Average	95 % upper	
Spring wheat	11-13	53.7	65.1	79.8	75
	20-24	41.7	49	57.5	55
	28-32	34.2	38.9	44.7	43
	33-35	19.7	23.8	28.8	27
	49-50	13.0	15.8	19.5	18
	59-68	14.1	17.3	21.3	20
	87-89	16.6	20.4	24.9	23
Crop	**Growth stage**	**Deposition (% of sprayed)**			
Sugar beet	(BBCH)	95 % lower	Average	95 % upper	
	11	84.3	99.8	100	100
	12	84.1	99.3	100	100
	13-14	81.3	93.1	100	98
	15-18	69.2	76.4	84.1	81
	20-22	36.6	42.7	49.9	47
	30-35	24.7	28.9	33.7	32
	39	6.4	7.6	8.9	8
Crop	**Growth stage**	**Deposition (% of sprayed)**			
Potatoes	(BBCH)	95 % lower	Average	95 % upper	
	10-19	-	100	-	100
	18-25	67.6	90.4	100	97
	30-32	56	74.6	99.5	91

	35-40	40.3	48.5	58.4	55
	59-79	5	6.4	8.2	8

[1] The Danish Environmental Protection Agency's calculation based on the following formula and assuming normal distribution of the data:

Approximated 80 per cent upper confidence interval = Average value + (1.282 x √variance).

Vegetation cover and deposition in different crops (Olufsdotter and Streibig, 1997):

Crop	**Treatment**	**Leaf stage**	**Growth stage**		**Vegetation cover**	**Deposition**
			Feekes	BBCH	%	% (of sprayed)[1]
Peas	herbicide x 2 insecticide	Newly germinated 1[2]	2 5-7	10-12 11-75	5-15 80-100	86-95 5-24
Winter rape[3]	herbicide Autumn herbicide Spring herbicide Insecticide	Before germination 3 leaves 6 leaves flowering	0 2,3 2,6 3,3-4	0 13 16 60-69	0 20-40 60-80 90-100	100 62-81 24-43 5-15
Spring rape	herbicide insecticide insecticide	3 leaves before flowering flowering	2,3 3,2 3,3-4	13 30-59 60-69	20-40 40-60 90-100	62-81 43-62 5-15

1 calculated on the basis of the following formula: percentage of spray product on soil = 100 - (0.95 x percentage vegetation cover)

2 pests are present in peas from the early stages of leaf development (pea weevil), during pesticide spraying and into the pod-formation stage, 80-100 per cent vegetation cover corresponds to late spraying against tortricidae and aphids.

3 Based on the ranges given and the crop development (cover increases more at higher stages than at lower), the following vegetation cover values are appropriate for BBCH 12 – 16: 12: 10 %, 13: 20 %, 14: 30 %, 15: 45 % and 16: 60 %.

Deposition of spray product on soil (percentage of amount sprayed) beneath various crops (from FOCUS groundwater, 2002).

Crop	**Bare earth – germination**	**Leaf development**	**Formation of side shoots/rosette growth and stem elongation**	Flowering	**Ripening/ Senescence**
	BBCH				
	00-09	**10-19**	**20-39**	**40-89**	**90-99**
Beans	100	75	60	30	20
Cabbage	100	75	60	30	10
Carrots	100	75	40	20	20
Grass*	100	60	40	10	10
Linseed	100	70	40	30	10
Maize	100	75	50	25	10
Onions	100	90	75	60	40
Soybean	100	65	45	15	35
Strawberries	100	70	50	40	40
Sunflowers	100	80	50	25	10
Tobacco	100	50	30	10	10
Tomatoes	100	50	30	20	50

* The value 10 is used for spraying on established grass.

Limitation

Assessment of cumulative ecotoxicological effects of chemical mixtures in products will be limited to include groups of organisms where the risk assessment is based on a quotient calculation, i.e. birds, aquatic organisms, mammals, earthworms and bees.

Methods

Two basic concepts for analysis of cumulative toxic effects of chemicals in mixtures are well established, i.e. independent action (IA) and concentration addition (CA) (Greco et al., 1995; McCarty og Borgert, 2006). IA is when toxicants act independently and have different modes of toxic action, and CA is when toxicants act on the same biological site by the same mode of action.
It is found that the model of CA can be recommended as the best reference model for both similarly and dissimilarly acting chemicals when evaluating cumulative effects of chemical mixtures (Boekelheide, K., 2007; Cedergreen et al., 2008).
In the workshop report from the "Expert workshop on combination effects of chemicals" held in January 2009 in Hornbæk, Denmark it is recommended that regulators use the model of CA as a default when evaluating cumulative effects, as it is a conservative model and further it requires less data than the model of IA.
Synergistic effects where the cumulative effect is higher than expected from the model of CA are rarely seen. Procloraz, a chemical causing hormone disrupting effects, has been identified as a potent synergist (Cedergren et al., 2008). However, procloraz is no longer approved in any products in Denmark and not been sold since 2005.

Based on the current knowledge the model of CA will be used when evaluating cumulative ecotoxicological effects (see also EFSA aquatic GD).

Method for risk assessment

Risk assessment for products containing several active substances (or problematic auxiliary chemicals) will be performed for:

- Test with the product
- 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 CA using the following equation:
  "TriggerA"-value/TERA + "TriggerB"-value/TERB + ….= SUM
  If SUM < 1 the risk assessment is acceptable

  Where:
  "Trigger"-value represent the uncertainty factor of chemical A, B etc.
  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.

Annex 13: Crop rotation - normal cultivation practices in Denmark

Crops for which normal cultivation practice exceeds one year crop rotation intervals. This is relevant as a potential refinement option in the groundwater leaching assessment.

Crop type and maximum and years between cultivation:

Years between cultivation	**Crops**
3	Sugar beets
4	Oil Seed Rape (winter and summer), potatoes, legumes (field peas, canned peas, peas for silage, beans, lupines)

Annex 14: Criteria for pesticides that can be used by and sold to non-professional users

Products must either comply with 1 and 3, or 2 and 3:

1. Ready-to-use products
   a. Products may not be classified for health effects[39]. This means that the label must not include any human health hazard statements, not even those listed in Table 1.
   b. It must not be necessary to use personal protective equipment to demonstrate safe use. However, if applicants recommend gloves on the label for reasons of routine hygiene it is permitted.

2. Concentrated products
   a. Products may not be classified for health effects. However, classification as local irritant or as contact allergenic with the hazard statements listed in Table 1 is acceptable, as long as the end-use solution fulfils requirements a. and b. under point 1.
   b. Products must be apportioned in dosage bags or have a dosage device or similar which enables easy measurement of the correct amount and ensures that contact with the concentrated product is restricted (stating the correct dosage on the bottle is not sufficient; it must also be ensured that the product can be poured or apportioned without the user coming into direct contact with the product).

3. Products sold in packages corresponding to treating a limited area of maximum 1,000 m^2 (0.1 ha), when used in accordance with the instructions for use.

Table 1

Hazard statements with respect to human health[1)]	
H315	Skin Irrit. 2 H315: Causes skin irritation
H317	Skin sens. 1 H317: May cause an allergic skin reaction.
H319	Eye Irrit.2 H319: Causes serious eye irritation
H335	STOT SE 3, H335: May cause respiratory irritation
EUH066	EUH066: Repeated exposure may cause skin dryness or cracking[40]

1) Regulation no 1272/2008 (EC) of the European Parliament and of the Council

[39] EUH208 is not considered a classification but merely a labelling and does not prevent the product from being sold to non-professionals.

[40] The relevance of labelling dilutions with EUH066 should be made case by case. A weight-of-evidence approach should be employed, taking into account test data on in-use dilutions, bridging, human use experience, the concentration of substances labelled with EUH066 or classified as corrosive/irritant to skin in the in-use dilution and the number of treatments relating to the non-professional use. A concentration limit of ingredients labelled with EUH066 that triggers labelling of a mixture/dilution with EUH066 is not specified in Regulation (EC) No 1272/2008. However, as labelling with EUH066 is regarded as less severe than classification for skin irritating properties, the concentration limits specified for classification of mixtures for skin irritating properties based on data on individual components may be used as a starting point (point 3.2.3.3. in Annex I of Regulation (EC) No 1272/2008)

Annex 15: Beneficial organisms (other than bees).

For indoor pesticides it must be stated on the label (instructions for use) to what degree the product is compatible with biological control with beneficial arthropods. If no information regarding the effects on beneficial arthropods is available this must be mentioned on the label.
Products will be classified by IPM impact in accordance with established IOBC criteria:

- Based on field or semi-field test data:
  N = harmless or slightly harmful (< 50 % reduction in beneficial capacity)
  M = moderately harmful (51-75 % reduction in beneficial capacity)
  T = harmful (> 75 % reduction in beneficial capacity)
- Based on laboratory test results:

Laboratory 1 (< 30 %)	N (harmless or slightly harmful)
Laboratory 2 (30-79 %)	M (moderately harmful)
Laboratory 3 (80-99 %) and 4 (>99 %)	T (harmful)

To obtain a clear label text the following classes will be used for the Danish labels:
< 25% mortality or reduction in beneficial capacity => Class 1 (harmless; skånsomt)
25 to 50 % mortality or reduction in beneficial capacity => Class 2 (relatively harmless; relativt skånsomt)
50 to 75% mortality or reduction in beneficial capacity => Class 3 (moderately harmful; moderat skadeligt)
> 75% mortality or reduction in beneficial capacity => Class 4 (harmful; skadeligt)

Products classified 1 or 2 in a worst case laboratory trial are considered harmless or relatively harmless to that specific beneficial organism and further testing under semi-field or field conditions is not required.
Products classified 3 or 4 in a worst case laboratory trial are considered moderately harmful or harmful to beneficial organisms, respectively, unless further testing under semi-field or field conditions is performed showing < 50% reduction in beneficial capacity, thereby changing the classification to 2 relatively harmless.

Some of the most common beneficial organisms in greenhouses are (but not restricted to):
- Lacewings (e.g. *Chrysoperla spp*.)
- Ladybugs (e.g. *Harmonia axyridis*)
- Parasitoid wasps (e.g. *Aphidius spp*. and *Encarsia formosa*)
- Predatory mites (e.g. *Amblyseuis spp*.)
- Midges (e.g. *Aphidoletes aphidimyza*)
- Pirate bugs (e.g. *Orius spp*.)

Wording for the Danish labels:

If no information regarding the effects on beneficial arthropods is available:
"Det er ikke oplyst, om midlet er foreneligt med biologisk bekæmpelse."

If information regarding the effects on the most common beneficial arthropods is available:
Class 1: "Midlet er skånsomt overfor populationer af xxxx."
Class 2: "Midlet er relativt skånsomt overfor populationer af xxxx."
Class 3: "Midlet er moderat skadeligt for xxxx."
Class 4: "Midlet er skadeligt for xxxx."

In addition, if information regarding the effects on only some beneficial arthropods is available, then the following sentence should be added:
”Foreneligheden med anvendelse af de øvrige nyttedyr er ukendt.”

Annex 16 - Danish requirements for groundwater metabolites of no toxicological concern

For metabolites without pesticide effect which fulfils specific Danish requirements for no toxicological concern a limit value of 0.75 µg/L can be set based on an "ad hoc" assessment. The limit of 0.75 µg/L can apply to a single metabolite or to a sum of metabolites and the active substance with similar structure and/or toxicological profile. If other sources (e.g. other active substances) also can contribute to the occurrence of a metabolites these should be counted in the sum.

It must be demonstrated that such metabolites are of low concern to human health.

Groundwater metabolites > 0.1 µg/L and below 0.75 µg/L are not considered to be harmful to human health if they do not possess the following properties:

- Meet the criteria to be classified for acute toxicity cat. 1-3, carcinogenicity, germ cell mutagenicity, reproductive toxicity or specific target organ toxicity according to Regulation (EC) No 1272/2008, or

- Are considered to potentially have endocrine disruptive properties.

The data requirements for the assessment for groundwater metabolites > 0.1 µg/L and below 0.75 µg/L are listed below:

Existing data and non-test information

A toxicological profile of each metabolite must be provided based on available toxicological data including open literature. Where no specific studies on metabolites are available the profiling should be based on read-across and QSAR[41] except for genotoxicity and ED effects where data are required, see below. The quality criteria from REACH should be followed according to Guidance on information requirements and chemical safety assessment Chapter R.6 (ECHA, 2008) for the QSAR. A conclusion on the QSAR predictions including analysis of the predictions and their reliability should be made.

Genotoxicity:

The metabolites should be tested for their genotoxic activity by a minimum of two *in vitro* tests[42] covering gene mutations and structural and numerical[43] aberrations. The Danish Environmental Protection Agency gives preference to an Ames test (OECD TG 471) and an *in vitro* Micronucleus test (EFSA Scientific opinion on genotoxicity testing strategies applicable to food and feed safety assessment, 2011). Grouping maybe proposed which should be justified for example based on profiling based on (Q)SAR (se also EFSA Guidance on the establishment of the residue definition for dietary risk assessment, 2016). For groups of metabolites at least one representative metabolite needs to be tested. The selection of the representative metabolite(s) should be justified.

Equivocal *in vitro* results could be followed up by relevant *in vivo* testing. Result interpretation and follow up test strategy should be made by reference to the Scientific Opinion on genotoxicity test-

[41] Read-across and QSAR of genotoxicity and end points covered by *in vitro* endocrine disruption endpoints are not necessary.

[42] *In vitro* studies cannot be derogated by *in vivo* studies unless the specific genotoxic effect is addressed for example chromosome aberration in the *in vivo* micronucleus test.

[43] A negative chromosomal aberration test is not considered to be sufficient to cover the numerical chromosomal aberration endpoint as this test is optimised for the detection of structural aberrations and may only give an indication for numerical chromosome aberrations (Opinion on genotoxicity testing Strategies, EFSA 2011).

ing strategies applicable to food and feed safety assessment (EFSA Scientific Committee 2011) and taking into consideration Scientific Opinion on clarification of some aspects related to genotoxicity assessment (draft EFSA 2017).

Endocrine disrupting properties:

Each metabolite should be tested and assessed for its endocrine disrupting properties according to level 1 and 2 in the OECD Conceptual framework for testing and assessment of endocrine disruptors)ED)(as revised in 2012). Eco-toxicological data should also be included in the assessment. Assays should be documented according to OECD guidance document 211 if no standardized test methods are available. A scientific justification is needed if metabolic systems are not included in the assay.

Currently, no *in vitro* thyroid assays are included in the OECD Conceptual framework. Thus, metabolites suspected to disturb the thyroid axis or metabolites of active substances with effects on the thyroid axis are not acceptable or additional toxicity studies need to be considered on a case-by-case basis but described according to OECD GD 211.

Metabolites which potentially may have ED properties determined by screening from level 1 and 2 data could be followed up by relevant *in vivo* testing according to OECD guidance document 150 (currently under update). The outcome and further testing strategy should be discussed with the Danish Environmental Protection Agency.

Strategy for repeat-dose *in vivo* toxicity testing:

The metabolites should be tested or addressed by a justified read across for their subchronic toxicity. For subchronic toxicity testing, an enhanced 28-day study (OECD TG 407) or a 90-day rat study (OECD TG 409) are suggested. However, the choice of study must always be justified case-by-case taking into consideration the nature of the alert. In regard to potential ED properties, relevant follow-up studies should be according to OECD guidance document 150

For groups of metabolites at least one representative metabolite needs to be tested. The selection of the representative metabolite(s) should be justified according to Guidance on grouping of chemicals (OECD 2014).

Combined toxicity:

The combined toxicity of all metabolites of no concern, according to the criteria above, should be considered where two or more metabolites could have an effect on the same endpoint (i.e. organ/tissue or equivalent effect seen in different organs/tissues, share a similar alert). In case the metabolites are likely to share a common adverse outcome their combined concentration in ground water must not exceed 0.75 µg/L.

Exceptions or metabolites which need specific considerations:

Metabolites of active substances classified or suggested to be classified as specific target organ toxic should be assessed on a case-by-case basis with respect to the toxicological profile of the active substance. Leaching of metabolites of neurotoxic active substances will usually not be accepted unless substantial data demonstrates that the metabolite is not neurotoxic. Metabolites or metabolites of parents with a toxicological profile of concern not foreseen by these requirements should also be assessed on a case-by case basis. The testing strategy should be discussed with the Danish Environmental Protection Agency.

Annex 17: Abbreviations

ADI –	Acceptable Daily Intake, i.e. the daily amount that can be ingested during a lifetime without risk of adverse effects on health.
AF -	Assessment Factor, also called an uncertainty factor or safety factor.
AV -	Avoidance Factor; if a bird completely avoids the treated food, then the AV= 0 and with no avoidance AV=1.
BBA -	Biologische Bundesanstalt für Land- und Forstwirtschaft (The Federal Biological Research Centre for Agriculture and Forestry - a Federal Authority and Federal Research Centre affiliated to Germany's Federal Ministry of Food, Agriculture and Consumer Protection).
DJF -	*Formerly* Danmarks JordbrugsForskning, *now* Det Jordbrugsvidenskabelige Fakultet (The Faculty of Agricultural Sciences)
DOC -	Dissolved Organic Carbon
DT_{50} -	Time taken for 50 per cent of the substance to degrade/disappear.
DT_{90} -	Time taken for 90 per cent of the substance to degrade/disappear.
EC_{50} -	Effective Concentration 50 per cent; the concentration that causes 50 per cent effects in a dose-response test.
EPPO -	European and Mediterranean Plant Protection Organization
ERO _	Ecological Recovery Option
ETE -	Estimated Theoretical Exposure; either as mg/kg bodyweight or as daily dose in mg/kg bodyweight/day.
ETO -	Ecological Threshold Option
HARAP -	Higher-Tier Aquatic Risk Assessment for Pesticides; international workshop 1998
JB -	Jordbundsnummer (soil type number)
K_d -	Distribution coefficient between soil and water
K_{oc} -	Soil organic carbon - water partitioning coefficient; K_d normalised to organic carbon content in soil.
K_{ow} -	Octanol/lipid-water partition coefficients; octanol is used as a model for lipids in organisms or carbon in soil.
LC_{50} -	Lethal concentration 50 per cent; concentration that kills 50 per cent of test organisms.
LD_{50} –	Lethal dose 50 per cent; dose that kills 50 per cent of test organisms.
LL HC5 -	Lower Level 5th percentile of species-sensitivity
NOAEC -	No observed adverse effect concentration; the highest dose for which no adverse effects are observed. In mesocosm studies it is interpreted as the highest dose for which no long-term adverse effects are observed. Recovery within a maximum of four weeks is regarded as acceptable.
NOEC/NOEL -	No observed effect concentration/level; the highest dose in a dose-response test that is not statistically different from the control.
OECD -	Organisation for Economic Co-operation and Development
PD -	Proportion of a food type in diet (between 0 and 1)
PEC -	Predicted Environmental Concentration

PT -	Proportion of food that is found in the treated area (between 0 and 1)
RAC -	Regulatory Acceptable Concentration
SETAC -	The Society of Environmental Toxicology and Chemistry
TER -	Toxicity-to-exposure ratio
TG -	Test Guideline
TOC -	Total Organic Carbon
TSW -	Thousand-seed weight, weight of 1000 grains/seeds (g)
TWA -	Time Weighted Average
US EPA -	United States Environmental Protection Agency

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